

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 laws. The SMP is intended to assist in identifying and managing known and foreseeable risks associated with any dealing with regulated substances 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 Appendix) 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, volunteers and contractors. The Procedure also applies to Controlled Entities and tenants of UQ buildings.
- (4) The SMP covers all UQ Organisational Units, and all Controlled Entities reflected in Appendix A UQ Approved Organisational Units/Locations.

Exclusions

- (5) The SMP does not apply to medicines and therapeutic substances 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 health professionals working as health professionals 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).
 - g. UQ workers regardless of School/Centre/Institute's affiliation if they are tenants of another organisation or buildings where UQ is not responsible for the management (e.g., Translational Research Institute (TRI)), as they must follow the established SMP of that building or organisation; and
 - h. 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. These are exempted under the <u>Medicines and Poisons (Poisons and Prohibited Substances)</u> Regulation 2021.

(6) UQ activities managed in accordance with the <u>Medicines and Poisons (Medicines)</u> Regulation 2021 (Qld), not requiring approval under this SMP are listed in <u>Appendix B - UQ Activities managed as per Medicines and Poisons (Medicines)</u> Regulation 2021, not requiring endorsement under this SMP.

Legislative Context

- (7) The Australian Government regulates medicines and poisons under the <u>Therapeutic Goods Act</u> 2019 (Qld), <u>Therapeutic Goods Regulation 2021</u> (Qld) and the subordinate <u>The Poisons Standard (the SUSMP)</u>, which contains ten schedules of substances classified according to their degree of potential harm and the degree of control over their availability.
- (8) The Queensland Government regulates medicines and poisons, including those scheduled in the Poisons Standard, under the <u>Medicines and Poisons Act 2019</u>, and related subordinate regulations.
- (9) 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).
- (10) This Procedure represents UQ's Substance Management Plan (SMP) required under of the <u>Medicines and Poisons</u> Act 2019.

Section 2 - Process and Key Controls

- (11) The objective of this Procedure is to address matters pertaining to medicines and poisons to maintain the health and wellbeing of users of regulated substances, as well as the general public who may be exposed to these substances. Key controls supporting the effectiveness of this Procedure include:
 - a. Eligible Persons identified in clauses 12-21 of this Procedure must be appropriately qualified, instructed and trained or supervised in all regulated activities with these substances.
 - b. A risk assessment must be completed in <u>UQSafe</u> by an eligible person before commencing regulated activities with scheduled substances.
 - c. Approval is required from the Health, Safety and Wellness Division (HSW Division) (refer to clauses 22-34) 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.
 - i. Purchase of regulated medicines and poisons using a corporate credit card is not permitted.
 - ii. High school students, undergraduate students, and work experience or research experience students are prohibited from purchasing regulated medicines and poisons.
 - e. Appropriate transport, storage (possession) and disposal processes are in place to ensure compliance and the safety of the public and the environment.

Section 3 - Key Requirements

Eligible Persons

(12) An Eligible Person (refer to Definitions in the Appendix) is a person with necessary qualifications or expertise required to perform regulated activities with scheduled substances in the course of their work, in research, teaching.

Training and qualification requirements are outlined in the relevant <u>Approval Application Form</u> and is also detailed in the 'Training' provisions of this Procedure.

(13) The following categories or worker's positions are considered as Eligible Persons and can seek approval from UQ to perform regulated activities, except undergraduate students and registered health professionals (this last category already holds an approval as approved persons under the <u>Medicines Regulation 2021</u>) after approval (refer to the 'Types of Approvals for Use of Regulated Poisons' provisions below).

Research Staff and Research Students (Higher Degree by Research, Masters by Research and Honours Students only)

(14) These users are eligible and may use scheduled substances for research purposes without supervision after approval (refer to the 'Types of Approvals for Use of Regulated Poisons' provisions below).

Teaching Staff

- (15) Teaching staff are eligible and may use scheduled substances for teaching purposes after approval (refer to the 'Types of Approvals for Use of Regulated Poisons' provisions below). These appropriately qualified and authorised persons are to supervise the use of scheduled substances by undergraduate students because these students are not approved for individual use.
- (16) The level of supervision is proportionate to the Schedule (refer to Definitions in the Appendix) of the substance and the risk.

Support Staff

(17) 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).

Students and Visitors

(18) These include high school, any undergraduate (e.g., medical or nursing students), work experience or research experience students and are eligible to use. Any use of scheduled substances by these students must be supervised by a qualified approved person (e.g., academic or researcher, qualified teacher), or health practitioner (who does not need approval under the SMP). Students or visitors cannot be approved as individuals or benefit from an Organisational Unit approval for low-risk poisons.

Training

- (19) Eligible Persons are required to have qualifications or expertise (refer to Definitions in the Appendix) and must complete the following online modules prior to approval to use and/or dispose of scheduled substances:
 - a. Chemical Safety (refresher every 2 years).
 - b. Code of Conduct.
- (20) Training must be completed and confirmed before any approvals are recorded in <u>UQSafe</u>. Training records are held in the Human Capital Management System (HCMS).

Risk Assessment

(21) Eligible Persons are required to complete a risk assessment in <u>UQSafe</u> for the activities where the use of scheduled substances is required prior to work commencing.

Approval Process

(22) Eligible Persons (except undergraduates), or Organisational Units for low-risk poisons, may seek approval to handle scheduled substances following the steps below:

- a. Complete the relevant online training.
- b. Complete the relevant <u>Approval Application Form</u>.
- c. Review the application with the local DO (if available) or, if there is not one available, the HSW Division.
- d. Submit the application for consideration of approval to the HSW Division (https://nswaug.edu.au).
- e. The HSW Division will:
 - i. check that the requirements for approval are met, and liaise further with relevant DO if necessary; and
 - ii. record and save the approval in **UOSafe**; and
 - iii. return electronically a copy of the issued, unique identified and recorded approval to the Eligible Person or the Organisational Unit, including the relevant DO; and
 - iv. seek corrections or reject the application if requirements of approval are not met.

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

Approval of Drugs and Poisons Officers (DOs)

(24) Eligible Persons seeking approval as DOs must be appointed and approved by their Head of Section in their relevant Organisational Unit, meet the qualification requirements and complete additional online modules prior to applying for approval.

Criteria for Appointment

- (25) 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 required training and refresher training every 2 years.
- (26) Applications for approval must be completed using the <u>DO Approval Application Form</u> and submitted to the HSW Division (<u>hsw@uq.edu.au</u>) for approval.
- (27) The approved DO must then apply for 'Drugs Commodity Approver' role in UniFi.

Types of Approvals for use of Regulated Poisons

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

- a. Low Risk Poisons medicines and poisons listed in Schedule 2, 3 and 4 (non-restricted medicines) of the <u>Poisons</u> Standard (SUSMP); and/or
- b. Restricted and High-Risk Poisons:
 - i. medicines and poisons listed as 'restricted Schedule 4 (RS4)' in Schedule 2, Part 1 of the <u>Medicines and Poisons (Medicines) Regulation 2021</u>; and/or
 - ii. poisons listed as 'Restricted Schedule 7 (RS7)' in Schedule 1 of the <u>Medicines and Poisons (Poisons and Prohibited Substances)</u> Regulation 2021; and/or

- iii. medicines and poisons listed in Schedule 8, 9 or 10 of the <u>Poisons Standard</u> (High-risk poisons and prohibited substances).
- (29) Approval applications are expected from individual workers, research groups or Organisational Units and are finalised when recorded in UQSafe. Table 1 in <u>Appendix D SMP Tables</u> document summarises the approval requirements depending on the Schedule and eligibility.
- (30) UQ workers must also ensure that any <u>additional required permits</u> (including ChemCert Accreditation or an Agricultural Chemicals Distribution Control Licence) are obtained prior to using regulated poisons as required in the <u>MP</u> Regulation.

Approvals for Manufacturing Regulated Medicines and Poisons for Internal Research Use Only

- (31) UQ workers must have an approval from the Health, Safety and Wellness Division before manufacturing scheduled substances for internal research/teaching laboratory use.
- (32) Where doubt exists regarding scheduling, an approval must be sought. Approvals follow the same requirements as for the use of scheduled substances, as specified in the 'Approval Process' provisions above.
- (33) This is not intended to capture accidental manufacture as a by-product in a chemical process.
- (34) Manufacturing for commercial purposes requires a General Approval from QLD Health and it is not covered under this SMP.

Procurement of Regulated Poisons

- (35) S2, S3 and S4 (non-restricted) substances can only be obtained by approved Organisational Units through the UQ central procurement system, and cannot be acquired by credit card purchase (refer to <u>Outgoing Payments Procedure</u>). High school students, all undergraduate students (including medical or nursing students for example), work experience or research experience students are prohibited from purchasing these substances.
- (36) UQ's central <u>Procurement</u> 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 required training.
- (37) S2, S3 and S4 (non-restricted) substances obtained by internal transfer or donation can only be received by approved Organisational Units after communicating that acquisition to the relevant Organisational Unit DO. An update to the chemical register will be required, refer to the Chemical Manifest Procedure.
- (38) Other regulated medicines (restricted S4 and all S8) and poisons (RS7, all S9 and all S10) can only be procured by the relevant and approved Organisational Unit DO.

Arrival of Scheduled Substances at a Controlled Delivery Point

- (39) When scheduled substances are delivered to the UQ store or other controlled delivery/goods receiving points, the approved attending staff will endeavour to notify the approved Eligible Person (as an individual or as part of the approved Organisational Unit) for S2, S3, and S4 (non-restricted). The relevant DO must be contacted in the case of RS4, RS7, S8, S9 and S10 arrivals.
- (40) 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 relevant approved person or DO.

Storage of Medicines and Poisons

- (41) Approved UQ workers, Research Groups 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.
- (42) Medicines and poisons must be stored securely in accordance with this SMP and the MP Regulations. At UQ this means:
 - a. Schedule 2, 3 substances (Medicines) and Schedule 4 (Non-restricted medicines) must be kept in areas where there is no public access (e.g., swipe card access only/locked room). S4 must be kept in a cupboard, dispensary, drawer, storeroom or similar within that restricted area.
 - b. Schedule 5 and 6 (Poisons) must be kept in areas where there is no public access (e.g., swipe card access only/locked room).
 - c. Non-Restricted Schedule 7 (Poisons) must be kept in areas where there is no public access (e.g., swipe card access only/locked room).
 - d. Restricted Schedule 7 (Regulated Poisons), any RS7 should 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 shall 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).
 - e. Schedule 4 (restricted, RDD and RRD), 8, 9 and 10 substances (Controlled Drug and Prohibited Substance) 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 <u>Queensland Health departmental standard Secure storage of Schedule 8 medicines</u>). 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

(43) Where possible, scheduled substances should remain in the original container. If there is a requirement to decant/aliquot a scheduled substance, a suitable label must be present on the new container. For details on labelling requirements see the Chemical Labelling Guideline.

Disposal and Destruction

Low-risk Poisons

- (44) Eligible Persons from an approved Organisational Unit may dispose of Schedule 2, 3 and 4 (non- restricted) poisons as clinical waste using the UQ <u>Clinical Waste Procedure</u> on the Properties and Facilities <u>Sustainability</u> <u>webpages</u>.
- (45) Locked clinical waste bin/s (240L yellow bin) must be used at the approved Organisation Unit for the disposal of S2, S3 and (non-restricted) S4s. The locked clinical waste bin must be stored in a secure location (e.g., swipe card access only/locked room) until the scheduled collection time.

Restricted and High-risk Poisons

(46) Restricted S4 and S7, and all S8, S9 and S10 substances must be destroyed by being rendered unusable, unrecognisable and unfit for human or animal use and incapable of growth or germination. These scheduled substances will be disposed of by the DO under the supervision of a witness. The disposal must be recorded in the

relevant Usage Log by the DO and witnessed by an appropriately qualified person, e.g., the WHSC, HSW Manager or Facilities Manager of the relevant area or the DO of a different area. A summary of the disposal requirements is reflected in Table 2 in Appendix D - SMP Table.

(47) Restricted S4 and S7, and all S8, S9 and S10 substances can be disposed as other chemical waste through the Science Store, if not destroyed by the experimental process or use.

Transport

- (48) When medicines and poisons require transfer within a Campus, they must be in a double contained, labelled container (e.g., container within a hard esky) and in possession of the approved Eligible Person at all times.
- (49) When medicines and poisons require transfer between Campuses or remote sites, a licenced courier must be used, they will organise relevant compliant paperwork with secure and safe packaging.
- (50) Any loss or other discrepancy during transit must be immediately reported as outlined in the 'Discrepancies and Incident Reporting' provisions below.

Field Work with Scheduled Substances

- (51) 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.
- (52) The minimum requirements are:
 - a. a secure transport container that can be securely attached to the vehicle, preventing unauthorised access; and
 - b. a documented process for reporting loss of substance while in the field; and
 - c. a transport manifest of items carried.
- (53) The approval record provided by the Health, Safety and Wellness Division must be attached to the <u>UQSafe-Field</u> <u>Trip</u> application.

Section 4 - Roles, Responsibilities and Accountabilities

(54) Generally, UQ workers, DOs and others are responsible for ensuring they are appropriately qualified and approved, and that:

- a. regulated medicines and 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 above);
- b. regulated medicines and poisons in their possession are disposed of in accordance with the 'Disposal and Destruction' provisions above;
- c. any intentional or accidental misuse, theft, diversion or other loss is reported (see 'Discrepancies and Incident Reporting' provisions below); and
- d. for restricted and high-risk poisons, DOs will purchase, record their arrival, use and disposal.

Vice-Chancellor's Risk and Compliance Committee

(55) The Vice-Chancellor's Risk and Compliance Committee (VCRCC) endorses the SMP. The VCRCC receives regular reports of overall compliance with the SMP from the HSW Division.

Chief Operating Officer

(56) The Chief Operating Officer (COO) applies to Queensland Health as an authorised person for UQ (the Executive Officer) for a general approval to buy, possess, supply, apply and dispose of regulated poisons (other than non-restricted S7s) 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

(57) 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. suitably qualified Eligible Persons are appointed and approved as DOs to support the implementation and maintenance of this SMP in their Organisational Unit; and
- b. sufficient resources are available to enable compliance with the security, storage and disposal requirements of this SMP.

UQ Drugs and Poisons Officer (DO)

(58) DOs are responsible for:

- a. completing the 'Privacy at UQ' and 'Drug Officer and Drugs Commodity approver role' online training modules prior 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 medicines and poisons to approved UQ workers (EPs) within the Organisational Unit they are appointed to,
 - iv. user training,
 - v. secure and complaint storage, and
 - vi. on work practices to facilitate compliance, as required;
- c. applying regulated medicines and poisons, if their role requires it (e.g., Biological Resources Facilities);
- d. authorised to supply to approved Eligible Persons or Research Groups of restricted and high-risk medicines and poisons:
 - i. NOTE: in some research support areas, these activities could be performed for multiple schools and Institutes or external organisations, e.g., DOs employed by UQ Biological Resources. These or any other UQ facility that also service non-UQ workers (e.g., other universities or companies under relevant internal agreements and approvals) are permitted to supply medicines and poisons to those from other organisations, 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 will need to check and have a record of those general approvals/SMP from those organisations;
- e. disposing of restricted and high-risk poisons as required;
- f. functioning as an Organisational Unit Drugs Commodity Approver within central procurement;
- g. uploading relevant records into UQSafe as required;
- h. maintaining the Organisational Unit's Usage Log(s) for restricted and high-risk poisons;
- i. conducting periodic audits (at least at 6-month intervals) of the Organisational Unit's Usage Log(s), and storage facilities; and
- j. report 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

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

- a. providing 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 substance;
- e. ensuring that any incidents relating to the use of these regulated substances 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 substances under their management are met, e.g., animal ethics or other approvals; and
- g. appointing a person to audit low risk scheduled substances (S2, S3 and non-restricted S4) at least annual and report these to the DO.

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

(60) Local WHSC and HSW Managers should:

- a. assist with advice on the application/approval process, storage and disposal regarding regulated medicines and poisons in consultation with the DO;
- b. assist with the completion of risk assessments on activities using medicines and poisons; and
- c. work with Supervisors and Managers on monitoring compliance with this SMP.

UQ Workers and Others

(61) Eligible Persons and others planning to work with regulated medicines and poisons are responsible for:

- a. reviewing, understanding and complying with this SMP and any associated procedures;
- b. completing the required training; and
- c. ensuring they have the required approval prior to using regulated medicines and poisons (after that they must follow the 'Approved Persons' provisions below).

Approved Persons

(62) Eligible Persons, or Organisational Units for low-risk poisons use only, that have been approved to perform regulated activities with medicines and poisons are responsible for:

- a. reviewing, understanding and complying 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 compliance with this SMP;
- d. establishing, using and maintaining Usage Logs for high-risk poisons, in conjunction with DOs;
- e. disposing or destroying regulated medicines and poisons low-risk poisons appropriately;
- f. notify any discrepancies between the quantity or volume of low-risk poisons to Supervisor and the DO; in case

- of a DO's absence, to the HSW Division; and
- g. notify any discrepancies between the quantity or volume of restricted and high-risk poisons to Supervisor with the DOs; and in case of a DO's absence, to the HSW Division.

Health, Safety and Wellness Division

- (63) The Health, Safety and Wellness Division (HSW Division), in consultation with UQ stakeholders, oversees the implementation of the SMP.
- (64) The HSW Division is responsible for:
 - a. managing the implementation of the SMP (in consultation and with Schools, Centres, Faculties, Divisions and Institutes);
 - b. advising and supporting the UQ DOs and other Eligible Persons;
 - c. approving the use of regulated substances, 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 compliance with this Procedure and that any compliance 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 quality, safety and security of scheduled substances;
 - k. maintaining <u>UQSafe</u>;
 - I. producing quarterly reports of overall compliance with the SMP to the VCRCC; and
 - m. notifying the appropriate Regulator of any significant incident (e.g., discovered or suspected discrepancies in usage logs or storage) or notifiable event.

Section 5 - Monitoring, Review and Assurance

- (65) Approved Eligible Persons must ensure stocks of low risk scheduled substances (S2, S3 and non-restricted S4) are accounted for to avoid diversion or misuse, at least annually. This annual inspection report must be completed by a local designated approved person, and be submitted to the approved DO in the relevant area. The report must reconcile records of purchases for those scheduled substances that have been approved by the relevant DO, with the primary containers stored in their secure area.
- (66) UQ DOs will conduct periodic inspections of their Organisational Unit's restricted and high-risk poisons usage logs, and storage facilities, to monitor the general level of compliance by the Organisational Unit with this SMP. Audits must be conducted at least at 6-month intervals, using the iAuditor template 'UQ HSW Medicines and Poisons Inspection Checklist' or the Facility/Laboratory Inspection part of the 'UQ HSW Annual Workplace Inspection Checklist'. This will also inform DOs on work practices that will add value to their advice and imparted training, if required.
- (67) A record of the inspection, including recommended actions to address non-compliances shall be maintained by the Organisational Unit DO, and they will encourage the Organisational Unit to address actions in a timely manner.
- (68) The HSW Division is responsible for reviewing this SMP every five years, Appendixes (A, B, C and D) and

application forms as often as required (although at least annually), to ensure they remain current, accurate and relevant to the needs of UQ and reflects legislative requirements. To inform this, annual audits of compliance with this Procedure will be conducted, for one selected approved research group and two approved individuals, and at least one approved Organisational Unit/section will be audited every five years. Audit requirements are summarised in Table 3 of Appendix D of SMP Tables.

Section 6 - Recording and Reporting

Usage and Disposal Log

(69) UQ DOs must maintain a Usage Log (refer to 'Definitions' in the Appendix) recording the use of all medicines and poisons listed in:

- a. Schedule 8 (including Pentobarbital), Schedule 9 and Schedule 10 of the Poisons Standard; and/or
- b. Restricted Schedule 7 Poisons (included in Schedule 1 of the Regulation); and/or
- c. Restricted Schedule 4 drugs listed in Schedule 2, Medicines and Poisons (Medicines) Regulation 2021.

(70) The Usage Log must record each transaction and use involving the regulated substance, be signed on each occasion by the relevant DO, and be retained for five years from the date of the last entry. Usage Logs are available from the Health, Safety and Wellness Division webpage. UQ Biological Resources facilities are permitted to use The Dispensary Guild of Australia Controlled Drug Register to record their use of RS4, RS7, S8, S9 and S10 as determined by their internal Standard Operating Procedure.

(71) This Usage Log must also reflect disposal of those high-risk poisons and could have a record of the periodic inspections or audits performed.

Discrepancies and Incident Reporting

- (72) Approved workers that discover or suspect a discrepancy between the quantity or volume of a regulated medicine or poison and the balance recorded in the Usage Log, must immediately notify their Supervisor, the relevant DO and the HSW Division (<a href="https://nxwo.new.org/nxwo.new.new.org/nxwo.new.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo.new.org/nxwo
- (73) The HSW Division will notify Queensland Health of discrepancies as required.
- (74) Discrepancies, misuse, diversion or any other significant event must also be reported as an incident in <u>UQSafe</u> which will trigger an investigation by HSW Division.

Section 7 - Appendix

Definitions, Terms, Acronyms

Terms	Definitions	
	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:	
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; Chemical Management Consultant; Managers - HSW; Health & Safety Advisers/Consultants, HSW Division. 	
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 Person	Eligible person who holds an approval to use scheduled substances recorded by the HSW Division.	
Applicant	Refers to the person applying for approval under SMP.	
Disposal	Is the placement in clinical waste bins of low-risk poisons (S2, S3, and S4- non-restricted) stocks. Placement in chemical waste stream (<u>UQ Science Store</u>) for restricted and high-risk poisons (RS4, RS7, S8, S9 and S10) stocks; alternatively the destruction by experimental use or the destruction by being rendered unusable, unrecognisable and unfit for human or animal use and incapable of growth or germination, and as outlined in the UQ's general approval.	
Usage Log	Queensland Health has defined records of all relevant scheduled substances (RS4, RS7, S8, S9 and S10) must be kept in a physical or electronic book/record (so long as they allow for signatures of witness for the disposal) which is regularly maintained and must include the following information: 1. Incoming stock: a. date of obtaining; b. source; c. quantity; d. order number. 2. Outgoing stock: a. date of use; b. quantity used; c. name of the person using the scheduled substance; d. balance of regulated substance remaining. 3. Disposal of stock: a. date of disposal; b. quantity disposed; c. name of the person disposing the scheduled substance; d. name of the person witnessing the disposal of the scheduled substance.	
Drugs Commodity Approver	A DO appointed by a Head of Section to monitor the purchases of medicines and poisons within the UQ procurement system and approve those if the purchase complies 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 required to perform regulated activities in the course of their occupation or engagement. For example this would include persons in a support role, students or engagement at UQ. Also includes persons registered or those undergoing training to become a registered health professional or veterinary surgeon.	
Low Risk Poisons	Medicines and poisons listed in Schedule 2, 3 and 4 (non-restricted medicines) and Schedule 7 (non-restricted hazardous poisons) of the <u>Poisons Standard</u> (<u>SUSMP</u>).	

Terms	Definitions	
Medicine	A Scheduled substance in the category of an S2, S3 or S4 medicine. Also, in general, a substance applied to a person or animal for therapy.	
Monitored Substance	A S8 Medicine or substance prescribed by Regulation to be a monitored substance.	
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.	
Poison	A Scheduled substance in the category of an S5, S6 or S7 poison. Also, Scheduled substances S8, S9 and S10 only used in research and teaching activities.	
Possess	Having custody or control of, and the ability or right to obtain custody or control of the drug, poison or other substance.	
Prohibited Substance	A Scheduled substance in the category of an S9 or S10/Appendix C prohibited substance.	
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. 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 on poisons management with one month supervision after completion of the Chemical Safety online training and any other relevant online modules is required.	
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.	
Restricted Medicine	An S4 or S8 Medicine, listed in the Poisons Standard or prescribed by Regulation.	
	1. medicines and poisons listed as 'restricted Schedule 4 (RS4)' in Schedule 2, Part 1 of the Medicines and Poisons (Medicines) Regulation 2021; and/or	
Restricted and High- Risk Poisons:	2. poisons listed as 'Restricted Schedule 7 (RS7)' in Schedule 1 of the <u>Medicines and Poisons (Poisons and Prohibited Substances)</u> Regulation 2021; and/or	
	3. medicines and poisons listed in Schedule 8, 9 or 10 of the Poisons Standard (High-risk poisons and prohibited substances).	
Relevant Occupation	Occupation such as dentist, doctor, indigenous health worker, midwife, optometrist, podiatrist, registered nurse or veterinary surgeon.	
Scheduled Substance	Substances declared as an emerging substance, in the Poisons Standard and those listed in the current <u>SUSMP</u> .	
Schedule 2	Pharmacy Medicine: Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.	
Schedule 3	Pharmacist Only Medicine: Substances, the safe use of which requires professional advice but which may be available to the public from a pharmacist without a prescription.	
Schedule 4	Prescription Only Medicine or Prescription Animal Remedy: Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.	

Terms	Definitions	
Schedule 5	Caution: Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.	
Schedule 6	Poison: Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.	
Schedule 7	Dangerous Poison: Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special Regulations restricting their availability, possession, storage or use may apply. Restricted S7 (RS7): as per list in Schedule 1 Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021 and including cyanide.	
Schedule 8	Controlled Drug: Substances that should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.	
Schedule 9	Prohibited Substance: 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.	
Schedule 10	Substances prohibited for sale, supply and use: Substances of such danger to health as to warrant prohibition of sale, supply and use (formerly Appendix C). In Queensland, Schedule 10 substances include many common chemicals that have been prohibited for use in particular circumstances such as human therapeutic or domestic use.	
	The oversight by the Supervisor of the regulated activities of the other person for;	
	 directing, demonstrating and monitoring the regulated activities; and checking the other person's level of competency for the regulated activities. 	
Supervision	This must be accomplished in a proportionate manner to the schedule of the substance and the risk.	
Supervision	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 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; contractors, subcontractors and consultants; Higher Degree by Research students (inc. Honours, Master's and PhD); visiting academics or researchers; academic title holders, visiting academics, Emeritus Professors, adjunct and honorary title-holders, Industry Fellows and conjoint appointments; visiting research students; and volunteers and students undertaking work experience engaged by UQ. 	

Status and Details

Status	Current
Effective Date	20th September 2022
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Enquiries Contact	Health, Safety and Wellness Division