Substance Management Plan for Medicines and Poisons Procedure

Section 1 - Purpose and Scope

(1) The University of Queensland (UQ) Substance Management Plan (SMP) outlines the approach to managing risks associated with UQ workers, students and others performing regulated activities with scheduled substances (medicines, poisons and therapeutic goods). The SMP details how to comply with the requirements of the Medicines and Poisons Act 2019 (Qld) and associated legislation. The SMP is intended to assist in identifying and managing known and foreseeable risks associated with any dealing with regulated medicines and poisons and provides the overarching risk framework that is dynamic and proportionate to the risk associated with regulated activities.

(2) This Procedure, referred herein as the Substance Management Plan (SMP), applies to all UQ workers and undergraduate students who are occupants of UQ regulated places (refer to SMP Appendix A - UQ Approved Organisational Units/Locations) that involve regulated medicines and poisons for research, teaching and other UQ work/study-related purposes. It includes formal agreements between UQ and external organisations when UQ occupies a building and is responsible for the management of the facility e.g. a remote clinic, and any other activity directly controlled by UQ.

(3) For the purposes of this Procedure, the definition of UQ workers is broad – including staff, Higher Degree by Research (HDR) and Honours students.

(4) Volunteers and contractors are prohibited from using substances under the control of UQ that fall within the scope of the SMP.

(5) The SMP applies to all UQ Organisational Units, Controlled Entities and tenants reflected in SMP Appendix A - UQ Approved Organisational Units/Locations.

Exclusions

(6) The SMP does not apply to dealings with medicines and therapeutic substances which are covered by the Medicines and Poisons (Medicines) Regulation 2021 (Qld). As such the SMP does not apply to medicines and therapeutic substances which are bought, manufactured, stored/possessed, supplied (dispensing of stock; or dispensed, given as a treatment dose or otherwise for a person or animal), prescribed, administered and disposed by:

a. UQ Staff working as health practitioners in hospitals and health clinics (e.g. Queensland Health hospitals, UQ Centre for Clinical Research, UQ Health Care);
b. UQ veterinary surgeons or registered veterinarians working as such within UQ Biological Resources Facilities, the Hidden Vale Wildlife Centre, the School of Agricultural and Food Sciences, the School of Veterinary Science, UQ Veterinary Teaching Hospitals at Gatton and Dayboro Campuses, or when based at RSPCA locations;
c. UQ First Aid Officer (e.g. EpiPens, etc.);
d. Royal Flying Doctor doctors and their medical kits (e.g. at Heron Island Research Station);
e. UQ workers and undergraduate students for personal needs (e.g. prescription medication);
f. commercial entities located on UQ campuses (e.g. commercial pharmacies).

(7) UQ activities managed in accordance with the Medicines and Poisons (Medicines) Regulation 2021 (Qld) not requiring endorsement under this SMP are listed in SMP Appendix B.

(8) If an activity is excluded from the SMP but involves the use of a substance that was acquired under the SMP, requirements under Section 6 'Recording and Reporting' must be complied with (e.g. a Scheduled substance purchased under the SMP is used in a therapeutic procedure by a Veterinary Surgeons Board registered veterinary surgeon).

(9) The UQ SMP does not apply to UQ workers if they are using poisons controlled and managed by another organisation, e.g. Translational Research Institute (TRI), as they must follow the established SMP of that building or organisation.

(10) The SMP does not apply to reference material containing one (1) gram or less of a regulated poison at an analytical or chemical laboratory; or reference material containing 0.5 grams or less of a regulated poison in a portable testing device. An exempted reference material under the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 means a substance used to calibrate analytical equipment, or validate an analytical measurement process, that has been manufactured by an accredited laboratory in compliance with AS ISO/IEC 17025:2018 General Requirements for the Competence of Testing and Calibration Laboratories and AS ISO 17034:2018 General Requirements for the Competence of Reference Material Producers (available via Standards Databases through UQ Library).

Legislative context

(11) The Australian Government regulates medicines and poisons under the Therapeutic Goods Act 1989 (Cth), Therapeutic Goods Regulations 1990 (Cth) and the subordinate Poisons Standard (SUSMP), which contains schedules of substances classified according to their degree of potential harm and the degree of control over their availability.

(12) The Queensland Government regulates medicines and poisons, including those scheduled in the Poisons Standard, under the Medicines and Poisons Act 2019 (Qld), and related subordinate regulations.

(13) There are other obligations and restrictions placed on UQ through other relevant legislation for medicines and poisons (e.g. Work Health and Safety Regulation 2011).

(14) This Procedure represents UQ's SMP required under of the Medicines and Poisons Act 2019.

Section 2 - Process and Key Controls

(15) Key controls supporting the effectiveness of this Procedure include:

a. Eligible Persons (refer to Definitions in the Appendix) identified in this Procedure must be appropriately qualified, instructed, trained and supervised in all regulated activities with these substances.
b. A risk assessment must be completed in UQSafe by an Eligible Person before commencing regulated activities with scheduled substances.
c. Approval is required from the Health, Safety and Wellness Division (HSW Division) to conduct regulated activities with scheduled substances.
d. Procurement of regulated medicines and poisons under this Procedure must be through UQ's central procurement system.

Section 3 - Key Requirements

Eligible Persons

(16) The following categories or worker's positions are considered as Eligible Persons and can seek approval from UQ to perform regulated activities after approval. Training and qualification requirements are outlined in the 'Eligible Persons Training' provisions of this Procedure.

Research staff and research students (Higher Degree by Research, masters by research and honours students only)

(17) These users are eligible and may use scheduled substances for research purposes without supervision after approval.

Teaching staff

(18) Teaching staff are eligible and may use scheduled substances for teaching purposes after approval. These appropriately qualified and authorised persons are to supervise the use of scheduled substances by undergraduate students who are not eligible to be approved for individual use. The level of supervision is proportionate to the Schedule of the substance and the risk.

Support staff

(19) Staff who support research or teaching activities (e.g. teaching support staff, goods receiving staff) who may be required to handle scheduled substances, are eligible and may receive approval to undertake their work duties (e.g. set up practicals, receive, store and distribute scheduled substances to the approved users or approved waste pathway).

Visiting researchers

(20) Visiting researchers involved in collaborations with UQ staff may seek an approval to use scheduled substances. Before an approval is considered the visiting researcher must meet the minimum qualification and training requirements in this Procedure and must be registered by the sponsoring Organisation Unit as per the Volunteer, Contractor and Visitor Health and Safety Training and Induction requirements.

Eligible Persons training

(21) Eligible Persons are required to have minimum qualifications or expertise (refer to Definitions in the Appendix) and must complete the following online modules (via Workday for Staff and HDR candidates or Blackboard for Honours students and non-UQ staff) prior to approval to use and/or dispose of scheduled substances:

a. Chemical Safety (via Workday) / Chemical Safety (via learn.UQ) (refresher required every 2 years).
b. Staff Standards of Conduct (via Workday) (refresher required every 2 years).

(22) Training must be completed and confirmed before any approvals are recorded. Training records are held in Workday.

Use of scheduled substances by non-eligible persons

(23) Students (high school, any undergraduate (e.g. medical or nursing students), work experience or research experience students) may only use scheduled substances if supervised. Any use of scheduled substances by these students must be supervised by a qualified Eligible Person under an appropriate approval (e.g. academic or researcher) or by a class of person authorised under the Medicines and Poisons (Medicines) Regulation 2021 (Qld)

(e.g. health practitioner).

Standard operating procedure

(24) An Organisational Unit which purchases, uses, stores or disposes of low-risk, restricted or high-risk poisons must have a documented standard operating procedure (SOP) which specifies how the requirements of the SMP will be operationalised.

(25) Appropriate transport, storage (possession) and disposal processes must be documented to ensure conformance and the safety of workers, the public, and the environment by preventing unwanted degradation, interaction or cross-contamination of regulated poisons. Emergency procedures must be documented that address first-aid and post-exposure protocols, and spill containment, cleanup and disposal.

Risk assessment

(26) Eligible Persons are required to complete risk assessment(s) in UQSafe for the activities involving the use of regulated poisons prior to work commencing, and if following approval, there is a change in how the listed substances are to be used.

(27) Risk assessments must be detailed and specific to the activity being performed, and make reference to the following:

a. name of the regulated poison/s;
b. how the regulated poison/s will be used safely in the specific procedure or experiment including appropriate controls;
c. how waste or unused portions of the substance will be disposed of;
d. documented first aid measures / post-exposure protocols if a person was to be exposed;
e. documented spill procedures which outline containment, cleanup and disposal in the event of a spill that mitigates exposure to workers, the public, and the environment;
f. if unintentional release of a regulated poison would require evacuation of an area, documented procedures outlining the evacuation process including how unauthorised re-entry to an area will be prevented and who the emergency contacts are. If it is deemed that evacuation would never be applicable, this should be noted in the documentation to demonstrate it has been considered;
g. how the regulated poison will be securely stored to prevent unauthorised access, diversion or theft at all times from acquisition until destruction or disposal;
h. how the regulated poison will be stored to mitigate the risk of degradation, spillage, contamination of, or by other substances and interaction with chemically incompatible substances;
i. how regulated poison usage, destruction and disposal is recorded and witnessed to prevent diversion or theft;
j. controls in place to ensure safe and secure transport of the regulated poison (commensurate with the type of transport, e.g. within a building, between buildings, between campuses or sites).

(28) Organisational Units in which regulated activities occur must have a risk assessment in place which addresses regulated poison safety and security.

Approvals for use of regulated poisons

(29) UQ workers and Organisational Units must ensure an approval is recorded by the HSW Division prior to acquiring or using the following regulated medicines and poisons at UQ for research and/or teaching:

a. Low-risk Poisons which are substances listed in Schedule 2, 3 and 4 of the Poisons Standard (SUSMP), excluding Restricted Schedule 4 poisons.

b. Restricted Poisons which are:
    i. Restricted Schedule 4 poisons (RS4) - Poisons Standard Schedule 4 substances listed in Schedule 2 of the Medicines and Poisons (Medicines) Regulation 2021;
    ii. Restricted Schedule 7 poisons (RS7) - poisons in Schedule 1 of the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021.
c. High-risk Poisons which are substances listed in Schedule 8 or Schedule 9 of the Poisons Standard.
d. For the purposes of the SMP, pentobarbital (e.g. Lethabarb / Valabarb) must be managed as S8 (high-risk poison) in all forms.

(30) Approvals may be held by an Eligible Person, a Chief Investigator / Group Leader for their research group or by an Organisational Unit, depending on the Schedule of a substance. Table 1 in SMP Appendix C - SMP Tables summarises the approval requirements and eligibility.

(31) Forms for approval application are available at the Work Health and Safety internet page, in the section on Medicines and Poisons.

(32) UQ workers must also ensure that any additional required permits (including ChemCert Accreditation or an Agricultural Chemicals Distribution Control Licence) are obtained prior to using regulated poisons as required in the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021.

Low-risk poisons

(33) Eligible Persons can perform regulated activities with low-risk poisons under an Organisation Unit Low-risk Poison approval.

Restricted poisons

(34) Eligible Persons can perform regulated activities with restricted poisons under one of the following approvals:

a. Research Group approval:
    i. Obtained by the Group Leader or Chief Investigator.
    ii. The Group Leader or Chief Investigator applicant must be an Eligible Person, have completed the Eligible Persons training, and must have a supervisory role in relation to the Eligible Person performing the regulated activity under the group approval.
    iii. Workers performing regulated activities under a Research Group approval must be an Eligible Person and have completed the Eligible Persons training.
    iv. Research group approvals may be granted for the use of RS4 Pentobarbital, i.e. packed and labelled for injection (e.g. Lethabarb / Valabarb) but must otherwise be managed as S8 (high-risk poison) under this SMP.
    v. Prior to an Eligible Person possessing, using or applying a poison under a Research Group approval, their name must be listed in the usage log for that poison and be signed by the Group Leader or Chief Investigator.
b. Individual approval.

High-risk poisons

(35) Eligible Persons can perform regulated activities with high-risk poisons under one of the following approvals:

a. Individual approval.
b. Organisational Unit S8 Poisons for Animal Use approval.

Making regulated poisons for internal research

(36) UQ workers must have an approval from the HSW Division before making (includes chemical synthesis, isolation, concentration or any other process which produces a regulated poison) for research/teaching laboratory use. Approvals follow the same requirements as for the use of the substance. This is not intended to capture accidental production as a by-product in a chemical process. Where doubt exists regarding the need for an approval, an approval must be sought.

(37) Manufacturing for commercial purposes requires a General Approval from Queensland Health and it is not covered under this SMP.

Application process for individual and research group approvals

(38) Eligible Persons seeking an Individual approval or a Group Leader / Chief Investigator seeking a Research Group approval must do the following:

a. Complete a suitably detailed risk assessment.
b. Complete the Eligible Persons online training.
c. Complete the relevant Approval Application Form.
d. Review the application with the local Drugs Officer (DO).
e. Submit the application for consideration of approval to the HSW Division (hsw@uq.edu.au).
f. The HSW Division will:
    i. check that the requirements for approval are met, including an approved risk assessment that is specific for the activity being conducted, and liaise further with relevant DO if necessary; and
    ii. seek corrections or reject the application if requirements of approval are not met; and
    iii. record the approval in UQSafe.

(39) Eligible Persons will provide copies of all recorded approvals to the local Health, Safety and Wellness Manager (HSW Manager) or Work Health and Safety Coordinator (WHSC) (as determined by the local Organisational Unit).

(40) Once an approval has been issued, the HSW Division must be notified of any change of details so that the approval can be amended accordingly. For example, if the Eligible Person wishes to use restricted or high-risk poisons not listed on the approval, or if there is a change in how the listed substances are to be used which would require a new or modified risk assessment.

Application process for an Organisational Unit Low-Risk Poisons Approval

(41) Organisational Units seeking an approval for low-risk poisons must do the following:

a. Complete a suitably detailed risk assessment.
b. Complete the Organisational Unit Low-Risk Poisons Approval application.
c. Review the application with the local Drugs Officer (DO).
d. Submit the application to the HSW Division (hsw@uq.edu.au).

Application process for an Organisational Unit S8 poisons for Animal Use Approval

(42) Organisational Units seeking an approval for use of S8 Poisons in animals must do the following:

a. Complete a suitably detailed risk assessment.
b. Complete the Organisational Unit S8 Poisons for Animal Use Approval application, available from the HSW Division (hsw@uq.edu.au).

c. Review the application with the local Drugs Officer (DO).
d. Submit the application to the HSW Division (hsw@uq.edu.au).

(43) Workers applying poisons under an Organisational Unit S8 Poisons for Animal Use Approval must be an Eligible person and have completed the Eligible Persons online training.

(44) The use, handling and storage of the poisons listed in the Organisational Unit S8 Poisons for Animal Use Approval must conform with requirements for such poisons as outlined elsewhere in the SMP.

Approval of Drugs and Poisons Officers (DOs)

(45) An Eligible Person seeking approval as a DO must be appointed and approved by their Head of Section in their relevant Organisational Unit, meet the qualification requirements and complete Eligible Persons online training modules prior to applying for approval.

Criteria for appointment

(46) The criteria for appointment as a DO are:

a. be a current UQ staff member (excludes all students);
b. have an appropriate level of authority within the local area (e.g. HSW Manager, WHSC, Floor/Lab Manager/Technical officers or Supervisor); and
c. complete the Eligible Persons training and the 'Privacy at UQ' and 'Drug Officer and Drugs Commodity approver role' online training modules prior to their appointment.

(47) Applications for approval must be completed as outlined on the UQ HSW Medicines and Poisons website. The HSW Division will apply on behalf of the approved DO to be given the 'Drugs Commodity Approver' role in UniFi, unless otherwise requested.

Instances where an internal approval cannot be granted

Substances of such danger to health as to warrant prohibition of supply and use

(48) Any dealing with substances intended for a purpose listed in the Poisons Standard Schedule 10 is prohibited.

Supply of regulated poisons

(49) UQ does not possess a Queensland Health General Approval to supply Scheduled substances. In order to supply a Scheduled substance to a person that is not a UQ worker, the individual wishing to supply the substance must be granted an approval by Queensland Health. The HSW Division (hsw@uq.edu.au) can assist with the application process.

Procurement of regulated poisons

(50) S2, S3 and S4 (non-restricted) substances can be procured by an Eligible Person who belongs to an Organisational Unit which holds an Organisational Unit approval for low-risk poisons. Purchase must be through the UQ central procurement system.

(51) Restricted S4, restricted S7, S8 and S9 substances can only be procured by an approved Organisational Unit DO. Purchase must be through the UQ central procurement system.

(52) High school students, all undergraduate students (including medical or nursing students for example), work experience or research experience students are prohibited from purchasing scheduled substances for use at UQ under this SMP.

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(53) UQ's central procurement system has an embedded Drugs Commodity Approval workflow which is routed to the relevant Organisational Unit DO for approval. The DO will action approval after confirming the individual requesting the low-risk poison/s or carrying out a dealing within the approved Organisational Unit, have completed the Eligible Persons training, is covered by an appropriate approval and has a risk assessment in place.

(54) When placing free format orders in UniFi:

a. the "Drugs > Restricted" category must be selected for restricted S4, restricted S7, S8 and S9 substances.
b. the "Drugs > Non-restricted" category must be selected for S2, S3 and non-restricted S4 substances.

(55) When any S2, S3 or S4 (non-restricted) substance is received, the local chemical inventory must be updated. When the package is finished and disposed of, it must be removed from the chemical inventory. When acquired by transfer or donation the local DO must be informed.

(56) In rare instances where the purchase of a regulated poison through UQ's central procurement system is not possible or highly impractical, a request may be made through a Drugs Officer to the HSW Division to consider a corporate credit card purchase prohibition exemption.

Arrival of scheduled substances at a controlled delivery point

(57) When S2, S3 and S4 (non-restricted) substances are delivered to controlled delivery/goods receiving points, the attending staff will notify the appropriate Eligible Person (covered by the Organisational Unit Low-Risk Approval).

(58) When RS4, RS7, S8 and S9 substances are delivered to controlled delivery/goods receiving points, the attending staff must notify the appropriate DO. A record of the delivery must be kept, and the goods held in a secure and safe storage location (e.g. swipe card access only/locked room and segregated if applicable in appropriate cabinets or fridge/freezers) until it can be collected by the DO.

Storage of medicines and poisons

(59) Approved Eligible Persons, Research Groups, Organisational Units and DOs are responsible for the safe and secure storage of regulated medicines and poisons listed in their approval and for ensuring that any legislated minimum storage requirements are met. Substances must be stored in sealed and clearly labelled containers. They must be clearly identifiable and stored in such a manner to prevent cross contamination with other products or substances.

(60) Medicines and poisons must be stored securely in accordance with this SMP and the MP Regulations. At UQ this means:

a. S2, S3 and S4 (non-restricted) substances must be kept in areas where there is no public access (e.g. swipe card access only/locked room). S4 (non-restricted) substances must be kept in a cupboard, dispensary, drawer, storeroom or similar within that restricted area.
b. S5, S6 and non-restricted S7 substances must be kept in areas where there is no public access (e.g. swipe card access only/locked room).
c. Restricted S7 poisons must be stored in a locked cabinet that is in a secure or restricted area and not accessible to the public (e.g. swipe card access only/locked room). The key to the storage location must be kept in such a manner that it can only be accessed by the relevant DO (e.g. appropriate locked cabinets, cupboards or fridge/freezers).
d. Restricted S4, S8 and S9 substances must be kept in a secure location that is only accessible to DOs for those substances (e.g. designated drug safe, locked fridge/freezer in a restricted area; refer to the Queensland Health departmental standard - Secure storage of Schedule 8 medicines). The DO must always keep the receptacle or secure place locked and personally possess the key or combination to the safe, receptacle or place.

Labelling of decanted scheduled substances

(61) Where possible, scheduled substances should remain in the original container. If there is a requirement to decant/aliquot a scheduled substance which will not be used immediately, a suitable label must be present on the new container. For details on labelling requirements see the Labelling of Workplace Hazardous Chemicals Code of Practice 2021. Where there are space limitations on small containers, the minimum labels elements are:

a. the product identifier.
b. a hazard pictogram or hazard statement that are consistent with the correct classification of the chemical.

Disposal and destruction

Low-risk poisons

(62) Eligible Persons from an approved Organisational Unit must dispose of S2, S3 and S4 (non-restricted) poisons as clinical waste. Clinical waste bins must be locked and stored in a secure location while awaiting collection (e.g. swipe card access only/locked room or enclosure).

(63) Chemical waste containing low-risk poisons may be sent to the UQ Science Store for collection and disposal by a waste management contractor if the poison has been rendered unusable and unidentifiable.

Restricted and high-risk poisons

(64) If not destroyed by the experimental process or use, restricted S4, restricted S7, S8 and S9 substances must be disposed of at the point-of-use by rendering the material unusable and unidentifiable by dispersal in absorbent material and addition of liquid detergent before being sent for destruction via incineration.

(65) If there are hazards associated with a substance that precludes disposal via the clinical waste stream (e.g. cyanides), the material should be destroyed and made safe for disposal by reaction with an appropriate chemical reagent and subsequently disposed of via the UQ chemical waste stream or by sewer if compatible. Reactive chemical destruction procedures must be risk assessed and performed by persons with a chemistry degree and relevant experience and training in performing chemical reactions.

(66) If the substance cannot be destroyed and disposed of at the point-of-use, special arrangements can be made with the UQ Science Store whereby the material will be collected by an approved waste management company for destruction.

(67) Disposal of restricted and high-risk poisons must be performed in the presence of a DO and witnessed by either the WHSC, HSW Manager or Facilities Manager of the relevant area or the DO of a different area. The method of disposal must be recorded in the relevant usage log or high-risk poisons register by the DO and counter-signed by the witness.

Transport

(68) When medicines and poisons require transfer within a campus, they must be double contained and in break resistant, labelled containers (e.g. container within a hard esky) and in possession of the approved Eligible Person at all times. Any loss or other discrepancy during transit must be immediately reported as outlined in the ‘Discrepancies and Incident Reporting’ provisions of this Procedure.

(69) Medicines and poisons can be transferred between campuses or to a remote site by:

a. vehicle accompanied by an approved Eligible Person in safe packaging (e.g. double-contained, break-resistant) within a locked compartment which is part of, or secured to, the vehicle (e.g. glovebox, car boot, utility tray

chest etc). If the substances are transported in the passenger area or luggage compartment (e.g. in a hatch-back or sport utility vehicle), they must be in a locked container which is secured to the vehicle (e.g. a lockbox which can be attached to an anchor point in the luggage compartment with a lockable cable);

b. a courier in secure and safe (e.g. double-contained, break-resistant) packaging.

Field work with scheduled substances

(70) If there is a requirement to transport substances off campus for the purpose of field work, this requirement must be specified in the application for approval. The requirements for maintaining the security of the substance will vary based on the schedule and category. The approval record provided by the HSW Division must be attached to the UQSafe Field Trip application.

(71) The minimum requirements are:

a. provisions specified for the transfer of medicines and poisons to a remote site under the Transport section of this Procedure; and
b. a documented process for reporting loss of a substance while in the field; and
c. a transport manifest of items carried which records the substance name or identifier, form (solid, liquid, solution, patches etc), concentration or purity and the amount; and
d. a safety data sheet (SDS) which may be accessed at any time while in the field.

Section 4 - Roles, Responsibilities and Accountabilities

(72) UQ workers, DOs and Organisational Units are responsible for ensuring they are appropriately qualified and approved, and that:

a. regulated poisons in their possession are stored securely and, where applicable, in accordance with legislative requirements and this SMP (see 'Storage of Medicines and Poisons' provisions);
b. regulated poisons in their possession are disposed of in accordance with the 'Disposal and Destruction' provisions;
c. any intentional or accidental misuse, theft, diversion or other loss is reported (see 'Discrepancies and Incident Reporting' provisions); and
d. for restricted and high-risk poisons, DOs will purchase, record their arrival, use and disposal.

University Senior Executive Team (USET)

(73) The University Senior Executive Team (USET) endorsed this SMP. The Senate Risk and Audit Committee (SRAC) receive regular reports of overall conformance with the SMP from the HSW Division through USET.

Chief Operating Officer

(74) The Chief Operating Officer (COO) applies to Queensland Health on a yearly, two yearly or three yearly basis as an authorised person for UQ (the Executive Officer) for a general approval to buy, possess, supply, apply and dispose of regulated poisons for the purpose of research, teaching and analysis for non-therapeutic use at UQ under the Medicines and Poisons Act 2019 and the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021.

Executive Deans, Institute Directors, Division Directors and Heads of School

(75) Executive Deans, Institute Directors, Division Directors and Heads of School are responsible for overseeing the

Organisational Unit's management of regulated medicines and poisons, including ensuring that:

a. approved Eligible Persons are appointed as DOs to support the implementation and maintenance of this SMP in their Organisational Unit; and
b. sufficient resources are available to enable conformance with the use, handling, security, record keeping, reporting, storage and disposal requirements of this SMP.

UQ Drugs and Poisons Officers (DOs)

(76) DOs are responsible for:

a. completing the 'Chemical Safety', 'Staff Standards of Conduct', 'Privacy at UQ' and 'Drug Officer and Drugs Commodity approver role' online training modules prior to their appointment;
b. providing advice and support to Eligible Persons in the Organisational Unit regarding:
    i. approval requirements and application process,
    ii. how to safely and legally buy, possess, apply and dispose of low-risk poisons,
    iii. how to safely and legally, buy, possess, and apply restricted and high-risk poisons to approved Eligible Persons within the Organisational Unit they are appointed to,
    iv. user training,
    v. minimum requirements for risk assessments as outlined in this Procedure,
    vi. secure and complaint storage, and
    vii. work practices to facilitate conformance, as required;
c. applying regulated medicines and poisons, if their role requires it (e.g. UQ Biological Resources facilities);
d. supply of restricted and high-risk poisons to approved Eligible Persons or Research Groups:

    NOTE: in some research support areas, these activities may be performed for multiple Schools and Institutes or external organisations, e.g. DOs employed by UQ Biological Resources. Any UQ facility that services non-UQ workers from external organisations are permitted to supply medicines and poisons either with an individual general approval from Queensland Health or approved under their own organisational SMP, if the management and life cycle of the scheduled substances is accomplished within the facilities under this SMP. DOs are required to check and have a record of general approvals/SMPs from those organisations;
e. disposing of restricted and high-risk poisons as required;
f. functioning as an Organisational Unit Drugs Commodity Approver within the procurement system;
g. uploading relevant records into UQSafe or Workday as required;
h. maintaining the Organisational Unit's restricted poisons usage log(s) and high-risk poisons register;
i. conducting a review (at least annually) of the Organisational Unit's processes in relation to maintaining conformance with this SMP and maintaining a record of the review;
j. providing an annual update of holdings of regulated poisons to the HSW Division;
k. at any given time, generating a report detailing all high-risk poisons and the amounts of which are possessed; and
l. reporting incidents, misuse or discrepancies in UQSafe, to their Head of Section and to the HSW Division as soon as possible after the incident or breach.

Supervisors and Managers

(77) Supervisors and Managers are responsible for, in their area of control:

a. facilitating induction, instruction, supervision and training to UQ Workers in relation to regulated medicines and poisons, especially to those new to the process or the area;

b. ensuring that Eligible Persons are approved under the SMP;
c. ensuring that appropriate, detailed and active risk assessments are in place for the tasks dealing with regulated medicines and poisons;
d. ensuring appropriate security and safe storage necessary for the Schedule of the regulated poison;
e. ensuring that any incidents relating to the use of these regulated poisons under their management, and any discrepancies in quantities or concentrations of these are promptly reported in UQSafe and to the relevant DO;
f. ensuring that all other requirements for the appropriate use of these regulated poisons under their management are met, e.g. animal ethics or other approvals; and
g. appointing a person to conduct a stocktake of low-risk scheduled substances (S2, S3 and non-restricted S4) at least every two years to ensure the chemical inventory is accurate and to identify substances surplus to requirements which can be disposed of.

Work Health and Safety Coordinators (WHSC) and Health, Safety and Wellness Managers (HSW Managers)

(78) Local WHSC and HSW Managers should:

a. assist with advice on the application/approval process, storage and disposal regarding regulated poisons in consultation with the DO;
b. assist with the completion of risk assessments for activities involving regulated poisons; and
c. work with Supervisors and Managers to monitor conformance with this SMP.

UQ Workers and others

(79) Workers and others planning to work with regulated poisons are responsible for:

a. reviewing, understanding and conforming with this SMP and any associated procedures;
b. completing the required training; and
c. ensuring they have the required approval prior to using regulated poisons.

Approved Eligible Persons

(80) All approved Eligible Persons, including those operating under Research Group or Organisational Unit approvals, that have been approved to perform regulated activities with regulated poisons are responsible for:

a. reviewing, understanding and conforming with this SMP and any associated procedures;
b. ensuring they have an approval recorded and returned by the HSW Division before buying (includes obtaining by transfer), possessing, supplying, applying or disposing of medicines and poisons;
c. storing regulated medicines and poisons safely, securely and, in conformance with this SMP;
d. establishing, using and maintaining restricted poisons usage logs and high-risk poison registers, in conjunction with DOs;
e. disposing or destroying regulated poisons appropriately;
f. notify their Supervisor and DO, of any suspected diversion of low-risk poisons; and
g. notify their Supervisor and DO, of any discrepancies in records of, or suspected diversion of restricted and high-risk poisons.

Health, Safety and Wellness Division

(81) The Health, Safety and Wellness Division (HSW Division) is responsible for:

a. managing the implementation of the SMP in consultation with UQ stakeholders;
b. advising and supporting the DOs and other Eligible Persons;
c. approving the use of regulated poisons, at the School, Centre, Faculty, Division, Institute and at the individual user level;
d. maintaining centralised records of approvals;
e. providing regular updates and advice sessions to stakeholders including DOs, Health and Safety Representative (HSR) and Eligible Persons as required;
f. overseeing and facilitating the monitoring of medicines and poisons;
g. assessing whether Organisational Units and UQ workers can demonstrate conformance with this Procedure and that any issues identified are actioned in a timely manner;
h. conducting periodic audits against this Procedure;
i. providing advice on risk management where necessary;
j. investigating and following up any adverse events relating to the safety and security of scheduled substances;
k. maintaining UQSafe;
l. producing quarterly reports of overall conformance with the SMP to Executive Committees; and
m. notifying the appropriate Regulator of any significant incident (e.g. discovered or suspected discrepancies in usage logs, high-risk poisons register or storage) or notifiable event.

(82) The HSW Division is responsible for providing an updated list of regulated poisons holdings for each approved Organisational Unit to Queensland Health on request and must be updated annually. This list, known as Appendix D, contains sensitive information which is held in restricted access files at the HSW Division.

Section 5 - Monitoring, Review and Assurance

(83) A stocktake of low-risk scheduled substances (S2, S3 and non-restricted S4) must be conducted by approved persons at least every two years, and be submitted to the DO in the relevant area.

(84) Restricted poison usage logs must be reconciled at least every six months by a DO to confirm the amount recorded matches the physical holding. This six-monthly reconciliation must be recorded in the usage log and witnessed by the DO and another approved person (HSW Manager, WHSC or Facilities Manager of the relevant area, or the DO of a different area).

(85) High-risk poisons registers must be reconciled at least monthly by a DO to confirm the amount recorded matches the physical holding. This monthly reconciliation must be recorded in the register and witnessed by the DO and another approved person (HSW Manager, WHSC or Facilities Manager of the relevant area, or the DO of a different area).

(86) DOs will conduct an annual inspection of their Organisational Unit’s processes and facilities to monitor conformance with this SMP. A record of the inspection, including recommended actions to address non-conformances will be maintained by the DO, and they will encourage the Organisational Unit to address actions in a timely manner.

(87) The HSW Division is responsible for reviewing this SMP every five years, or as soon as possible after a review incident occurs (in accordance with the Poisons Regulation). Appendixes of the SMP and application forms may be reviewed more frequently to ensure they remain current, accurate and relevant to the needs of UQ and reflects legislative requirements.

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Section 6 - Recording and Reporting

Usage logs and High-Risk Poisons Registers

(88) DOs must maintain usage logs (refer to Definitions in the Appendix) recording the use of all Restricted Schedule 4 and Restricted Schedule 7 substances. Usage logs for RS4 and RS7 substances are available from the HSW Division Medicines and Poisons website.

(89) DOs must maintain a high-risk poison register (refer to Definitions in the Appendix) recording the use of all substances listed in Schedule 8 and Schedule 9 of the Poisons Standard, and pentobarbital packed for injection (e.g. Lethabarb / Valabarb).

(90) High-risk poisons registers must be in the form of a book such that pages cannot be removed without detection, pages sequentially numbered, for example, use of the Dispensary Guild of Australia Controlled Drug Register.

(91) Entries in a usage log or high-risk poisons register must be written in English, legibly and in ink and must include the following information:

a. Incoming stock:
    i. name of substance;
    ii. date of acquisition;
    iii. source;
    iv. quantity;
    v. form;
    vi. strength;
    vii. order number
    viii. risk assessment ID# specific to the storage and handling of the substance;
    ix. name and signature of an Eligible Person who witnessed entering the scheduled substance.
    x. name and signature of the DO entering the scheduled substance and Eligible Person witnessing the transaction.
b. Outgoing stock:
    i. date of use;
    ii. quantity used;
    iii. description of use;
    iv. risk assessment ID# specific to the activity being undertaken;
    v. name and signature of the person receiving the scheduled substance;
    vi. name and signature of the DO dispensing the scheduled substance;
    vii. balance of regulated poison remaining.
c. Disposal of stock:
    i. date of disposal;
    ii. quantity disposed;
    iii. method of disposal
    iv. risk assessment ID# specific to the method of disposal;
    v. name and signature of the person performing the disposal or an Eligible Person witnessing the disposal;
    vi. name and signature of the DO witnessing the disposal of the scheduled substance.
    vii. balance of the regulated poison remaining.

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d. Details of any other transaction or event involving the regulated poison including reconciliation or discrepancies.

(92) Only a single substance should be recorded on each page, and where a substance is recorded on multiple pages, include backwards and forwards references for traceability. No pages are to be skipped or left blank.

(93) Corrections to usage logs and high-risk poisons registers must be made in such a way that the original entry is legible (i.e., not cancelled, deleted or obliterated when the correction is made) and must include:

a. Date correction was made;
b. Name and signature of the person who made the correction;
c. Name and signature of the person who witnessed the correction;
d. Reason for the correction.

(94) A usage log or high-risk poisons register kept in an electronic form must be compliant with the requirements stated in the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 and this Procedure.

(95) Usage logs and high-risk poisons registers must be retained for five (5) years from the date of the last entry which corresponds to the balance of all substances being zero. Other records associated with medicines and poisons must be easily retrievable, cannot be altered, obliterated, deleted or removed without detection and must be kept for five (5) years from the day it is recorded.

Discrepancies and incident reporting

(96) Workers that discover or suspect a discrepancy between the quantity of a regulated medicine or poison and the balance recorded in the usage log or high-risk poisons register, must immediately notify their Supervisor, the relevant DO and the HSW Division (hsw@uq.edu.au). The same applies if a usage log or high-risk poisons register is damaged, lost or suspected of being tampered with. Discrepancies, misuse, diversion or any other significant event must be reported as an incident in UQSafe.

(97) DOs who discover or suspect any discrepancies or incidents, or are informed of such, must notify their Head of Section and the HSW Division. The HSW Division will notify Queensland Health of discrepancies as required.

Section 7 - Appendix

Definitions, Terms, Acronyms

Terms	Definitions
Appropriately Qualified	Refers to someone having the qualifications, experience or standing appropriate to the exercise of the power. A person assigned the following positions are appropriately qualified: • Vice-Chancellor, Pro-Vice-Chancellors, Deputy Vice-Chancellors; • Executive Deans, Institute Directors; • Heads of Schools, Institute Centre Directors, Faculty Centre Directors, University Centre Directors; • Institute Managers, Deputy Directors, Associate Directors, Faculty or School Managers, other Senior Managers; • Level A to E Academics; • Fellows; • Drugs and Poisons Officers; • Technical Managers; • Laboratory Managers; • WHSCs; • HSW Managers; • HSW Division staff.

Terms	Definitions
Authority	The power to make decisions and/or enforce conditions a person has under the Regulation.
Approval (under the SMP)	Endorsement by the Head of Section to use scheduled substances (regulated medicines and poisons) for teaching and research and recorded by the HSW Division.
Approved Organisational Unit	A recognised unit within UQ (e.g. a School, a Centre, a Division or Institute) as per the UQ Organisational Units site, which is listed in SMP Appendix A - UQ Approved Organisational Units/Locations.
Approved Person	Eligible Person who holds an approval to use scheduled substances recorded by the HSW Division.
Applicant	Refers to the person or unit applying for approval under SMP.
Drugs Commodity Approver	A Drugs and Poisons Officer appointed by a Head of Section to monitor the purchase of medicines and poisons within the UQ procurement system and approve those if the purchase conforms with this SMP.
Drugs and Poisons Officer (DO)	A person authorised by a Head of Section to monitor the use and storage of scheduled substances, act as a Drugs commodity approver, and assist and provide advice to Eligible Persons wishing to use regulated medicines and poisons.
Eligible Person	Person with a suitable position and qualifications or expertise (see definition) required to perform regulated activities in the course of their occupation or engagement.
Health Practitioner	A person holding a current Australian Health Practitioner Regulation Agency (AHPRA) registration.
High-risk Poisons	Medicines and poisons listed in Schedule 8 or Schedule 9 of the Poisons Standard, and pentobarbital (e.g. Lethabarb / Valabarb) packed and labelled for injection.
High-risk Poisons Register	Record of Schedule 8 and Schedule 9 substances in a physical book or electronic form (must be compliant with the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 and this Procedure) which is regularly maintained.
Low-risk Poisons	Medicines and poisons listed in Schedule 2, 3 and 4 of the Poisons Standard (SUSMP), excluding Restricted Schedule 4 poisons.
Medicine	A Scheduled substance in the category of an S2, S3 or S4 medicine.
Notifiable Event	Refer to Health and Safety Incident and Hazard Reporting Procedure.
Organisational Unit	A recognised unit within UQ (e.g. a School, a Centre, a Division or Institute) as per the UQ Organisational Units site.
Possess	Having custody or control of, and the ability or right to obtain custody or control of the drug, poison or other substance.
Qualifications	Appropriate qualifications are a Diploma or Bachelors' degree in a relevant field (Science, Chemistry, Biomedical Science, Biotechnology, Biosciences, Biotechnology, Laboratory Sciences, Dental Science, Equine Science, Environmental Science, Agriculture and Food Science, Animal Science, Exercise and Nutrition Sciences, Engineering, Health Sciences, Medicine, Midwifery, Mining, Nursing, Occupational Health and Safety Science, Pharmacy, Veterinary Science, Veterinary Technology, Wildlife Science), or 3 years of work experience in the relevant field, or records of hands-on training in poisons management.
Regulated Activity	A person performs a regulated activity for a Scheduled substance if they buy, possess, manufacture, supply, administer, apply the substance or directs or authorises another person to perform any of these activities for teaching and/or research.
Regulated Place	Location where the substance is to be stored and / or used as required under section 93(2)(a)(ii) of the Act, including details of how the substance will be stored at the location.
Regulated Poison	A Scheduled substance in the category of S2, S3, S4, S7, S8 and S9.
Restricted Poisons	Restricted Schedule 4 poisons (RS4): Poisons Standard Schedule 4 medicines and poisons listed in Schedule 2 of the Medicines and Poisons (Medicines) Regulation 2021; and Restricted Schedule 7 poisons (RS7): poisons in Schedule 1 of the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021.

Terms	Definitions
Relevant Occupation	Occupation such as dentist, doctor, indigenous health worker, midwife, optometrist, podiatrist, registered nurse or veterinary surgeon.
Restricted Schedule 4 poison (RS4)	Poisons Standard Schedule 4 medicines and poisons listed in Schedule 2 of the Medicines and Poisons (Medicines) Regulation 2021.
Restricted Schedule 7 poisons (RS7)	Poisons in Schedule 1 of the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021.
Scheduled Substance	Substances and derivatives thereof listed in the current Poisons Standard (SUSMP).
Supervision	Oversight of a person involving: 1. directing, demonstrating and monitoring regulated activities being conducted by the person; and 2. checking the person's level of competency for the regulated activities. This must be accomplished in a manner proportionate to the schedule of the substance and the risk. Examples: • Dentistry students learning to administer S4 substances require general supervision, where an approved Eligible Person is within the area and able to aid. • Research students or staff learning to use poisons in a laboratory setting will initially require direct supervision until they are deemed competent by the Supervisor. Direct supervision is watching the process and being in a position to immediately intervene if there is any danger.
Supply	For a Scheduled substance, means to sell, dispense, give a treatment dose/s, or dispose of the substance as waste. At UQ, DOs are the only approved persons allowed to 'dispense, give a treatment dose/s'.
Therapeutic Use	Is preventing, diagnosing, curing, or alleviating a disease, ailment, defect or injury in human beings and animals.
Transaction	An event by which a controlled drug, restricted drug or poison comes into or goes out of a person's possession; or the composition, form or strength of, or way of packing, a controlled or restricted drug or poison is changed; for example: moving a controlled or restricted drug or a poison from one place to another (with or without a change of ownership).
Tenants	For the purposes of this Procedure, they are occupiers of buildings or spaces owned and managed by UQ.
UQ Workers	For the purposes of this Procedure includes: • UQ staff, including continuing, fixed-term and casual staff; • Higher Degree by Research students (inc. Honours, Master's and PhD); • visiting researchers; and • academic title holders, visiting academics, Emeritus Professors, adjunct and honorary title-holders, Industry Fellows and conjoint appointments.
Usage Log	Record of restricted Schedule 4 (RS4) and restricted Schedule 7 (RS7) poisons in a physical or electronic form (must be compliant with the Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 and this Procedure) which is regularly maintained.

Status and Details

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