WORKING WITH SCHEDULED POISONS

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1 INTRODUCTION

Some chemicals are classified as Scheduled Poisons. These medicines, poisons and drugs have restrictions in relation to public use and access which include implications for their purchase and use within the university. The Poisons and Therapeutic Goods Act 1966 and the NSW Poisons and Therapeutic Goods Regulation 2008 describe the scheduling of these chemicals and prescribed management actions in how these medicines and poisons should be supplied, labelled, stored and disposed.

2 PURPOSE

This guideline has been developed in support of the University’s Chemical Safety Standards. Faculties, schools, research groups and professional services units are encouraged to use this document as a primary reference when developing local procedures for the management of scheduled poisons and restricted drugs.

This guideline does not detail requirements of supply, prescription or administration of scheduled drugs by a practitioner in the clinical environment.

3 CLASSIFICATION OF SCHEDULED POISONS

The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) is the list of chemicals to which regulatory control applies. Medicines and poisons are classified into eight schedules (Table 1) which determines public accessibility and different levels of regulatory control. Different conditions apply to the purchase, storage, labelling and disposal of scheduled medicines and poisons depending on their classification in the Poisons Standard. For example, Schedule 3 medicines must be personally sold only by pharmacists (other shops are not licensed to sell them) and Schedule 4 medicines are only to be supplied on prescription.

The schedule and label descriptor for a chemical can be found in the Safety Data Sheet and on the label.

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2</td>
<td>“Pharmacy medicine”</td>
<td>Chemicals which are dangerous to life if misused or carelessly handled, but which should be available to the public for therapeutic use or other purposes without undue restriction.</td>
</tr>
<tr>
<td>S3</td>
<td>“Pharmacist only medicine”</td>
<td>Drugs of higher potency which are for therapeutic use. Professional advice may be required by the user in respect to dosage, frequency of administration and general toxicity.</td>
</tr>
<tr>
<td>S4</td>
<td>“Prescription Only medicine” “Prescription Animal Remedy”</td>
<td>Prescribed restricted substances as per the schedule. Substances which in the public interest should be supplied only by, or upon the written prescription of, an authorised practitioner.</td>
</tr>
<tr>
<td>S5</td>
<td>“Caution”</td>
<td>Poisonous substances of a dangerous nature commonly used for domestic purposes which should be readily</td>
</tr>
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</table>
available to the public but which require caution in their handling, use and storage.

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>S6</td>
<td>Schedule 6 “Poison”</td>
<td>Moderate potential for harm; industrial and agricultural poisons. Substances which should be readily available to the public for agricultural, pastoral, horticultural, veterinary, photographic or industrial purposes or for the destruction of pests.</td>
</tr>
<tr>
<td>S7</td>
<td>Schedule 7 “Dangerous Poison”</td>
<td>Substances with a high potential for causing harm at low exposures. Substances of exceptional danger which require special precautions in their manufacture, packaging, storage and use.</td>
</tr>
<tr>
<td>S8</td>
<td>Schedule 8 “Controlled Drug”</td>
<td>Drugs of addiction as per the schedule maintained by the PSB. Substances which are addiction producing or potentially addiction producing. Possession, supply, prescribing and use are strictly limited.</td>
</tr>
<tr>
<td>S9</td>
<td>Schedule 9</td>
<td>Prohibited substances</td>
</tr>
</tbody>
</table>

Table 1: Description of poison schedules

Further information:

Alphabetic list of poisons, restricted substances and drugs of addiction
Pharmaceutical services FAQs for Analysts and Researchers

4 RISK ASSESSMENT

In the first instance every effort should be made to eliminate the use of hazardous chemicals. Investigation of alternative methods or the use of an alternate chemical is recommended. If an alternative is not possible then a risk assessment must be completed in consultation with the workers who could be exposed. The use of highly dangerous S7 poisons, S8 and S9 drugs is prescribed through regulation.

The risk assessment aims to identify the potential for exposure during the planned activity and detail the control measures proposed to manage the risk, including training and supervision requirements. Once agreed and approved, control measures must be adhered to as a condition of use.

Whenever assessing the risk associated with an activity or task, various risk factors must be considered including the:

- Nature of the chemicals involved and other hazards;
- Work environment;
- Physical activities required to complete the task;
- Psychological demands of the task; and
- Individual workers involved in the activity.

A detailed risk assessment must be completed prior to the initial purchase of a highly dangerous S7, S8 and S9 poison.
5 SAFE WORK PROCEDURES

5.1 PURCHASING

A Schedule 8 drug must not be purchased until the Pharmaceutical Services Unit has issued an authorisation for the relevant supervisor to use the specific scheduled drug (refer Authorisation).

Chemical suppliers will require confirmation of authorisation (S8) and completion of an end user declaration (EUD) to verify how the chemical will be used and that the use of the chemical has been approved by the organisation (highly dangerous S7, S8 controlled drugs).

Restricted Schedule 4 pharmaceuticals, Highly dangerous Schedule 7 poisons or Schedule 8 controlled drugs that are delivered to the University must be stored in a secure location until pick up and promptly collected by the purchaser.

5.2 STORAGE

In the laboratory, storage of all poisons should be in accordance with standard laboratory storage requirements. In addition:

- A poison should be clearly labelled with the descriptive phrase (e.g. “Dangerous Poison”) and schedule number.
- Containers that have held poisons must not be re-used.
- Schedule 5, 6 or 7 poisons cannot be repacked and must be kept in the manufacturer’s original, unopened container. This applies particularly to stock medicines and agricultural chemicals.

Further conditions apply to the storage of Schedule 4, 7, 8 and 9 poisons.

5.2.1 Schedule 4

All Supervisors must ensure that Schedule 4 drugs are stored in a secure storage area e.g. locked laboratory. If a freezer or refrigerator is used for the storage of these substances it must be secured in a room with restricted access controls. There is no requirement for a drugs register to be kept for Schedule 4 drugs, other than for pentobarbitone sodium (when used as a restricted S4 substance for euthanising animals).

5.2.1.1 Special requirements for Schedule 8 Controlled drugs and pentobarbitone sodium

An authorised person who uses a Schedule 8 controlled drug or pentobarbitone sodium must keep these substances separately from all other goods in a safe or locked secure cupboard. Securely attach the safe or cupboard to a part of the premises. If these substances are to be kept in a freezer or refrigerator, the freezer or refrigerator must be kept securely locked when not in immediate use and only used for that purpose.

5.3 HANDLING

5.3.1 Drug register

An authorised person must keep a drug register for all Schedule 8 controlled drugs and pentobarbitone sodium that is obtained or used. There is no need to keep a separate S4 Drugs Register if there is a page reserved specifically for pentobarbitone sodium (S4) in an S8 drugs register.

The drugs register must have:

- Pages that cannot be removed or replaced i.e. a bound book,
- Consecutively numbered pages,
- Separate pages in the register for each S8 drug, each form and strength of the drug,
• Space for specific entry requirements of the drugs register as shown in Table 2.

Approved drugs register books may be purchased from the chemical supplier.

<table>
<thead>
<tr>
<th>Date drug received or used</th>
<th>Supplier or Name of person who using S8 drug</th>
<th>In</th>
<th>Out</th>
<th>Balance</th>
<th>Dispenser’s original dispensing number or letter</th>
<th>Authorised person Name</th>
<th>Authorised person Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date and address to whom drug dispensed, administered, used or received</td>
<td>Original volume received from supplier</td>
<td>Amount taken from original for use</td>
<td>Amount remaining</td>
<td>Laboratory – purpose for which drug used Animal – Name of Veterinarian</td>
<td>Printed Name of Authorised person</td>
<td>Signed by Authorised user</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Name and Address to whom drug dispensed, administered, used or received</td>
<td>In</td>
<td>Out</td>
<td>Balance</td>
<td>Dispenser’s original dispensing number or letter</td>
<td>Authorised person Name</td>
<td>Authorised person Signature</td>
</tr>
</tbody>
</table>

Table 2: Example of the format of a Scheduled Drugs Register

5.3.1.1 Drug register entries

A “Scheduled Drugs Register” must be kept to record all use by authorised persons working with these substances. When any pentobarbitone sodium (S4) is received or used the authorised person must enter in the register the:

• Quantity that was received or used,
• Name and address of the supplier,
• Number and species of animals for which it was used,
• Total quantity held by the authorised person after the entry is made.
• Date and sign each entry

The authorised person who receives, administers or uses an S8 drug is responsible for entering the details in the drugs register. Each entry must be:

• Made on the date authorised person receives or uses an S8 drug,
• Written permanently and in English,
• Legible, complete and in sufficient detail,
• Dated and signed by the person by whom it is used,
• True and correct.

The balance recorded in the S8 register should always coincide with the actual stock on hand. A mistake in any entry in a drug register must be corrected by making a marginal note or footnote and by initialing and dating it. If the cause of the discrepancy is identified and found to involve a minor error (e.g. arithmetic) or departure from procedures (e.g. omission of recent use) include a comment to that effect against the amending entry. Alterations, obliterations or cancellations in a register are not permitted and multiple errors must be drawn to the attention of the Head of School or Dean.

Opening and closing balances should be verified and signed when the drug register is completed and a new drug register is commenced. In addition balances should be checked and verified from page to page. Whenever possible balances carried forward to a new page or book should be verified by a second authorised person.

If a quantity of S8 drug is removed from a stock solution and subsequently diluted to become a working solution then both entries need to be made on the S8 drugs register. A different page is used for each concentration. As an example: 50 ml of Ketamine stock solution is listed on a page in the drugs register. 5 ml of this is removed to be diluted thus the entry recorded in the register is that 5 ml is removed and 45 ml of this stock solution remains.

The 5 ml is then diluted to 50 ml. This becomes a 10% Ketamine Working Solution and should be recorded on a new page with a 50 ml starting volume. Each removal is recorded in the usual manner. The working solution should be appropriately labelled and dated and stored in the S8 approved storage area.

Drugs registers must be kept for at least 2 years, from the last date on which any:
• Entry was made in the register; or
• S8 drug was received, administered or used.

5.3.1.2 Drug register auditing

The person responsible for maintaining a drugs store and register must:

• Make an accurate inventory of all S8 drugs held twice each year (recommended March and September),
• Endorse the drugs register, immediately under the most recent entry for each S8 drug, with the quantity of each drug actually held and the date on which the inventory was made,
• Sign each entry in the drug register.

When checking stock, physically count opened containers of drugs, do not open sealed packs but rather check that the seals are intact and, if they are sealed record the quantity as labelled. Measure the volume of drugs in liquid form only when removing the last of the contents, if there is reasonable discrepancy (e.g. up to 3%), make a note of that fact against the entry. Up to that point estimate the volume by observation and note the entry as "estimated".

A complete inventory of S8 drugs must also be made if:

• There is loss or destruction of a drugs register,
• A person assumes control for a period of one month or more over any drugs store.

Drugs registers must be made available for inspection on demand by the Pharmaceutical Services Unit, the Police or any authorised officer from the NSW Ministry of Health.

5.3.2 Reporting theft and loss

The NSW Poisons and Therapeutic Goods Regulation 2008 require authorised persons to report to the Director-General of Health any:

• Suspected or actual loss or theft of an S8 drug,
• Suspected or actual loss or theft of an S4 drug ‘prescribed restricted substance’,
• Suspected or actual loss or destruction of a drugs register.

The following incidents must be reported immediately and without delay, firstly to the Head of School and/or Dean and then to the Director-General. Notice of the fact and circumstances of the loss or destruction must be given in writing using the form Notification of Loss or Theft of Accountable Drugs (S8 and S4 substances). This form is to be completed and submitted electronically or e-mailed to pharmserv@doh.health.nsw.gov.au.

5.4 DISPOSAL

All scheduled poisons, with the exception of Schedule 8 and 9 drugs, are to be disposed as outlined University hazardous waste program.

5.4.1 Schedule 4

Schedule 4 (Restricted Substances) must not be disposed of ‘in any place or any manner likely to constitute a risk to the public’. Until removal waste Schedule 4 drugs should be kept secure in a waste depot or laboratory.

5.4.2 Schedule 8 and Schedule 9

Schedule 8 and Schedule 9 must not be wilfully destroyed except under the direct personal supervision of an authorised person in charge of a laboratory and under the conditions of the authorisation.
The disposal of S8 drugs can be arranged by contacting the Duty Pharmaceutical Advisor at Pharmaceutical Services Unit. The Pharmaceutical Services Unit will arrange a suitable time to collect the S8 drugs and will make the required entry in the drugs register as a record of the authorised destruction.

General inquiries (including calls for Duty Pharmaceutical Officer)
Telephone: (02) 9391 9944 Email: pharmserv@doh.health.nsw.gov.au

If the person is a medical, dental or veterinary practitioner, destruction can be arranged through a pharmacy or the police. The destruction must be noted in the drugs register and include the date and the name, professional registration number and signature of the pharmacist (or authorising police officer) and the name and signature of the relevant practitioner.

6 AUTHORISATION FOR USE

6.1 SCHEDULES 2 - 6

Authorisation from the NSW Ministry of Health is not required for the use and storage Schedule 2 through to Schedule 4 poisons.

“A scientifically qualified person who is in charge of a laboratory or department, or a person acting under the direct personal supervision of such a person, is authorised to possess and use any Schedule 2, 3 or 4 substance that is required for the conduct of medical or scientific research or instruction or the conduct of quality control or analysis”.

For Schedule 5, Schedule 6 poisons there are no specific authorisation requirements for use.

6.2 SCHEDULE 7

Use of a Schedule 7 poison which is used for research, analytical or instructional purposes in the university is exempt from the requirements of obtaining an authorisation from the NSW Ministry of Health.

Chemical suppliers will require an end user declaration (EUD) to be completed for the purchase of highly dangerous S7 poisons. This EUD and approval for purchase must be signed by the Head of School or Head of the relevant organisational unit.

Schedule 7 poisons which are described as “highly dangerous substances” are:

- arsenic,
- cyanides,
- fluoroacetamide,
- fluoroacetic acid,
- hydrocyanic acid,
- strychnine,
- thallium
- any substance listed in Appendix C of the current Poisons Standard

6.3 SCHEDULE 8 AND SCHEDULE 9

Possession of Schedule 8 and 9 drugs is prohibited without written authority from the Director-General, NSW Ministry of Health. A suitably qualified person (a person in charge of a laboratory used for the purpose of research, analysis or instruction) may apply for authorisation to possess the following substances for the purpose of research, analysis, or instruction:

- Substances listed in Schedule 8 of the NSW Poisons Standard,
- Prohibited substances in Schedule 1 of the NSW Drug Misuse and Trafficking Act 1985.
Authorisation is issued, in writing, to the **person** working with the chemical and is not transferable. Refer to the:

- Application for Authority to Possess Drugs of Addiction or Prohibited Substances for the Purpose of Research, Analysis or Instruction
- Checklist for making an application

Applications to obtain written authority from the NSW Ministry of Health for the purpose of scientific research have the following additional requirements.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Specific Requirement</th>
</tr>
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<tbody>
<tr>
<td>Schedule 8 drugs for use on animals, for example ketamine and buprenorphine</td>
<td>Include approval from the Animal Ethics Committee</td>
</tr>
<tr>
<td>Prohibited substances in Schedule 1 of the Drug Misuse and Trafficking Act 1985, such as cannabis</td>
<td>Include approval from an appropriate Human Research Ethics Committee, if human clinical trials are proposed.</td>
</tr>
<tr>
<td>Prescription of Schedule 8 drugs (or prohibited substances) for use in human clinical trials</td>
<td>Telephone the Monitoring and Compliance Section at Pharmaceutical Services during business hours on (02) 9424 5923.</td>
</tr>
</tbody>
</table>

**Steps to obtain authorisation**

1. Supervisor completes a detailed risk assessment for the activity involving the S8 or S9 poison in consultation with all workers who will undertake the activity.
2. The Pharmaceutical Services Unit application for authorisation is prepared by the supervisor.
3. The draft risk assessment and Pharmaceutical Services Unit application form is submitted to Safety Health and Wellbeing for review.
4. The completed risk assessment is submitted to the head of the relevant organisational unit for approval.
5. If approved, the supervisor lodges the completed application for Authorisation with the Pharmaceutical Services Unit, NSW Ministry of Health.
6. The Pharmaceutical Services Unit will review the application either issue or refuse authorisation.
7. If the activity is authorised by the Pharmaceutical Services Unit an authorisation letter will be sent to the supervisor.
8. The supervisor must provide a copy of the authorisation letter to Safety Health & Wellbeing and the head of the relevant organisational unit.

An authority will remain current until it is suspended, cancelled or surrendered.

Commonly used substances and preparations classified as Drugs of Addiction are listed in Schedule 8 of the NSW Poisons List. Unauthorised possession of a drug of addiction is illegal.

**7 REVIEW AND EVALUATION**

Performance standards and the associated procedures and guidelines will be reviewed by Safety Health & Wellbeing at least once every two years to identify and implement opportunities for improvement.

**8 REFERENCES**

1. [Alphabetic Poison List](#) NSW Ministry of Health alphabetic list of poisons, restricted substances and drugs of addiction in alphabetical order
9 DOCUMENT CONTROL

<table>
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<tr>
<th>Acknowledgements</th>
<th>NSW Ministry of Health, Pharmaceutical Services</th>
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<tr>
<td>Related Documents</td>
<td>WHS_CHE_STD_1_Chemical Safety Standards</td>
</tr>
<tr>
<td></td>
<td>WHS_CHE_GUI_1_Chemical storage</td>
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