



Poisons permits for medical treatment

Guidance for permit holders and on-site staff

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Who should read this information?

This information is intended for those who wish to apply for or who already hold a permit under the *Poisons Act 1964* to allow them to purchase medicines for administration to personnel at mining and resource sites, particularly in remote areas. The information is also relevant to staff who work at these sites.

The information should be read in conjunction with the Code of Practice for Poisons Permits for Medical Treatment.

Background

Why is access to medicines and poisons regulated by legislation?

The Poisons Act 1964 and the subsidiary Poisons Regulations 1965 regulate and control the possession, sale and use of medicines and poisons in Western Australia. This legislation is in place to protect public health. The controls over access to medicines and poisons by consumers aim to:

- minimise accidental and deliberate poisoning
- minimise medicines misadventure
- reduce illicit use and diversion of pharmaceutical drugs.

The poisons schedules

Under the Poisons Act 1964, medicines and poisons are classified into nine different 'schedules'. The chosen schedule for each substance is based on a nationally agreed assessment of the risk of harm to human health. Control of access to the substances in each schedule is through the following mechanisms:

- professional authorisation (medical practitioners, nurse practitioners, dentists, veterinary surgeons, registered nurses and other health practitioners endorsed for scheduled medicines by their national boards)
- licences to sell
- permits to purchase
- packaging and labelling
- storage controls.

Medicines are included in four schedules:

Schedule 2 (S2) – pharmacy only

Schedule 3 (S3) – pharmacist only

Schedule 4 (S4) – prescription only

Schedule 8 (S8) – controlled drugs (sometimes referred to as 'drugs of dependence').

Some medicines appear in more than one schedule. Where a medicine is in Schedule 4, lower strength and/or smaller pack size preparations may be available in Schedules 2 and/or 3. Sometimes small packs are exempt from scheduling, as is the case with small packs of paracetamol and ibuprofen.

Schedules 5, 6 and 7 are for poisons. Some of these poisons will be commonly used on mine sites such as cyanide and mercury, both of which are Schedule 7 poisons. A poisons permit to allow purchase and use of Schedule 7 poisons will usually be held by the mine manager, a senior metallurgist or laboratory manager.

Why were ‘medical treatment’ poisons permits for remote mining and resource industry sites developed?

Some years ago, a working party developed the Code of Practice for Poisons Permits for Medical Treatment. The working party included regulators, emergency medicine specialists, occupational health physicians and ambulance service personnel.

The intention was to support access to medicines for the treatment of personnel at remote industrial sites. Improving the availability of prescription and over-the-counter medicines was intended to help resource companies in their ‘duty of care’ to employees working in high-risk industries in remote environments. These permits are applicable where the usual supply chain cannot be used due to isolation and where there is limited access to registered health practitioners such as doctors, nurses and pharmacists.

The issuing of a poisons permit for medical treatment is not intended to replace the treatment of ongoing or chronic health conditions by an employee’s usual medical practitioner or other health care provider. The access to scheduled medicines was intended to improve medical treatment in the event of an on-site accident, other medical emergency and for health conditions which, if untreated, would preclude an employee being considered ‘fit for work’.

Permit holders should assess the risks associated with any administration of medicines which will occur at remote sites. For example, the risk of administering preventative immunisations at a remote site should be considered in view of the limited access to tertiary health services. Permit holders need to weigh up the benefit of on-site vaccination programs against the risk associated with the rare occurrence of anaphylactic reactions to vaccines and the availability of medical evacuation and tertiary care.

Why is a poisons permit needed to provide medicines at mining and resource industry sites?

Most on-site staff are registered nurses, paramedics or others with industrial or occupational first aid training. These staff do not have prescribing rights under the Poisons legislation. The issuing of a poisons permit was seen as a way of providing for purchase, storage and use of scheduled medicines where the permit holder is authorised to prescribe but where they are not physically located at the treatment site.

The Code of Practice requires the authorised prescriber to use:

- clinical practice guidelines (protocols)
 - telephone/fax or other electronic authorisation methods
- or
- a combination of these methods to authorise on-site staff to administer doses of medicines to employees.

Compliance with the Code of Practice for Poisons Permits for Medical Treatment is a mandatory condition on all such poisons permits.

Can on-site staff supply medicines which can be sold in supermarkets and other general sales outlets?

Medicines sold at general sales outlets are either 'unscheduled' or 'exempt from scheduling'.

Unscheduled medicines, such as many complementary healthcare products and vitamins, are not considered to require any access, labelling and packaging controls through the state/territory poisons legislation. However, there are controls through the Commonwealth's Therapeutic Goods legislation. It is recommended that products supplied or used on site be limited to those included on the Australian Register of Therapeutic Goods. These products will have either an AUST L or AUST R number included on their label.

Medicines which are exempt from scheduling are only exempt from the 'primary' schedule of the medicine by virtue of strict conditions around pack size, labelling and indications. For example, the 'primary' schedule for ibuprofen is Schedule 4 (prescription only). Packs of up to 100 tablets with a recommended dose of up to 1200 mg per day may be sold in pharmacies (Schedule 2 or Schedule 3 depending on tablet strength). Packs of up to 25 x 200 mg tablets, with certain warning statements around contraindications and potential interactions are exempt from scheduling and may be sold at any retail outlet.

Summary:

- If a medicine is not scheduled, anyone can supply but only if supply is made in the original manufacturer's packaging with all warnings, indications, doses etc. intact.
- Ideally, only one pack should be supplied at a time.

As a best practice measure, permit holders may wish to provide clinical practice guidelines for the supply and use of these medicines.

What about 'pharmacy medicines' (Schedule 2 medicines)?

These medicines have been assessed as safe for sale where pharmacist advice is available, if required by the consumer. A pharmacy must store these medicines so they cannot be self-selected by customers, usually behind the counter. Other authorised health practitioners can also use and supply these medicines as part of a consultation with a patient but they cannot have them available for open sale.

Where a pharmacy service is not available a Schedule 2 retail licence may be issued. Generally, this type of licence will only be issued where the nearest pharmacy is at least 25 km away. Some mining and resource sites have Schedule 2 retail licences, usually as part of hospitality services. Where an employee purchases a 'pharmacy medicine' from a Schedule 2 retailer, the individual employee is taking responsibility for making the purchase including the correct use of the medicine.

Where these medicines are being supplied under a poisons permit for medical treatment, the permit holder (medical practitioner) should provide a protocol to site staff to cover administration of doses and supply of unbroken packs. Alternatively, the permit holder may choose to authorise administration and supply via telephone/fax or other electronic means on each occasion.

What about ‘pharmacist only’ medicines (Schedule 3 medicines)?

Generally, these medicines can only be sold or supplied by a pharmacist in a pharmacy. If supply of a ‘pharmacist only’ medicine is to occur outside a pharmacy, these medicines must be treated like a prescription medicine.

Assessment of the patient’s therapeutic need for the medicine prior to supply is mandated by the Poisons legislation.

The poisons permit holder must provide either a protocol or telephone/fax authorisation for every administration of a dose of a pharmacist only medicine. Similarly, authorisation must occur if a ‘pharmacist only’ pack is to be supplied for later use. Only the original pack can be supplied with all directions and warnings intact.

Normally only a single pack of the medicine should be supplied. ‘Pharmacist only’ medicines are usually intended for short term treatment and requests for multiple packs or repeated supply should be referred to a medical practitioner.

Are there different rules for ‘prescription medicines’ (Schedule 4) and ‘controlled drugs’ (Schedule 8)?

Yes. For these medicines, only doses may be administered to employees.

Only a pharmacist or an authorised prescriber (for example, medical practitioner, nurse practitioner, dentist) can supply a pack of a prescription medicine or controlled drug to someone for later use. Supply for later use is termed ‘dispensing’ and for a paramedic, first aider, industrial medic or registered nurse to perform this activity they must be under the ‘direct personal supervision’ of an authorised prescriber or pharmacist.

There are also specific labelling and recording requirements when a medicine is ‘dispensed’.

Why is dispensing different to administration of doses?

There are different risks associated with supply for later use compared to administration of doses. Less supervision and monitoring of the patient will occur when medicines are supplied for later use.

Dispensed medicine must be labelled so that the patient knows what dose to take and when and how to best take the medicine. Some medicines are also required to be labelled with warnings about the risk of drowsiness (particularly an issue where the patient may be driving or operating machinery) and the risk of interaction with alcohol.

What are the responsibilities of the permit holder of a poisons permit for medical treatment?

The permit holder is responsible for ensuring compliance with all relevant parts of the Poisons Act 1964, Poisons Regulations 1965 as well as the Code of Practice for Poisons Permits for Medical Treatment. Compliance may be audited by the Department of Health's authorised inspectors and action can be taken if non-compliance is discovered.

Permits will be issued to a medical practitioner who holds the permit on behalf of his or her medical treatment/occupational health business. This business is then contracted by a resources company to provide medical treatment services, which includes the use of scheduled medicines.

Code of Practice for Poisons Permits for Medical Treatment

Compliance with the Code is a condition on all poisons permits issued for medical treatment. Some elements of the Code simply provide more explicit detail of the requirements of the Poisons Regulations 1965. Other aspects are in addition to the controls through the legislation.

The Code covers general requirements for these permits, the administrative responsibilities of the permit holder, the requirements which must be met in relation to site personnel who will handle medicines and instructions about the ordering, storage and recording of use of the medicines, including the particular recording requirements for Schedule 8 medicines.

General requirements

The permit holder must ensure his/her company can provide access to a medical service or medical advice 24 hours a day, seven days a week for each site listed on the permit. Except in an emergency, the permit holder's company must be the only medical treatment provider to the site.

In the event that two separate companies, with separate groups of employees, operate from the same physical location, an exception to these requirements will be considered. Any application where this would apply should include information explaining why more than one medical treatment provider is required.

Supply of medicines to sites

The permit holder must authorise which scheduled medicines will be held at and used at each site. They must also authorise all orders from wholesalers for scheduled medicines. Site staff are not permitted to order medicines from wholesalers without active oversight by the permit holder of the products and quantities ordered.

Orders should be shipped directly to the sites by the wholesaler. The permit holder is not authorised to purchase medicines and then distribute them on to the sites.

In the event that direct supply is not logistically possible, any method used for supply from the medicines wholesaler to the sites must be supported by standard operating procedures and there must be an auditable record of the movement of the medicines from the wholesaler to the site.

Responsibilities of the permit holder and on-site staff

Even where the provision of on-site staff is contracted to a different company to the company of the holder of the poisons permit, the permit holder retains overall responsibility for compliance with the Poisons legislation and the Code of Practice. However, the permit holder can delegate some responsibilities in writing.

On-site personnel should check what delegations they hold.

As on-site staff work under the authorisation of the permit holder, it is expected that the permit holder will ensure staff who administer medicines to site personnel have appropriate qualifications and competencies.

The permit holder must also ensure that adequate checks of the bona fides of on-site personnel have been carried out including either evidence of health practitioner registration or a recent (within the last three years) national police clearance.

A poisons permit will not be issued and/or sites added to an existing permit until the Department of Health has evidence of suitable storage including a suitable safe for Schedule 8 medicines and locked storage for other scheduled medicines.

Changes to sites and movement of sites to a different poisons permit

The permit holder is responsible for notifying the Department about changes to sites on their permit including addition, deletion and changes to the schedules of medicines held. The Department cannot process any requested changes until the changes have been authorised by the current permit holder.

If a site wishes to move to a different medical treatment provider, the holder of the poisons permit on which the site is currently listed must first authorise the Department to remove the site from their permit. The new medical treatment provider must also authorise the addition of the site to their permit. Sites will not be moved from one permit to another without the authorisation of both medical treatment providers.

Protocols for administration of medicines and other written procedures

If protocols are to be used for authorisation of medicines administration, the permit holder must provide clinical practice guidelines for administration of every medicine held on site. It is expected that such guidelines will include information on the indications for the medicine, doses and duration of therapy, any contraindications to use, any patient monitoring that must be done, commonly expected side-effects and the clinical circumstances where there must be direct contact with a medical practitioner is required.

The permit holder cannot delegate sign off on the content of the clinical practice guidelines.

The permit holder must also ensure each site has written procedures for:

- checking for expired stock
- organising a consumer level recall if required
- disposing of out of date or substandard medicines.

The permit holder is also responsible for the safe disposal and/or destruction of scheduled medicines if a site closes.

Records

The permit holder must make a record every time they give advice about medicines to a permit site.

On-site personnel must make a record every time they administer a dose (or supply a manufacturers' pack of a Schedule 2 or Schedule 3 medicine).

All records must be kept for at least two years or at least seven years if Schedule 8 medicines are involved. However, staff should be mindful of the retention periods for medical records in general which is usually much longer than the periods mandated by the Poisons legislation.

Permit holders should ensure they monitor medicines usage on their sites as part of their audit procedures.

Special requirements for Schedule 8 medicines

Recording transactions involving Schedule 8 medicines

All transactions must be recorded in a Schedule 8 Register. This includes incoming stock, doses administered to patients and any stock returned to suppliers or destroyed by authorised persons.

The Schedule 8 Register approved for use in Western Australia (WA) is designated HA14. The current version of this register has a series of columns which ensure the required details about administration of each dose is recorded. This includes recording the amount discarded when a part ampoule is used. Those giving doses must sign each entry and also print their name.

The other registers available in WA (designated HA210 and HA176) are intended for use by wholesalers and pharmacies. They are not suitable for use in patient care areas.

A separate register page must be used for each formulation, strength and pack size so that the balance on hand is clearly apparent at any point in time.

Entries must not be altered, obliterated or cancelled. Incorrect entries should be corrected with a marginal or footnote or by writing out a new line.

Every entry in the Schedule 8 Register must be signed and dated.

Inventory of Schedule 8 medicines

An inventory of stock on hand must be made every time there is a change of custody (e.g. when one medic leaves and another arrives) or at a minimum of once a month.

If there is a discrepancy between the amount recorded in the Schedule 8 Register and the amount in the safe, on-site staff must notify the permit holder who is responsible for notifying the Department of Health.

Destruction of Schedule 8 medicines

Only certain people are authorised to destroy Schedule 8 medicines such as morphine and oxycodone. It is illegal to 'wilfully' destroy Schedule 8 medicines – in other words, stock can only be destroyed if there is a good reason to do so such as it being out of date or heat damaged.

The reason for the destruction must be recorded in the Schedule 8 Register.

Two authorised persons must sign off any destruction. Authorised people are:

- permit holder plus a pharmacist
 - other medical practitioner plus a pharmacist
- or
- two pharmacists.

In hospitals, the Director of Nursing also has authority to destroy Schedule 8 medicines (with a witnessing pharmacist or medical practitioner).

Paramedics, first-aiders and other 'medics' have no authority to destroy Schedule 8 medicines. The permit holder can only delegate this task to a medical practitioner or a pharmacist.


The only exception to this is where a partially used ampoule is being discarded following the administration of a dose. In this case recording the administration of the dose in the Schedule 8 Register (HA14) includes taking responsibility for appropriately discarding the remainder of the ampoule. The Schedule 8 Register for use in all patient care areas (designated HA14) includes a column to record the amount discarded.

Key points

- All activities under a Poisons Permit can be audited by the Department of Health.
- The permit holder must decide which medicines are held on site and must sign off on all orders to wholesalers.
- On-site staff should make sure they have the authority of the permit holder (either via a clinical practice guideline or a telephoned/faxed/electronic order) before using any scheduled medicine.
- Everything done by on-site staff that relates to scheduled medicines must be supported by standard operating procedures (SOPs).
- Everything done by on-site staff that relates to scheduled medicines must be documented.
- On-site registered nurses, paramedics or other staff qualified in first aid may only administer doses of prescription medicines.
- On-site registered nurses, paramedics and other staff may only supply Schedule 2 and Schedule 3 medicines provided the medicine is supplied in the original manufacturer's pack and they have the authorisation of the permit holder to make the supply.
- If there are discrepancies in the quantity of Schedule 8 medicines on hand or the loss/theft of any medicine on-site staff must immediately report to the permit holder. Loss or theft of medicines must also be reported to the WA Police. The Department of Health must also be contacted where Schedule 8 medicines are involved. It is the responsibility of the permit holder to ensure this occurs even where reporting has been delegated to on-site staff.

Need further information?

Contact the Pharmaceutical Services Branch by telephone on (08) 9222 6883 or by email at poisons@health.wa.gov.au



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request for a person with a disability.

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