1. Purpose
This communiqué informs the UQ community about the consultative process and potential new compliance arrangements under the Medicines, Poisons and Therapeutic Goods Bill (MPTG Bill) which, when enacted in 2017, will supersede the current Health (Drugs and Poisons) Regulation 1996.

2. Consultation
UQ has participated in consultation about the development of the MPTG Bill throughout 2015-2016 and further opportunity for comment about the final Bill and indicative regulation is likely to occur in late 2016-first quarter 2017. At this time there may also be opportunity for consultation about proposed fee models and quantum of fees.

The Queensland Health Legislation Improvement Unit (the Regulator) advises that there will be a short turn-around time for the proposed upcoming consultation in order to meet Parliamentary timelines. The OHS Division will keep you informed in this regard, and will continue to coordinate the UQ community’s feedback to the Regulator.

3. Key features under the new licensing arrangements

General Approval – UQ Entity
A General Approval will include substance authorities i.e. authorities for which the entity (such as UQ) can perform the regulated activities for the scheduled substances stated in the approval. Regulated activities applicable to the UQ entity will be for research, teaching or analytical purposes only.

Permits for regulated activities and substances that are currently held by individual UQ employees (eg researchers, managers, drugs officers) will be moved onto the new UQ entity General Approval under the new MPTG legislation. This will occur throughout a 12-month transition period that is likely to begin in Q1 2017. At the end of the transition period to the new legislation, current individual approvals will cease to be valid.

During the transition period UQ staff who are authorised to purchase, store, use, issue and dispose drugs and poisons will be required to take appropriate actions, as guided by the UQ OHS Division, to ensure that UQ remains compliant under the new regulatory arrangements.

The OHS Division is working closely with the Regulator, the UQ Drugs Officer network and UQ OHS community to ensure that all compliances are maintained and risks are managed as we plan our move toward the new arrangements.

Scheduled Substance Management Plan
As an entity under the new regulation, UQ will be required to have a Scheduled Substance Management Plan (SSMP) that sets out a strategy for managing known and foreseeable risks associated with UQ performing regulated activities for scheduled substances, for which UQ has an authority.
Consultation with the UQ community about UQ’s draft SSMP is planned. At this early stage the draft SSMP structure includes:

- Research, learning and teaching activities and scheduled substances to be covered by the Plan
- UQ roles
  - UQ staff who are endorsed* under UQ’s General Approval to conduct regulated activities for scheduled substances (eg researchers, academics, purchasers, issuers, consumers/users)
  - Drugs Officers
  - Drugs Reviewers
  - Custodian and Manager of the SSMP
- Eligible persons
  - UQ staff who are registered medical practitioners, veterinarians and those undergoing training to become registered will become Eligible Persons under the new legislation. If their approved activities are considered to operate under UQ’s General Approval for research, teaching and analytical activities rather than an individual authority or a Drug Treatment Approval, then they would be included for that purpose only on the UQ General Approval.
- Risk Management
- Communication and Training
- Endorsement process for research, teaching or analytical purposes
- Conditions of Endorsement
- Drugs Officers and Drugs Reviewers conditions/obligations
- Procurement
- Arrival at a controlled delivery point
- Possession Responsibilities
- Procurement, labeling, storage, security and access, disposal, inventory and record keeping
- Records, disposal, labeling, storage, restricted access, inventory control
- Unaccounted drugs and incident reporting
- Requirements for cross-regulated drugs and poisons
- Appendix 1: Endorsement Flow Chart
- Appendix 2: Sample Regulated/Controlled Drugs and Poisons Log

* UQ will become responsible for endorsing individual UQ staff to conduct regulated activities for scheduled substances under the UQ General Approval. Our current understanding is that the UQ endorsement will replace any individual permits that are currently issued by the Regulator.

4. New UQ internal workflows
The new regulation will require UQ to self-govern and self-manage its endorsements, monitoring and conduct of regulated activities with scheduled substances by UQ staff. With this in mind, UQ will establish new workflows and business rules to:
- Establish and coordinate a central UQ Register and local Faculty/Institute/School Registers of scheduled substances and endorsed UQ staff.
- Endorse UQ staff proposing to conduct new/modified regulated activities for new/existing scheduled substances for research or teaching purposes.
- Confirm removal of scheduled substances, regulated activities and endorsed UQ staff from the local and central Registers, as needed eg when research is completed, a laboratory decommissioned or a staff member leaves UQ.

5. Key offences
The MPTG Bill makes provisions for significant and general offences applicable to persons acquiring, handling or using scheduled substances, medicines and poisons in a way that is unauthorised. As such, UQ staff who are authorised to perform research, teaching or analytical activities with scheduled substances under the UQ entity General Approval, must do so in accordance with the UQ entity Scheduled Substance
Management Plan (SSMP). The SSMP will be a practical reference for assuring that the use of scheduled substances, medicines and poisons is done in an authorised way.

6. Activity timeline - assuring compliance under new MPTG legislation

- December 2016 - UQ OHS Division consultation with UQ Drugs Officer and OHS network and relevant other stakeholders.
- Late 2016 – Q1 2017: Regulatory consultation with stakeholders (including UQ) about indicative regulation. The regulator is seeking Parliamentary approval to include proposed fee models and quantum of fees in this consultation.
- Mid to late Q1 – 2017: Transition period to new licensing arrangements under the MPTG legislation starts including UQ General Approval
- Mid to late Q1 – 2018: UQ’s full compliance with the MPTG legislation is confirmed by regulatory approval.

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