UOW SAFE@WORK

SCHEDULED

DRUGS AND

GUIDELINES

POISONS



AUSTRALIA

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1 Introduction

The University of Wollongong (*UOW*) uses scheduled drugs and poisons for research, analysis and teaching activities. This procedure will ensure that such drugs and poisons are regulated in a manner consistent with legislative requirements in order to eliminate or control potential health, safety and security risks.

2 Scope

This guideline applies to all UOW analysis, research and teaching activities that involve the use of scheduled drugs or poisons. This guideline details University practice in relation to the regulation of drugs or poisons including authorisation, information, training and supervision, storage, record keeping, disposal, security and reporting.

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

3 Definitions

PSU	Pharmaceutical Services Unit of NSW Department of Health
Schedule 2 (S2)	Pharmacy medicines.
Schedule 3 (S3)	Pharmacy only medicines.
Schedule 4 (S4)	Prescribed restricted substances as per the schedule maintained by the PSU. PSU web site must be consulted for the <u>current list of schedule 4 drugs</u> .
Schedule 5(S5)	Low potential for harm. Domestic poisons.
Schedule 6 (S6)	Moderate potential for harm. Industrial and agricultural poisons.
Schedule 7 (S7)	Substances with a high potential for causing harm at low exposures. <u>Alphabetical list of poisons.</u>
Schedule 8 (S8)	Drugs of addiction as per the schedule maintained by the PSB. The PSB web site must be consulted for the <u>current list of schedule 8 drugs</u> .
Schedule 9 (S9)	Prohibited substances. Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities. Any substance listed in Schedule 1 of the <u>NSW Drug Misuse and Trafficking Act 1985</u> , such as cannabis.
Schedule 10 (S10)	Substances of such danger to health as to warrant prohibition of sale, supply and use.
Competent person	A person who has acquired through training, qualifications or experience, or a combination of them, the knowledge and skills to carry out that task.
Authorised person	The person who has written authority from the Pharmaceutical Services Unit of NSW Department of Health (PSU) to possess and use S8 drugs for research and teaching activities at the university.

Approved Person	A competent person who has been approved by the Authorised Supervisor to possess, use or store S8 drugs for the purposes of analysis, research and teaching and who is acting under their supervision.		
Approved Storage Area	A separate room, safe, cupboard or other receptacle (e.g. freezer or refrigerator) securely attached to a part of the premises and kept securely locked when not in immediate use.		

4 Risk assessment

In the first instance every effort must be made to eliminate the use of hazardous chemicals. Investigation of alternate methods or use of alternative chemicals is recommended. If an alternative is not possible then a risk assessment must be completed in consultation with workers who could be exposed. The use of highly dangerous S7 and S10 poisons and S8 and S9 drugs is prescribed through regulation. A detailed risk assessment must be completed prior to the initial purchase of highly dangerous S7 and S10 poisons, S8 and S9 drugs.

5 Authorisation for use

5.1 Schedule 2-6

Authorisation from the NSW ministry of health is not required for the use and storage of Schedule 2-4 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 analysis."

A drug register and specific storage and handling procedures are required if using Pentobarbitone sodium as a restricted S4 substance for euthanising animals.

For Schedule 5 and 6 poisons there are no specific requirements.

5.2 Schedule 7 and Schedule 10

Use of a schedule poison which is used for research, analytical or instructional purposes is exempt from the requirements for obtaining authorisation from the NSW ministry of health.

5.3 Schedule 8 and 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 <u>NSW Drug Misuse and Trafficking Act 1985</u> (Schedule 9)

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
- <u>Checklist for making an application</u>

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

Substance	Additional requirements		
Schedule 8 drugs for use on animals, for example ketamine and buprenorphine	Include approval from the Animal Ethics Committee		
Schedule 9	Include approval from an appropriate Human Research Ethics Committee, if human clinical trials are proposed.		
Prohibited substances in Schedule 1 of the Drug Misuse and Trafficking Act 1985, such as cannabis			
Prescription of Schedule 8 drugs (or prohibited substances) for use in human clinical trials	Telephone the Monitoring and Compliance Section at Pharmaceutical Services during business hours on (02) 9424 5923.		

5.3.1 Steps to obtain authorisation

- 1. Supervisor completes a detailed risk assessment for the activity involving the S8 or S9 drug 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 completed risk assessment is submitted to the head of the relevant organisational unit for approval.
- 4. If approved, the supervisor lodges the completed application for Authorisation with the Pharmaceutical Services Unit, NSW Ministry of Health.
- 5. The Pharmaceutical Services Unit will review the application and either issue or refuse authorisation.
- 6. If the activity is authorised by the Pharmaceutical Services Unit an authorisation letter will be sent to the supervisor.
- 7. The supervisor must provide a copy of the authorisation letter to the <u>WHS unit</u> and the head of the relevant organisational unit.

An authority will remain current until it is suspended, cancelled or surrendered. Researchers with authority from the PSU (i.e. authorised supervisors) are permitted to allow persons acting under their supervision to possess and use scheduled drugs for research and teaching.

6 Purchasing

6.1 Schedule 2-7 and Schedule 10 poisons

Chemical suppliers will require an end user declaration (EDU) to be completed for the purchase of S4, highly dangerous S7 and S10 poisons (For schedule 10 poisons refer to the <u>Poisons standard</u>). 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

Restricted Schedule 4 pharmaceuticals, *Highly dangerous* Schedule 7 and Schedule 10 poisons that are delivered to the University must be stored in a secure location until pick up and promptly collected by an approved person.

6.2 Schedule 8 and 9 drugs

A Schedule 8 or Schedule 9 drug must not be purchased until the Pharmaceutical Services Unit has issued an authorisation for the relevant supervisor to use the specific scheduled drug. The supplier will require confirmation of authorisation and completion of an end user declaration (EUD) to verify how the drug is being used and that the use of the drug has been approved by the organisation.

The approved person who is ordering the S8 or S9 drug must highlight on the purchasing requisition form (or equivalent) the following wording:

S8 DRUG - MUST BE COLLECTED BY AN APPROVED PERSON or

S9 DRUG - MUST BE COLLECTED BY AN APPROVED PERSON

The wording must be highly visible in bold and capitals to assist the staff receiving the package (e.g. stores staff or reception). The stores/reception staff is then required to contact the approved person requesting the substance and let them know the substance has arrived and must be collected. The material must be stored in a secure location until pick up. If the named 'Approved Person' on the purchasing form cannot be contacted then the associated Authorised Personnel can provide the contact details for an alternative 'Approved Person'. Each laboratory ordering S8 or S9 drugs will supply the store/reception staff with two approved persons who can collect the drugs.

7 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, 7 and 10 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, 9 and 10 poisons.

7.1 Schedule 4, 7 and 10

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.

Where schedule 4, 7 and 10 poisons are used, they must be kept:

- apart from food intended for consumptions by humans or animals, and
- in such a way that, if the container breaks or leaks, the poison cannot mix with or contaminate any food intended for consumption by humans or animals, and
- in a room or enclosure to which the public does not have access.

7.2 Schedule 8, 9 and pentobarbitone sodium (S4)

An authorised person who uses Schedule 8 and 9 drugs 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.

The approved storage area must be secured at all times. A key to the storage area will be issued to researchers authorised by the PSU, and a copy will be held by the relevant Laboratory Manager or other officer nominated by the relevant Head of School/Unit, for the purpose of inspections and/or inventories. The activity of maintaining an approved storage area may be delegated in writing to a competent person.

8 Handling

When handling any scheduled poisons or drugs ensure all safety directions are followed. There are specific legislative requirements for the handling of Schedule 8, 9 and pentabarbitone sodium (S4) which are outlined below.

8.1 Drug register

An *authorised* person must keep a drug register for all Schedule 8, Schedule 9 drugs and pentobarbitone sodium (S4) 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 drug, each form and strength of the drug,
- Space for specific entry requirements of the drugs register as shown in below.

Approved drugs register books may be purchased from a drugs supplier. The format of an example drugs register is shown below:

Date	Name and address of person or company to whom dispensed, sold, supplied, or from whom obtained	In	Out	Balance	Dispenser's original dispensing number or letter	Name of Authority	Signature of dispenser or administrator
Date drug used	Name of person who used the drug & animal identifier (where relevant)	Original volume received from supplier	Amount used/withd rawn from original	Amount remaining	For laboratory work, use this space to record the purpose for which the drug was used e.g. ethics approval no.	Name of Authorised person	Signed by user of the drug

When using any pentobarbitone sodium (S4) all the above information must be entered in the register as well the number and species of animals for which it was used.

Drugs registers must be kept for at least 2 years, from the last date on which any:

- Entry was made in the register; or
- any drug was received, administered or used.

8.2 Drug register entries

A "Scheduled Drugs Register" must be kept to record all use by authorised persons working with S8, S9 **pentobarbitone sodium (S4)**.

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

- Made on the date authorised person receives or uses a 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 drug register should always coincide with the actual stock on hand (the lot number of the drug should be documented so the usage history can be tracked accurately). A mistake in any entry in a drug register must be corrected by making a marginal note or footnote and by initialling 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.

8.3 Recording dilutions in the register

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 stored in the stored and stored in the S8 approved storage area.

8.4 Drug register auditing

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

- Make an accurate inventory of all drugs held twice each year (recommended March and September),
- Endorse the drugs register, immediately under the most recent entry for each 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. When using the last of the contents ensure the liquid amount is measured to check for discrepancy in expected volume, 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 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 anydrugs 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.

8.5 Compliance Monitoring

The <u>Schedule Drugs Compliance Checklist</u> should be used as a compliance monitoring tool. It should be completed by the authorised personnel (or delegate) at the time of an inventory of S8 and S9 drugs. The checklist should be forwarded to the Head of School/Unit for information and corrective action, as required.

8.6 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 or S9 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 <u>Notification of Loss or Theft of Accountable Drugs</u> (S8, S9 and S4 substances). This form is to be completed and submitted electronically or e-mailed to pharmserv@doh.health.nsw.gov.au

9 Disposal

All scheduled poisons, with the exception of Schedule 4, 8 and 9 drugs are to be of disposed as outlined the UOW <u>Hazardous Waste Disposal Guidelines</u>.

9.1 Disposal of S4 Drugs

Schedule 4 (Restricted Substances) must not be disposed of 'in any place or any manner likely to constitute a risk to the public' (Clause 66 Poisons and Therapeutic Goods Regulation 2008).

At UOW, disposal of such materials follows the same path as for any material which is to be incinerated. The two methods which can be used are:

- Vials and ampoules of S4 substances can be disposed of in the sharps containers. Absorbent material can be used to provide soakage in the event that a spillage could occur. These containers are removed by UOWs biological waste contractor and are incinerated.
- The S4 substances can follow the path of cytotoxic substances and can thus be collected in the cytotoxic waste bins. Cytotoxic waste is removed by UOWs biological waste contractor and is incinerated.

9.2 Schedule 8 and Schedule 9

Schedule 8 and Schedule 9 drugs 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 or S9 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 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.

10 Maintaining the Scheduled Drugs Authority Register

The relevant Head of School/Unit, or their nominee, should ensure that a record is maintained of authorised personnel and all persons working with S8, S9 drugs or pentobarbitone sodium (under their authority). The records will be held in a Scheduled Drugs Authority Register and maintained by the relevant Laboratory Manager or other officer nominated by the relevant Head of School/Unit.

11 Information, Training and Supervision

The Head of School/Unit, or their nominee, should ensure that all authorised supervisors and approved persons are provided with information and training in the secure storage, handling and record keeping of scheduled drugs.

Authorised persons are responsible for the ongoing supervision of approved persons working with scheduled drugs under their authority and for compliance with the relevant legislative requirements.

12 Related Documents and references

- Poisons & Therapeutic Goods Act 1966 Poisons & Therapeutic Goods Regulation 2008
- Drug Misuse and Trafficking Act 1985
- Poisons Standard July 2016
- Work Health and Safety Act 2011
- Work Health and Safety Regulation 2011
- <u>NSW Health Pharmaceutical Services department</u> drugs schedules and procedures
- Schedule Drugs Checklist

13 Acknowledgements

- University of Western Sydney
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- University of NSW

14 Version Control Table

Version Control	Date Released	Approved By	Amendment
1	July 2011	Manager OHS	Document created
2	March 2012	Manager OHS	Rebrand
3	December 2012	Manager WHS	Title changed from 'Schedule 4 and 8 Drugs Procedure' to 'Scheduled Drugs and Poisons Procedure'. Document updated to include information on schedule 7 poisons, and to reflect the unit name change to WHS Unit.
4	May 2013	Manager WHS	Document updated to make distinctions between the disposal and storage process for S4 and S8 drugs.
5	July 2016	Manager WHS	Document updated to reflect the changes in legislation. Updated to include requirements for all scheduled poisons and drugs.