Medicines and Poisons (Medicines) Regulation 2019

Explanatory notes for SL 2019 No. ###

made under the

Medicines and Poisons Act 2019

General Outline

Short title

Medicines and Poisons (Medicines) Regulation 2019

Authorising law

Section 240 of the *Medicines and Poisons Act 2019*.

Policy objectives and the reasons for them

Following a review of the existing legislation, it was determined that the *Health Act 1937*, *Pest Management Act 2001*, *Health (Drugs and Poisons) Regulation 1996*, *Health Regulation 1996* and *Pest Management Regulation 2003* would be repealed and replaced with the *Medicines and Poisons Act 2019* (the Act), *Therapeutic Goods Act 2019*, *Medicines and Poisons (Medicines) Regulation 2019* (Medicines Regulation), *Medicines and Poisons (Pest Management, Poisons and Other Regulated Substances) Regulation 2019* (Poisons Regulation) and the *Therapeutic Goods Regulation 2019*.

Medicines and poisons are scheduled by the Therapeutic Goods Administration in the Commonwealth *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard). Chemicals used for pest management activities, are registered or permitted for use as pesticides or fumigants by the Australian Pesticides and Veterinary Medicines Authority. Additionally, many pesticides and fumigants are also scheduled poisons and listed in the Poisons Standard.

A key objective of the Act is to ensure substances, including medicines and poisons, are used safely and effectively and do not cause harm to human health. The Act and Regulations cover activities that involve both Therapeutic Goods Administration-scheduled and Australian Pesticides and Veterinary Medicines Authority-registered or permitted substances. Collectively, the substances will be referred to as ‘regulated substances’.

The Medicines Regulation deals specifically with medicines and complements the Act by authorising activities that would otherwise be unlawful, and defining the outcomes required of lawful actions. Key objectives of the Medicines Regulation include:

- supporting the objectives of the Act to ensure regulated substances are used safely and effectively and to reduce public harm;
- more modern electronic medication management to better support public health outcomes;
- improving terminology for medicines that are associated with increased risks of diversion or harm, providing more clarity around restriction of use and reporting obligations;
- clarity around authorised activities and approved persons, previously known as as-of-right-authorities, to reduce reliance on approvals;
- more flexible requirements for a number of authorised activities, such as storage and disposal, that are commensurate with the approved person's qualifications and activities and the public health and safety risk of the medicines; and
- better facilitation of the prescribing and delivery of medicated animal feed for use by primary producers.

The Poisons Regulation deals specifically with poisons and pest management, gives effect to the Act's objectives and supports implementation of the Act. Key policy objectives of the Poisons Regulation include:

- protecting the public from the health risks associated with the inappropriate access to, and use of, poisons;
- adopting a contemporary approach to regulating poisons in Queensland that introduces a more responsive and outcomes-focused regulatory framework;
- streamlining the regulatory controls governing poisons to reduce the associated regulatory costs for industry, consumers and government;
- enhancing consistency with national regulatory frameworks by implementing decisions of the Council of Australian Governments (COAG) in relation to the regulation of poisons and pest management activities; and
- improving security controls in the use and storage of poisons to prevent diversion for unlawful purposes.

Achievement of policy objectives

Approved persons

The Medicines Regulation provides for particular classes of persons (approved persons) to be authorised to carry out regulated activities with regulated substances that are medicines because of their profession or occupation, or because of the position they hold. The majority of these authorities will be granted to individuals to facilitate the provision of health and veterinary services in various settings, including community settings such as schools.

The different types of authorities granted under the Health (Drugs and Poisons) Regulation have been streamlined and classified by each category of approved person. The Act includes the necessary regulation-making heads of power to enable the following information to be more clearly set out for each of the occupations, professions or positions that will be prescribed as an approved person under the Medicines Regulation:

- the particular medicines for which an approved person will be authorised to have access;
- the regulated activities that may be carried out with particular medicines, such as possess, administer, supply or prescribe;
- any applicable conditions governing the activities to be carried out with a particular medicine (e.g. the person must hold particular qualifications or comply with recognised industry or government standards).

The amendments achieve the policy objectives by ensuring the broad model provided in the Health (Drugs and Poisons) Regulation is both retained and streamlined.

To support the Medicines Regulation, specific departmental standards will be developed. For example, the proposed standard for the storage, transport and record-keeping of medicines is a standard dealing with 'best practice when carrying out a regulated activity to ensure regulated substances are securely stored and transported so as to be fit for purpose'. Persons who deal with regulated substances will be required to comply with the standards applicable to the activity they are performing. Standards are discussed in more detail below.

Adoption of parts 2 and 4 and appendices D and H of the Poisons Standard

The Poisons Standard provides for the uniform scheduling of substances classified from Schedule 2 (S2) to Schedule 10 (S10). All States and Territories refer to the Poisons Standard when regulating possession, access and use of scheduled substances.

The Medicines Regulation will achieve the policy objectives by adopting, by reference, parts 2 and 4 and appendices D and H of the Poisons Standard, subject to any modification made by regulation.

Part 2 of the Poisons Standard includes model provisions about packaging and labelling and other controls for the management of medicines and poisons risks. The matters predominantly apply to sale and supply. The Medicines Regulation also includes additional requirements about these controls (e.g. the requirement to label a S3 medicine with the name of the person for whom it is supplied).

Part 4 classifies medicines and poisons into Schedules:

- Schedule 2 – pharmacy medicine (S2);
- Schedule 3 – pharmacist only medicine (S3);
- Schedule 4 – prescription only medicine or prescription animal remedy (S4);
- Schedule 5 – low harm poison (S5);
- Schedule 6 – moderate harm poison (S6);
- Schedule 7 – dangerous poison (S7);
- Schedule 8 – controlled medicine (S8);
- Schedule 9 – prohibited substance, should only be available for medical or scientific research, or for analytical, teaching or training purposes (S9); and
- Schedule 10 – prohibited substance, known for their dangerous properties (S10).

Appendix D includes recommendations about additional controls on the possession or supply of medicines included in S4 or S8. The Medicines Regulation reflects the controls in Appendix D including restricting who can prescribe certain specified medicines.

Appendix H lists the S3 substances permitted to be advertised directly to consumers.

To achieve the policy objectives, the Medicines Regulation:

- inserts a penalty provision for non-compliance with any provision of part 2 of the Poisons Standard;
- inserts a provision that states that despite the labelling requirements, a person does not commit an offence if a substance has been rescheduled and the person labelled and packaged the substance prior to the rescheduling taking place;
- inserts a provision that places additional controls on certain dealings with medicines listed in Appendix D of the Poisons Standard; and
- inserts a provision that places controls on the advertising of medicines.

Offences

The Act introduces a simplified and consistent regime of general offences, to replace the numerous offences throughout the Health (Drugs and Poisons) Regulation, Health Regulation and Pest Management Regulation.

The Act provides that no offence is committed where a person holds the necessary authority, licence or approval to perform the activity in question and that the activity is performed in the way specified under the Act, Regulations or a Standard.

The Act makes provision for substance authorities to have conditions which may be prescribed in a regulation or may be set out in the authority instrument. Failure to comply with a condition of an authority will constitute an offence under the Act.

While the Act broadly addresses offences associated with authorities or performing regulated activities with regulated substances, the Medicines Regulation provides for some offences that are not covered by the Act.

The Medicines Regulation inserts offence provisions for non-compliance with requirements around electronic medication management systems, advertising, packaging and labelling, and a prohibition on sale of scheduled medicines from a vending machine.

Licensing

The new regulatory regime rationalises the licensing requirements for medicines and poisons and streamlines and simplifies the licensing process.

Under the Medicines Regulation licences may be required for:

- manufacturing of medicines;
- the sale by wholesale of medicines; and
- the retail sale of S2 medicines.

The amendments will achieve the policy objectives by streamlining the licensing regime in the following ways:

- under the Health (Drugs and Poisons) Regulation, holders of a Commonwealth (Therapeutic Goods Administration or Australian Pesticides and Veterinary Medicines Authority) manufacturing licence must also hold a Queensland manufacturing licence. Under the new medicines and poisons regulatory framework, Commonwealth manufacturing licences will be recognised as authorising the holder to manufacture medicines. Consequently, the holders of these licences will not be required to hold a separate Queensland manufacturing licence;
- the Medicines Regulation authorises entities holding a manufacturing licence issued under a law of the Commonwealth to sell by wholesale the medicines they manufacture under the Commonwealth licence;
- a licence holder that manufactures or supplies medicines at more than one location in Queensland, may apply to consolidate their licences into one licence that will cover all locations; and
- representatives of medicines manufacturers and wholesalers who supply sample packs of medicines to prescribers and pharmacists required a licence under the Health (Drugs and Poisons) Regulation. Under the Medicines Regulation this activity is now authorised by way of an approved person authority.

Some standard conditions have been prescribed in the Medicines Regulation, with additional conditions able to be prescribed on the authority instrument depending on the substance involved, the purpose of use, and any other relevant criteria.

Medicines wholesalers are required to comply with the Code of Good Wholesaling Practice which, together with possible licence conditions, will ensure traceability of substances of high illicit value and allow for the recall of substances that do not meet product specifications or other compliance requirements.

General approvals

A general approval will authorise the holder of the approval to undertake a regulated activity with the regulated substance stated, and under the conditions stated in the approval. The Medicines Regulation also prescribes standard conditions for general approval holders. Additional conditions may be prescribed on the authority instrument depending on the substance involved, the purpose of use and any other relevant criteria.

General approvals may be granted to any legal entity for a range of regulated activities, including possession and administration of medicines for immunisation and animal welfare programs.

Fees

All licences granted under the Act will attract a fee. The new fee structure under the medicines and poisons regulatory framework reflects the licence changes identified above. In conjunction with the revised licence structure simplification, the revised fee structure will ensure no new fees or charges for existing licence holders transitioning to the new scheme. The streamlining and simplification of fees is achieved through a number of measures.

Under the medicines and poisons framework, there will be no changes to the fee amount payable by a licensee. General approvals will remain free of a fee levy.

Wholesale representatives who previously required a licence under the Health (Drugs and Poisons) Regulation and who are now authorised by way of an approved person authority will, consequently, no longer pay a licence fee.

As a consequence of Commonwealth manufacturing licence holders no longer being required to hold a separate Queensland manufacturing licence, they too will no longer have a licence fee levied to be authorised to manufacture and wholesale medicines.

In line with the Health (Drugs and Poisons) Regulation, Queensland licences authorising the manufacture and wholesale of medicines will attract a specific fee if the licence authorises the manufacture or wholesaling of S8 medicines in addition to S2, S3 or S4 medicines. Where only S8 medicines are manufactured or sold, only the specific S8 fee would apply. For example:

- manufacture of an S2, S3 or S4 medicine – one licence, one fee;
- manufacture of an S8 medicine – one licence, one fee; or
- manufacture of an S2, S3 or S4 medicine and manufacture of an S8 medicine – one licence, two fees.

Manufacturing licence holders with multiple sites may apply to consolidate their licences so that they may hold a single licence that covers each site. They will be required to pay a separate licence fee for each site operating under the licence. The same licence structure applies to state-based wholesale licences.

In a small number of cases, an existing licence holder with one licence will need two licences to perform the same activity. For example, the wholesaler of both S4 medicated animal feed and S7 agricultural poison only requires a restricted drug wholesaler licence under the Health (Drugs and Poisons) Regulation, but will require an S2, S3 or S4 wholesale licence and an S7 wholesale licence under the medicines and poisons regulatory framework. To ensure authority holders are not disadvantaged by this change, the new framework will require two licences to be issued, and a single fee levied, in situations where only one licence is required under the Health (Drugs and Poisons) Regulation. This will apply to both existing licence holders and new industry entrants.

Advantages of the revised fee structure compared to the fees charged under the Health (Drugs and Poisons) Regulation include:

- reduced administrative burden for holders of multiple licences who chose to consolidate to a single licence;
- no fees or licensing requirement for wholesale representatives;
- no increase in fees for existing licence holders; and
- no new fees for approval and permit holders.

Particular medicines

The Medicines Regulation updates the way medicines associated with certain risks are referred to. In the Health (Drugs and Poisons) Regulation, these medicines were called controlled drugs, regulated controlled drugs, regulated restricted drugs or restricted drugs of dependence. Although the rules and restrictions around the use of these medicines remains largely unchanged, the Medicines Regulation achieves the policy objectives of the Act by introducing

new terminology that is more meaningful, indicating the reason why the medicine is deemed to have risks to public health that require control of use. The new terminology is as follows:

- *Diversion-risk medicine* – refers to medicines that may have an illicit value, such as S8 medicines, S4 drugs of dependence, anabolic steroids, peptides or pseudoephedrine products. There are significant penalties for improperly purchasing or supplying these medicines.
- *High-risk medicines* – refers to prescription medicines that are S8 medicines and some specified S4 medicines that have a recognised therapeutic need but also have a higher potential for harm, impairment, misuse, abuse and dependence. There are specific offences around self-prescribing and self-administration of these medicines.
- *Monitored medicines* – refers to those medicines to be included in the real-time prescription monitoring database. The Medicines Regulation specifies the S4 and S8 medicines to be included in the monitored medicines database. The Act specifies that prescribers and dispensers must review the monitored substance medicines database prior to prescribing or dispensing these medicines.
- *Restricted medicines* – refers to S4 and S8 medicines identified as having specific health risks that may be mitigated by restricting availability through specialist medical practitioners and includes those medicines listed in Appendix D of the Poisons Standard, as requiring prescribing by a specialist.

Prescribing and Prescriptions

The Medicines Regulation regulates prescribing and prescriptions to facilitate the safe supply and administration of medicines by authorising only certain people to issue a prescription and provides the rules that must be followed when issuing prescriptions. This achieves the policy objective of ensuring regulated substances are used safely and effectively and reduces the risk of causing harm to the public.

The following are some of the ways the Medicines Regulation achieves the policy objectives:

- prescriptions that are written by a prescriber whose authorisation to prescribe is given under a prescribing approval must contain the prescriber's number;
- computer generated paper prescriptions for S8 medicines will no longer be required to have their components reproduced in handwriting on the prescription by the prescriber;
- a prescription authorising administration of a medicine in a person's medication chart must now contain the same elements as a prescription to supply, with the exception of the prescriber's address, qualification or quantity of medicine to be supplied;
- a prescription that authorises administration will be valid for the same duration as a prescription to supply, 12 months from the date it is written for a S2, S3 and S4 medicine and 6 months for S8 medicines;
- a medical practitioner or nurse practitioner can make a standing order for the treatment of patients in an institution, and at other places subject to approval. A standing order is a document that authorises a medicine to be administered or given as a treatment dose to or for a person or animal at the place, provided a number of conditions are met;
- supports the use of electronic prescribing by establishing the rules for the system and its operation; and
- permits authorised prescribers to direct the administration and supply of opioid replacement medicines using a prescription for a patient in an opioid treatment program.

Destruction of S8 medicines

To provide greater flexibility, more timely destruction of S8 medicines and reduce the burden on specific authorised people, the Medicines Regulation extends the authority to destroy medicines to a broader range of people, including pharmacists, medical practitioners, nurse practitioners, eligible midwives, dentists and veterinary surgeons.

To achieve the policy objectives, the Medicines Regulation inserts provisions to:

- permit specified persons to destroy S8 medicines in the presence of a witness;
- require that each time an S8 medicine is destroyed there must be a record made in an approved S8 medicines register that includes the date, item and quantity destroyed and the name of the person who witnessed the destruction; and
- provide that the destruction of a previously sterile container, unused portion of a tablet or a lozenge containing an S8 medicine that is not required for administration to a patient, can be destroyed by a person who is authorised under the Act to administer the medicine, without requiring a witness.

Supply generally

Pharmacists must adhere to their professional practice guidelines when supplying medicines. For other health practitioners, the Medicines Regulation provides that a person who is authorised to give a treatment dose must ensure that the medicine is supplied safely in compliance with the proposed standard for the supply of medicines by health practitioners.

To achieve the policy objective, the Medicines Regulation inserts multiple provisions authorising pharmacists to supply medicines by wholesale where the supply could be considered a part of normal pharmacy business. This would include:

- sale of small quantities of stock where the medicines are not for resale, such as emergency stock in an aged care facility;
- supplying a medical practitioner or other authorised prescriber with medicines, for example, supply for a doctor's bag; or
- selling S3 medicines, such as asthma relievers or adrenaline (epinephrine) to a school or authorised first aid provider.

To address a shortcoming in the Health (Drugs and Poisons) Regulation, the Medicines Regulation inserts a provision allowing a pharmacist to supply or loan stock to another pharmacist to fulfil a purchase order for an immediate customer request.

Storage

The Medicines Regulation recognises advances in technology, such as dispensing robots and automated drug cabinets. It achieves this policy objective, by introducing regulatory controls to ensure medicines being stored in these machines will not be compromised. As these machines and storage units are constantly being improved, the requirements for secure storage of medicines will be expressed in the proposed standard for the storage, transport and record-keeping of medicines.

Recording and reconciliation of S8 medicines

The Medicines Regulation introduces consistent requirements for recording the entry and removal of S8 medicine stock from secure storage and reconciling records of the stock of S8 medicines held. The Medicines Regulation achieves this by inserting a requirement that a register of S8 medicines is reconciled frequently enough to detect a discrepancy. The frequency of reconciliation may be different depending on the size and nature of an entity. However, at a minimum, reconciliation must be performed once a month.

Departmental Standards

Many of the prescriptive requirements contained in the Health (Drugs and Poisons) Regulation will be repealed, with the regime becoming more outcomes-focused. Where possible, the Medicines Regulation prescribes particular outcomes that must be met in order to achieve compliance and will refer to standards for acceptable methods by which to achieve prescribed outcomes.

The Act empowers the chief executive to make departmental standards relevant to the objectives and administration of the new regulatory framework. The standards will be outcomes-focused, and set minimum safety and accountability criteria that must be met in relation to particular activities. The standards which support the Medicines Regulation and its objectives will include standards relating to the storage of transport and medicines, and substance management plans.

A copy of the standards made by Queensland Health will be published on the Queensland Health website as well as being available for inspection, free of charge.

Substance management plans

The Act contains a new requirement for particular authority holders to develop substance management plans. The plan allows authority holders to achieve compliance by allowing them the flexibility to identify and manage the risks relevant to them. It recognises that there are many options for how compliance can be achieved rather than via the present highly-prescriptive model. A plan must also document accountabilities and responsibilities of persons employed or engaged by the authority holder.

The plan demonstrates that an authority holder has considered risks involving regulated substances and taken steps to ensure these are adequately mitigated or managed in the particular context of the practice and work environment of the authority holder. In developing and implementing a plan, there must be compliance with any relevant standards.

The Medicines Regulation contains a Schedule to the Regulation that prescribes who must have a substance management plan and who is the responsible person for making the plan at that place.

Selling scheduled substances

The Medicines Regulation continues the requirement under the Health (Drugs and Poisons) Regulation to place the onus on a seller supplying stock (medicine that is non-dispensed or not for a named patient) to ensure that they are selling to a person that is authorised to issue a purchase order for the medicine stock.

The Medicines Regulation achieves the policy objectives of the Act by providing that a person who supplies stock can only supply to someone who is authorised to purchase stock. This includes:

- an approved person as per their authority;
- a person or entity authorised under a substance authority (a substance authority holder); or
- an approved person working for a substance authority holder and authorised by the substance authority holder to purchase stock—the substance authority holder's management plan will articulate who is authorised to buy stock for that substance authority holder. The substance authority holder will need to provide that information to the supplier.

Procurement and purchasing certain medicines

The Act places controls on the supply of all regulated substances. The Medicines Regulation supports this objective by prescribing who may issue a purchase order. These include:

- holders of a manufacturing or wholesaling licence who may purchase regulated substances as allowed by the licence;
- holders of a general approval, who can purchase regulated substances as allowed by the approval;
- other persons in particular places specifically authorised by the Regulation. They include certain persons at aged care facilities, education and child care facilities, ships, detention centres, prisons, and watch-houses; and
- approved persons where the Regulation allows for this under the approved person's authority.

The Medicines Regulation achieves its objectives by providing more flexible approaches for certain authorised persons such as principals at a school or first aid providers to purchase certain medicines. For example, the Regulation clarifies that for classes of first aid providers, it is reasonable for a pharmacist to sell the first aid provider the necessary medicines, e.g. adrenaline (epinephrine) in an auto-injector, without requiring that the supply is for a specific and known patient.

Standing orders

A standing order is a type of direction that has been written in advance that allows certain authorised people to administer or supply a medicine without a patient specific direction. A lack of specificity about standing orders in the Health (Drugs and Poisons) Regulation means that they are sometimes used in circumstances in which patient-specific directions would be safer and more appropriate. The new framework inserts provisions that more formally recognise the use of standing orders as a type of instruction and also puts conditions on their use.

The Medicines Regulation achieves its objectives by still allowing timely access for the public to safe and effective treatment with medicines while ensuring that sufficient governance is in place to safeguard the use of standing orders.

Extended Practice Authorities

Similar to the Drug Therapy Protocols in the Health (Drugs and Poisons) Regulation, the Medicines Regulation authorises specified classes of approved persons in stated circumstances to supply or administer specified scheduled medicines without a prescription under an Extended Practice Authority approved by the chief executive. The Medicines Regulation states the class of health professional who is authorised under a specific Extended Practice Authority.

In order to ensure the purposes of the Act are met, ensuring people carrying out activities with medicines have the necessary competencies and that health and safety risks are appropriately managed, the Medicines Regulation also provides criteria the chief executive must consider in deciding to approve an Extended Practice Authority. These criteria include the types of medicines, the service need to be met by the authority and how the risks associated with the medicines will be managed.

Compounding of medicines

To ensure patients are able to access the medicines required, the Medicines Regulation continues the authority in the Health (Drugs and Poisons) Regulation for pharmacists to compound medicines for the treatment of a specific patient. To ensure that the compounded medicines are fit for its intended use and free from contamination, the Medicines Regulation replaces the relevant provisions of the Health Regulation with a Compounding Standard that an approved person who compounds a medicine must comply with.

Medicated animal feed

The Medicines Regulation changes the way veterinary surgeons can prescribe and order medicated animal feed for primary producers. The requirements under the Health (Drugs and Poisons) Regulation did not fit with industry practices, particularly as a prescribing veterinary surgeon may be based in a different state to the primary producer and significant quantities of ready to use medicated animal feed may be required to be given to a large herd. As a consequence, compliance with the Health (Drugs and Poisons) Regulation is difficult, costly and overly burdensome.

The Medicines Regulation achieves the policy objectives by ensuring control of the use of medicated animal feed rests with a veterinary surgeon and by reducing the regulatory burden and costs placed on primary producers by:

- providing that ready to use medicated animal feed can be ordered by the prescribing veterinary surgeon and delivered directly to the primary producer from the licenced manufacturer provided:
  - the veterinary surgeon has a bona fide professional relationship with the primary producer; and
  - the veterinary surgeon uses a compliant purchase order with full instructions for use.
- allowing a primary producer to mix medicated premix into animal feed for their own animals, on their own property, provided:

- the veterinary surgeon has a bona fide professional relationship with the primary producer;
- the veterinary surgeon uses a compliant purchase order with full instructions for use;
- the veterinary surgeon keeps appropriate records;
- the veterinary surgeon is satisfied that the primary producer is capable of effectively mixing the medication through the feed;
- feed is not used for other animals on a different property; and
- the medicine is contained in a mediated premix that is appropriately labelled.

Placing the responsibility for antibiotic stewardship predominantly onto a veterinary surgeon is appropriate given that as the authorised person with the requisite qualifications and training, they are best placed to manage the risks associated with prescribing large amounts of antibiotics.

Consistency with policy objectives of authorising law

The Regulation is consistent with the policy objectives of the Act.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

The regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The cost of implementing the new regulatory framework will be met within existing budget allocations, and the resources used to manage the existing regulatory framework will continue to be utilised to administer the new framework.

There are no new or increased fees under the proposed legislation. The Queensland Treasury Principles for Fees and Charges (January 2018) require agencies to set fees and charges to accurately reflect the full cost of providing their services. Agencies are also required to have processes in place to ensure the fees and charges maintain their value over time. Therefore, the proposed fees will continue to be subject to annual indexation in line with the Government indexation policy as advised by Queensland Treasury. The new regime will represent less duplication of some licence categories (e.g. Commonwealth and State manufacturing licences for medicines) and the discontinuation of wholesale representative licences, and some revenue may be lost as a result. This will be offset by a reduction in administration and monitoring costs under the Medicines and Poisons framework, resulting in a more revenue-neutral outcome.

Consistency with fundamental legislative principles

The Medicines Regulation is generally consistent with fundamental legislative principles. Potential breaches of fundamental legislative principles, based on the indicative draft regulation, are addressed below. Further justifications of any breaches will be included prior to the final regulations being made.

Rights and liberties of individuals

Does the legislation make rights and liberties, or obligations, dependent on administrative power only if the power is sufficiently defined and subject to appropriate review?

Section 4(3)(a) of the *Legislative Standards Act 1992* states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation makes rights and liberties, or obligations, dependent on administrative power only if the power is sufficiently defined and subject to appropriate review.

These powers are considered to be sufficiently defined and subject to appropriate review, as outlined below.

Clause 93 (Requirements for substance management plan) of the Act imposes obligations on the responsible person for a regulated place to make a substance management plan for the place before any dealing happens in relation to a regulated substance and that the plan is to be reviewed at the time prescribed by regulation. A substance management plan is a document setting out known and foreseeable risks associated with dealing with a regulated substance at a regulated place. Clause 110 (Review—Act, s93) of the Medicines Regulation provides that as soon as practicable after an incident identified in the *Substance Management Plan Standard* happens in relation to a place, and at least every 5 years after the day the substance management plan starts or the plan is reviewed following a review incident.

Examples of incidents which would require a review of the substance management plan might include a pharmacist dispensing expired medicines, or a residential aged care facility discovering losses of an S8 medicine over time. The occurrence of these incidents would indicate to the entity that the risk management measures in place to mitigate or prevent these risks are inadequate. As a consequence, the substance management plan would require a review around the activity of 'possessing' a regulated substance, but should be extended to ensuring there are no other gaps in harm mitigation measures, particularly where an incident is more serious.

The substance management plans are an important component in the management of all known and foreseeable risks associated with dealing with regulated substances at a regulated place when undertaking a regulated activity. The entity is best placed to review their plan as they have the knowledge and expertise based on their operating procedures and industry practices.

Does the legislation allow the delegation of administrative power only in appropriate cases and to appropriate persons?

Section 4(3)(c) of the Legislative Standards Act states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation allows for the delegation of administrative power only in appropriate cases and to appropriate persons.

Schedule 5, clause 2 (Buying and possessing stock for Queensland Ambulance Service) provides that the commissioner of the Queensland Ambulance Service, or the commissioner's delegate, may buy and possess stock of a medicine for a place or equipment used by the Queensland Ambulance Service. Delegation of these responsibilities from the Commissioner to a delegate of the Commissioner is critically required to enable the continuation of services by the Queensland Ambulance Service. It would be impossible for the Queensland Ambulance

Service to function without this delegation and the Commissioner is the appropriate person to determine such delegation. The Queensland Ambulance Service has a strict hierarchy and policies and procedures in place to ensure only appropriate persons are able to undertake certain activities.

Schedule 5, clauses 14 (Giving a treatment dose) and 15 (Administering) provides that a person in charge of the medicine chest, or the person's delegate, may administer, or give a treatment dose of a medicine from the chest to a patient on a prescription for the patient from any medical practitioner. Allowing for delegation means the Royal Flying Doctor Service is not hindered in its purpose of delivering emergency medical assistance and medical care to rural and remote Queenslanders.

Schedule 7, clause 21 (Giving a treatment dose at rural or isolated hospitals) provides that a registered nurse employed at a rural hospital or at a hospital in an isolated practice area may give a treatment dose of a medicine to a patient on a prescription for the patient from an authorised prescriber if the patient is being discharged from, or is an outpatient of, the hospital, the hospital does not employ a pharmacist or the pharmacist is absent from the hospital and the registered nurse is the hospital's director of nursing or a delegate of the hospital's director of nursing. This delegation is justified as the hospital's director of nursing may not always be available, or the most suitable available person, due to a variation in work schedules (shift times), increased number of patients, or triage situations. This allows for continuity of care and medicine administration so that patients' welfare is not put at risk.

Schedule 13, clause 6 (Buying and possessing) provides that the principal of a school or the principal's delegate, may buy and possess stock of adrenaline (epinephrine) autoinjectors or an inhaled asthma reliever, other than S4 medicines, when ensuring the health and wellbeing of a child at the school. The principal may need to delegate the buying of these emergency medicines to allow for situations where the principal is absent and medicines need to be replaced urgently after they have been used, or if the medicine stored is out of date.

Institution of Parliament

Does the subordinate legislation contain only matters appropriate to subordinate legislation?

Section 4(5)(c) of the Legislative Standards Act states that whether legislation has sufficient regard to the institution of Parliament depends on whether the subordinate legislation contains only matters appropriate to subordinate legislation.

Section 140 (Fees payable) provides that the fees payable are stated in schedule 19. These fees include the application for the granting or renewal of a manufacturing, wholesaling or retail licence. Prescribing fees by a regulation is appropriate, as it enables fee changes to be easily made, as they are subject to annual indexation, and are considered to be purely administrative in nature.

All licences granted under the Act will attract a fee. For existing licence holders, the amount paid will not change and there will be no changes to the classification or fee structure for pest management licences. The aim of the revised fee structure is to streamline and simplify the existing licence process, while ensuring no new fees or charges.

Advantages of the revised fee structure compared to the fees charged under the Health (Drugs and Poisons) Regulation include:

- one licence can cover multiple sites, which streamlines the application process;
- Queensland will now recognise Commonwealth manufacturing licences;
- Queensland manufacturing licence still includes a deemed wholesale licence;
- no increase in fees for licence holders; and
- no new fees for approval and permit holders.

Does the subordinate legislation allow for the subdelegation to appropriate persons or in appropriate cases?

Section 4(5)(e) of the Legislative Standards Act states that whether legislation has sufficient regard to the institution of Parliament depends on whether the subordinate legislation allows the subdelegation of a power delegated by an Act, only in appropriate case and to appropriate persons, and if authorised by an Act.

Under the Medicines Regulation, the chief executive has a range of administrative powers, including:

- Clause 41 (Making standing orders at other places) provides that a prescriber may make a standing order for a place other than a relevant institution (defined to be a hospital, aged care facility, prison or detention centre) if the chief executive has approved the use of standing orders at the place. A standing order for a place means a document applying to a place that authorises a medicine stated in the document to be administered or given as a treatment dose to or for a person or animal at the place if the circumstances and conditions stated in the document apply to the person or animal. Places (that are not institutions), that can demonstrate sufficient clinical governance to assure Queensland Health that the use of standing orders presents no, or minimal, increased risk to public health and safety, will be approved to use standing orders when necessary. Places that are approved by the chief executive to use standing orders will be published on the substance authority website.
- Clause 130 (Compliance with Poisons Standard, part 2) provides that the chief executive may approve another way of satisfying a part 2 requirement if the chief executive is satisfied the alternative requirement is as safe as the part 2 requirement and the alternative is published on the Queensland Health website and state the date it takes effect. For example, the chief executive may approve plain packaging and labelling for the purposes of research involving placebo medicines in randomised control trials. In this case, the chief executive may communicate the decision by means of an approved application. The chief executive may approve the alternative requirement only if they are reasonably satisfied it is as safe as any similar requirements for the medicine under the Medicines Regulation and may be subject to conditions.
- Clause 139 (Chief executive may set up electronic system for information) provides that the chief executive may establish or approve an electronic system to receive and record information for the notification requirement. The chief executive must take reasonable steps to ensure that any person the chief executive intends should use the electronic system is made aware of the establishment or approval of the system. With the constant development and high rate of change for innovative technology, it is reasonable that the chief executive considers new electronic systems. The chief executive would take into consideration whether a new system would improve business processes and be fit for purpose. Consultation with the key users of a new system and their feedback would also be taken into consideration to ensure that the system is able to be used in the correct way by the persons who are required to give notification. An implementation plan and communications plan for each respective type of user would be required as part of the chief executive's consideration.

- Clause 141 (Refunds) provides that the chief executive may refund an application for a substance authority or renewal of a substance authority fee, or a proportion of the fee, if they are satisfied it is appropriate and reasonable to do so in the circumstances. The chief executive is required to exercise flexibility in decision making around fees to account for administrative issues. When considering the proportion to retain, the chief executive may consider the cost of considering the application or renewal. For example, withdrawal of an application by an applicant or inadvertent errors in the application submitted by the applicant.
- Schedule 3, clause 1 (Definitions for schedule) provides that the chief executive must approve a document in the approved form, known as the practice plan, for an Aboriginal and Torres Strait Islander health practitioner. The practice plan is developed and signed by the health practitioner and the primary clinical supervisor for the practitioner and states the circumstances and conditions for the practitioner to administer or give a treatment dose of a medicine. Together, the practitioner and their clinical supervisor develop the practice plan to individualise the scope of practice specific to the practitioner's employed position. The approved from for the practice plan is published on the Queensland Health website at http://www.health.qld.gov.au/. It is considered that the rigour surrounding the development of the practice plan, its use in ensuring Queenslanders receive health care based on best clinical practice and the detailed nature of the document, justifies the need to sub-delegate by referring to an external document.
- Schedule 6, clause 19 (Definition for part) provides that the chief executive must approve a document in the approved form, known as the practice plan for a physician assistant. The practice plan is developed and signed by the physician assistant and the medical practitioner supervising the assistant and states the circumstances and conditions for the physician assistant to prescribe, administer or give a treatment dose of a medicine. Together, the physician assistant and their medical supervisor develop the practice plan to individualise the scope of practice specific to the physician assistants employed position. The approved from for the practice plan is published on the Queensland Health website at http://www.health.qld.gov.au/. It is considered that the rigour surrounding the development of the practice plan, its use in ensuring Queenslanders receive health care based on best clinical practice and the detailed nature of the document, justifies the need to sub-delegate by referring to external documents.
- Schedule 12, clause 8 (Administering) provides a speech pathologist may administer an S2 or S3 medicine, or an S4 medicine that is a topical antibiotic or a topical corticosteroid to a patient on a clinical protocol applying to the speech pathologist, or on a written prescription for the patient, if the speech pathologist has completed a safe medicine administration course. A safe medicine administration course means a training course approved by the chief executive about the safe administration of medicines.
  It is appropriate for the chief executive to approve training courses as this requires expertise in workplace training and assessment, including knowledge of required competencies and clinical application.

Departmental approved standards, extended practice authorities and protocols

Clause 232 (Making extended practice authorities) of the Act empowers the chief executive to make an extended practice authority, authorising an approved person to deal with a regulated substance. The extended practice authority may state the places or circumstances in which the approved person may deal with the regulated substance, impose conditions on dealing with the regulated substance or require the approved person to hold particular qualifications or training to deal with the registered substances. Subsection (3) provide that a regulation may prescribe

criteria about the matters the chief executive must consider before making an extended practice authority.

The following provisions reference extended practice authorities:

- Schedule 3, clauses 6 (Giving a treatment dose under extended practice authority) and 8 (Administering under extended practice authority) provide that an Aboriginal and Torres Strait Islander health practitioner may administer, or give a treatment dose of, a medicine to a patient stated in the *Aboriginal and Torres Strait Islander Health Practitioners Extended Practice Authority*.
- Schedule 3, clauses 12 (Giving a treatment dose under extended practice authority) and 14 (Administering under extended practice authority) provide that an Indigenous health worker may administer, or give a treatment dose of, a medicine to a patient stated in the *Indigenous Health Workers Extended Practice Authority*.
- Schedule 5, clause 3 (Administering under extended practice authority) provides that an ambulance officer may administer a medicine to a patient under the conditions of the *Queensland Ambulance Service Extended Practice Authority*. The ambulance officer must also comply with chapter 2, part 2, division 7 when administering the medicine.
- Schedule 5, clauses 9 (Giving a treatment dose under extended practice authority) and 11 (Administering under extended practice authority) provide that an isolated practice area paramedic may administer or give a treatment dose of a medicine to a patient on a prescription for the patient for an authorised prescriber or if the medicine is stated in the *Isolated Practice Area Paramedics Extended Practice Authority*.
- Schedule 7, clauses 10 (Giving a treatment dose under extended practice authority) and 12 (Administering under extended practice authority) provide that a midwife may administer, or give a treatment dose of, an S4 or S8 medicine, to a patient under the conditions of the *Midwives Extended Practice Authority*. The midwife must also comply with chapter 2, part 2, divisions 6 and 7 when giving the treatment dose or administering the medicine.
- Schedule 7, clauses 20 (Giving a treatment dose under extended practice authority) and 24 (Administering under extended practice authority) provide that a registered nurse practising in an area or program may administer or give a treatment dose of a medicine under the conditions of the *Registered Nurses Extended Practice Authority*. The registered nurse must also comply with chapter 2, part 2, divisions 6 and 7 when giving a treatment dose or administering the medicine. The conditions specified in the registered nurses extended practice authority will include for example, a registered nurse qualified to practise in a rural area or isolated practice area may administer, or give a treatment dose of, a stated medicine under the relevant conditions of the extended practice authority, a registered nurse qualified to practise in a sexual or reproductive health program may administer a stated medicine under the relevant conditions of the extended practice authority or a registered nurse qualified to practise in an immunisation program may administer a stated vaccine under the relevant conditions of the extended practice authority.
- Schedule 8, clause 9 (Administering under extended practice authority) provides that an orthoptist may administer an S2, S3 or S4 medicine to a patient under the conditions of the *Orthoptists Extended Practice Authority*. The orthoptist must also comply with chapter 2, part 2, division 7 when administering the medicine.
- Schedule 9, clause 12 (Administering under extended practice authority) provides that a pharmacist may administer a medicine to a patient under the conditions of the *Vaccinations by Pharmacists Extended Practice Authority*.

Extended practice authorities are not a new concept and are known as Drug Therapy Protocols under the Health (Drugs and Poisons) Regulation. Drug therapy protocols state the circumstances and conditions under which certain authorised persons are able to do certain activities defined by the regulations and scope of the protocol.

Prescribing requirements by reference to an external document may be seen to breach section 4(5)(e) of the Legislative Standards Act. An extended practice authority is a document certified by the chief executive of Queensland Health that sets out matters of technical detail for how an approved person can carry out a regulated activity with a regulated substance. The extended practice authorities will include details such as the route of administration, the specific dose, quantity, duration and restrictions placed on substances and the circumstances in which they may be administered. The extended practice authority is monitored and updated when necessary, aligns with clinical best practice and is published on the Queensland Health website (http://www.health.qld.gov.au/).

Extended practice authorities are updated regularly, with consideration given to the healthcare needs of specific patient populations, how care can be provided in a timely and safe manner and requirements for medical advice, referral or transfer to higher levels of care specific to the individual qualifications, skills and experience. Schedule 1, part 1 (Extended Practice Authorities) of the Medicines Regulation details the name of the extended practice authority and the date it is made. The regulation will be updated to reflect the name and date of the extended practice authority each time a new version is made. A copy of the updated extended practice authority will be tabled as extrinsic material each time the regulation is remade, to reflect the changed document. The Act provides that an extended practice authority has effect in relation to an approved person only if a provision of a regulation states it applies to the approved person.

By including a list of extended practice authorities in the schedule it creates certainty for professionals and the public about exactly which documents on the Queensland Health website form part of the law and when they commenced. This will be particularly important for future prosecutions. When making or amending an extended practice authority, relevant individuals or organisations with expertise in, or experience of, the matters under consideration will be consulted.

It is considered that the rigour surrounding the development of the extended practice authorities, their use in ensuring Queenslanders receive health care based on best clinical practice and the detailed nature of the documents, justifies the need to sub-delegate by referring to external documents in the Medicines Regulation.

Clause 233 (Making departmental standards) of the Act empowers the chief executive to make standards about carrying out regulated activities with regulated substances and other matters relating to purposes and administrations of the Act. A standard may include procedures for carrying out regulated activities, procedures for keeping, storing and managing regulated substances, training and competency requirements for persons carrying out regulated activities with regulated substances, procedures to ensure products containing regulated activities with regulated substances are safe and suitable for their intended use of the products and requirements for tracing the movement of a regulated substance from its manufacture to final disposal, including requirements about documentation and electronic transmission. Subsection (4) provides that a departmental standard has effect in relation to a person only if a provision of a regulation states it applies to the person.

The following provisions reference standards:

- Clause 31 (Compliance with monitored medicines standard) provides that if a medicine proposed to be stated in the prescription is a monitored medicine, the prescriber must prescribe the medicine in accordance with the *Monitored Medicines Standard*. This section does not apply to a prescription for an animal.
- Clause 49 (Compliance with monitored medicines standard) provides that if a medicine proposed to be dispensed is a monitored medicine, the dispenser must dispense the medicine in accordance with the *Monitored Medicines Standard*. This section does not apply to a monitored medicine proposed to be dispensed for an animal.
- Clause 62 (Compliance with standard) provides that an approved person must give a treatment dose of a medicine in accordance with the *Safe Supply of Medicines Standard*.
- Clause 109 (Prescribed matters—Act, s 93) provides that for section 93 of the Act, the matters to be addressed for a substance management plan are mentioned in the *Substance Management Plans Standard*.
- Clause 110 (Review—Act, s 93) provides that a substance management plan for a regulated place must be reviewed as soon as practicable after a review incident happens in relation to the regulated place and at least every 5 years after the day the substance management plan starts or the plan is reviewed. A review incident means an incident identified in the *Substance Management Plans Standard* as an incident in which a substance management plan must be reviewed.
- Clause 112 (Managing system) provides that a system manager, appointed to be responsible for setting up and maintaining the electronic medication management system, must ensure the system complies with the system requirements stated in clause 108 and the *Technical Requirements for an Electronic Medication Management System Standard*.
- Clause 119 (Compliance with storage standard) provides that the storage system controller must set up a system for storing stock of medicines that complies with the *Storage of Medicines Standard*.
- Schedule 3, clause 9 (Packaging and repackaging) provides that when giving a treatment dose, the Aboriginal and Torres Strait Islander health practitioner may package or repackage a medicine under the *Safe Supply of Medicines Standard*.
- Schedule 3, clause 15 (Packaging and repackaging) provides that when giving a treatment dose, the Indigenous health worker may package or repackage a medicine under the *Safe Supply of Medicines Standard*.
- Schedule 6, clause 14 (Packaging or repackaging) provides that a medical practitioner may package or repackage a medicine for supply to a patient in accordance with the *Packaging Medicines Standard*.
- Schedule 9, clause 15 (Compounding) provides that a pharmacist may compound an S2 or S3 medicine for supply to, and the treatment of, a patient provided the pharmacist complies with the *Compounding Standard*.

Prescribing requirements by reference to an external document may be seen to breach section 4(5)(e) of the Legislative Standards Act. A departmental standard is a document certified by the chief executive of Queensland Health that is relevant to the object and administration of the new legislation regime and provides guidance, allows flexibility on activities and applies to individuals and entities. The standards are monitored and updated when necessary, align with industry best practice and are published on the Queensland Health website (http://www.health.qld.gov.au/).

Standards are reviewed and updated regularly, with consideration given to changes in technology, changes to clinical treatment with medicines, for example monitored medicines,

and changes at a national level in relation to the monitored medicine database systems. Schedule 1, part 2 (Departmental Standards) of the Medicines Regulation details the name of the standard and the date it is made. The regulation will be updated to reflect the new name and date of the new version each time a new version is made. A copy of the updated standard will be tabled as extrinsic material each time the regulation is remade, to reflect the changed document.

By including a list of standards in the schedule it creates certainty for professionals and the public about exactly which documents on the Queensland Health website form part of the law and when they commenced. This will be particularly important for future prosecutions. When making or amending a standard, relevant individuals or organisations with expertise in, or experience of, the matters under consideration will be consulted.

It is considered that the rigour surrounding the development of the standards, their use in ensuring Queenslanders receive health care based on industry best practice and the detailed nature of the documents, justifies the need to sub-delegate by referring to external documents in the Medicines Regulation.

Poisons Standard

In accordance with the National Scheduling Policy Framework for Medicines and Chemicals, Queensland will continue to adopt the classification system for medicines and poisons under the current version of the Poisons Standard made under section 52D of the Therapeutic Goods Act 1989 (Cth).

Clause 130 (Compliance with Poisons Standard, part 2) provides that a person doing a thing mentioned in a part 2 requirement must comply with the requirement for doing the thing.

Clause 135 (Advertising medicines) provides that a person must not advertise, or cause someone else to advertise, a medicine, whether or not the medicine is name in the advertisement. This does not apply to an S2 or S3 medicine to which Appendix H of the Poisons Standard applies.

Schedule 9, clause 6 (Supply of S4 medicines in urgent circumstances) provides that a pharmacist may supply an S4 medicine to a patient without a prescription for the patient, if the pharmacist reasonably believes it is necessary to continue the treatment of the patient until the patient can obtain a prescription for the medicine and supply of the S4 medicine is in a container with a securely attached label, that complies with the requirements of part 2 of the Poisons Standard for a dispensing label.

These provisions may be seen to breach the principle that subordinate legislation should allow the subdelegation of a power delegated by an Act only in appropriate cases and to appropriate persons and if authorised by an Act (section 4(5)(e) of the Legislative Standards Act). Adopting the current version of the Poisons Standard will ensure key regulatory controls governing the availability and accessibility of medicines and poisons in Queensland will continue to be consistent with those in the other states and territories. In addition, the new legislation will enable regulations to be made so that short-term gaps in the scheduling of a medicine or poison at the national level to be addressed by the Queensland legislation if they arise in the future.

External Standards and Guidelines

In some cases, it is necessary to adopt or specify Standards that have been developed by relevant industry bodies (e.g. Australian Standards, Safe Work Australia and the Podiatry Board).

Schedule 8, clause 3 (Administering) provides that an optometrist may administer a topical S2, S3 or S4 medicine to a patient if the medicine is stated in appendix A of the *Guidelines for use of scheduled medicines* made by the Optometry Board and the optometrist administers the medicine under the guidelines.

Schedule 8, clauses 5 (Prescribing), 6 (Giving a treatment dose) and 7 (Administering) provide that an endorsed optometrist may prescribe, administer, or give a treatment dose of an S2, S3 or S4 medicine to a patient if the medicine is stated in appendix B or appendix C of the document called the *Guidelines for use of scheduled medicines* made by the Optometry Board and the optometrist prescribes, administers, or gives a treatment dose of, the medicine under the guidelines.

Schedule 10, clauses 6 (Prescribing), 7 (Giving a treatment dose) and 8 (Administering) provide that the endorsed podiatrist may prescribe, administer, or give a treatment dose of a medicine if the medicine is stated in Attachment A of the document called the *Registration standard: endorsement for scheduled medicines* made by the Podiatry Board and the podiatrist prescribes, administers, or gives a treatment dose of, the medicine under the standard.

The inclusion of references to the *Guidelines for use of scheduled medicines* and the *Registration standard: endorsement for scheduled medicines* may give rise to a potential breach of fundamental legislative principles. The Medicines Regulation refers to the scheduled list of medicines published by the relevant National Board. Relying on an external document that is not subject to parliamentary scrutiny may be seen to breach section 4(5)(e) of the Legislative Standards Act, which provides that the subdelegation of a power delegated by an Act should only occur in appropriate cases and to appropriate persons, and if authorised by an Act.

The Podiatry Board of Australia and the Optometry Board of Australia publish lists of classes of scheduled medicines, which are updated from time to time. To ensure the Medicines Regulation is kept up to date, the Regulation will be updated to reflect the date of the new version each time a new version is made. A copy of the updated guidelines and standard will be tabled as extrinsic material each time the regulation is remade, to reflect the changed standard or guideline.

There is a rigorous process to which National Registration Boards must adhere to in order to amend registration standards and guidelines. The process is governed by the Council of Australian Governments Health Council and any amendments must be approved by the Minister for Health from each jurisdiction. The Ministerial Council may, at any time, ask a National Board to review an approved or proposed registration standard for the health profession for which the National Board is established. The registration standards and guidelines are published online under the relevant sections on the respective Board's website.

- Optometry Board of Australia – https://www.optometryboard.gov.au
- Podiatry Board of Australia – https://www.podiatryboard.gov.au

This potential breach of the fundamental legislative principle is considered justified as it will ensure the Medicines Regulation is kept up to date.

Fundamental legislative principles not contained in Legislative Standards Act 1992

Offences

The offences and penalty amounts contained in the Medicines Regulation are generally consistent with similar offences and penalty amounts contained in the Health (Drugs and Poisons) Regulation and Health Regulation, with the exception of the new clauses and subsequent offences in relation to electronic medication management systems.

The high penalty levels are justifiable given the level of potential harm to people and/or the environment that can be caused by mistakes with, or misuse of, medicines. The remaining offence provisions and corresponding maximum penalties have been reviewed and the penalties are proportionate to the seriousness of the offences.

Clause 112(1) (Managing system) provides that it is an offence for an entity to fail to appoint a system manager to be responsible for setting up and maintaining the electronic medication management system. The offence carries a maximum penalty of 80 penalty units. This penalty is justified due to the seriousness of ensuring the security of an electronic medication management system is maintained. Setting up and managing the system correctly is crucial for information security and reduces the risks to public health and safety should the system be hacked. Electronic medication management systems allow for authorised health practitioners to prescribe electronically, should this system be set up or managed incorrectly, it could allow for an unauthorised person to fraudulently prescribe regulated substances for themselves or others.

Clause 112(2) provides that it is an offence if the system manager fails to ensure:

- the electronic medication management system complies with the requirements in clause 108 and the *Technical Requirements for an Electronic Medication Management System Standard*
- policies and procedures are prepared stating how the entity will comply with the *Technical Requirements for an Electronic Medication Management System Standard*
- the above policies and procedures are given to users of the electronic medication management system
- compliance with policies and procedures is monitored
- appropriately qualified persons are appointed to be responsible for the administration and maintenance of the system.

The offence carries a maximum penalty of 80 penalty units. This penalty is justified due to the serious consequences if the system does not comply with the listed requirements. For example, the system manager may be responsible for how the system works securely across a health practice where a number of doctors can have access to the system. The system manager will need to be aware of how the system is being used by the doctors and ensure that all doctors using the system are adequately informed of the policies. They will also need to add or remove doctors from the system as required.

Clause 113(2) (Requirements for system) provides that it is an offence if the electronic medication management system does not comply with the *National Requirements for*

Electronic Prescriptions made by the Australian Digital Health Agency. The offence carries a maximum penalty of 80 penalty units. This penalty is justified as the Australian Digital Health Agency is the peak coordinating body for the development and implementation of safe prescribing systems in the electronic environment nationally.

Clause 114(1) (Administration of system) provides that it is an offence if a system administrator gives access to the entity's electronic medication management system to a person who they do not reasonably believe requires access to perform the person's role or function for the entity. The offence carries a maximum penalty of 80 penalty units. This penalty is justified due to the seriousness of ensuring effective administration of an electronic medication management system. The effective administration is crucial for information security and reduces the risks to public health and safety should the system be hacked or compromised.

Clause 114(2) provides that it is an offence if a system administrator cannot prepare a report, at any given time, showing the name of the person and their secure system identifier, the date the person was given access, if applicable, the date the person's access was cancelled and the times and dates the person accessed or attempted to access the electronic medication management system. The offence carries a maximum penalty of 40 penalty units.

Clause 114(3) provides it is an offence if the system administrator fails to keep the information mentioned in clause 109(2) in a way that cannot be amended or deleted. The offence carries a maximum penalty of 40 penalty units.

Clause 115 (Using system) provides it is an offence for an authorised user permitted to use an electronic medication management system to fail to take reasonable steps to ensure the authorised users secure system identifier is not lost or stolen or another person does not use the authorised user's secure system identifier to access the system. The offence carries a maximum penalty of 20 penalty units. Examples of reasonable steps include, using a strong password for the person's secure system identifier or locking a device that can be used to access an electronic medication management system.

Clause 116 (Maintaining system) provides it is an offence if the system manager for an entity's medication management system fails to take reasonable steps to maintain the security of the system. The offence carries a maximum penalty of 80 penalty units. This penalty is justified due to the seriousness of a breach of security of an electronic medication management system. Having the system maintained correctly in relation to security measures is crucial for information security and reduces the risks to public health and safety should the system be compromised.

Clause 117(1) (Reporting system breaches) provides it is an offence for the system manager, or system administrator, of an entity's medication management system, to fail to notify the chief executive if they become aware that the system may have been fraudulently accessed or used to obtain a monitored medicine. The offence carries a maximum penalty of 80 penalty units. Reporting any breaches of the electronic medication management system is necessary so that Queensland Health can take the necessary compliance measures, or release statements of warning if required to prevent risks to the community.

Clause 130(1) (Compliance with Poisons Standard, part 2) provides that it is an offence for a person doing a thing mentioned in a part 2 requirement if they fail to comply with the requirement for doing the thing. The offence carries a maximum penalty of 40 penalty units.

It is a defence to the offence if the person possesses the regulated substance and the schedule of the Poisons Standard, in which the substance is listed, has changed since the regulated substance was originally labelled and packaged and the medicine is labelled and packaged in compliance with the schedule of the Poisons Standard in which the substance was listed before the change happened.

Part 2 of the Poisons Standard contains nationally agreed requirements regarding labels, containers, storage, disposal, record keeping and sale, supply, possession or use of poisons. If the matters referenced in the Poisons Standard were contained in the Act or Regulations, they would frequently be out of date and not reflect changing practices, substances and activities. It is necessary to refer to the Poisons Standard in the Regulation rather than to duplicate it in the Medicines and Poisons scheme, as it is technical and detailed in nature. The maximum penalty of 40 penalty units is similar to other offences under the Health (Drugs and Poisons) Regulation.

Clause 132(1) (Restriction on supplying medicines in used containers) provides it is an offence for a person preparing a medicine for supply to package the medicine in an immediate container that has previously been used. The offence carries a maximum penalty of 20 penalty units.

Clause 133(2) (Selling in original packaging) provides it is an offence for a person selling a medicine, other than medicated animal feed, to sell the medicine if it has been opened and in different packaging from how the seller received the medicine from the manufacturer or wholesaler of the medicine. This clause does not apply to a dispenser or person who is authorised to give a treatment dose of a medicine on a prescription. The offence carries a maximum penalty of 20 penalty units.

Clause 134(1) (Offence to install medicine vending machines) provides it is an offence for an owner or occupier to install a medicine vending machine on their premises. The offence carries a maximum penalty of 30 penalty units.

Clause 135(1) (Advertising medicines) provides it is an offence for a person to advertise, or cause someone else to advertise, a medicine, whether or not the medicine is name in the advertisement. The offence carries a maximum penalty of 80 penalty units. This is similar to the offence under the Health (Drugs and Poisons) Regulation.

Clause 137(2) (Reporting failure to give written prescriptions) provides that it is an offence for an authorised person who supplies or administers a medicine to fail to give notice to the relevant manager, as soon as practicable, if the person is employed by the same entity as the authorised prescriber, or to the chief executive within 48 hours after the end period for compliance. The offence carries a maximum penalty of 20 penalty units.

Clause 137(3) provides that it is an offence if a relevant manager fails to give the chief executive notice that the authorised person, after notifying the relevant manager of their failure to comply with clause 35 when prescribing a medicine, and the authorised prescriber does not rectify the problem with 48 hours. The offence carries a maximum penalty of 20 penalty units.

Clause 139(4) (Chief executive may set up electronic system for information) provides it is an offence for a person complying with a notification requirement to fail to use the electronic system established or approved for the notification requirement, unless the chief executive has not complied with subclause 139(3). The offence carries a maximum penalty of 40 penalty units.

Consultation

A wide range of stakeholders were invited to comment on the Medicines Regulation, including:

- Accord Australasia
- AgForce Queensland
- Association of Australian Medical Research Institutes
- Australian Anaesthesia Allied Health Practitioners
- Australian and New Zealand College of Perfusionists
- Australian College of Nurse Practitioners
- Australian Dental and Oral Health Therapists' Association Inc.
- Australian Dental Association (Queensland Branch)
- Australian Environmental Pest Managers Association
- Australian Laboratory Services
- Australian Medical Association Queensland (AMAQ)
- Australian Pesticides and Veterinary Medicines Authority
- Australian Physiotherapy Association, Queensland
- Australian Podiatry Association (Qld) Inc
- Australian Retailers Association
- Australian Society of Anaesthetists
- Australian Veterinary Association - Queensland Division
- Brisbane Catholic Education
- Chemistry Australia
- Composites Australia
- Commonwealth Scientific and Industrial Research Organisation (CSIRO)
- Independent Schools Queensland
- Jewellers Association of Australia
- Leading Age Services Australia – Queensland
- Local Government Association of Queensland
- Local governments
- Lutheran Education Queensland
- Medical Software Industry Association
- National Retail Association
- Optometry Queensland/Northern Territory
- Pathology Queensland
- Primary Health Networks
- Private Hospitals Association of Queensland
- QIMR Berghofer Medical Research Institute
- QML Pathology
- Queensland Aboriginal and Islander Health Council
- Queensland Ambulance Service
- Queensland Catholic Education Commission
- Queensland Farmers' Federation
- Queensland Nurses and Midwives' Union (QNMU)
- Queensland Resources Council
- Queensland universities
- Racing Science Centre

- Ramsay Health Care
- Royal Australian College of Physicians
- Royal Australian and New Zealand College of Psychiatrists
- Royal Australian College of General Practitioners
- Royal Australian Society for the Prevention of Cruelty to Animals
- Royal Flying Doctor Service
- Safe Food Production Queensland
- Safety in Mines Testing and Research Station (Simtars)
- St John Ambulance
- Stock Feed Manufacturers' Council of Australia
- Sugar Research Institute
- Sullivan Nicolaides Pathology
- Symbio Laboratories
- Mater Group
- The Pharmaceutical Society of Australia – Queensland Branch
- The Pharmacy Guild of Australia – Queensland Branch
- The Society of Hospital Pharmacists of Australia
- Therapeutic Goods Administration
- Translational Research Institute
- UnitingCare Health
- Veterinary Surgeons Board of Queensland.

Some stakeholders provided feedback on drafting matters. This feedback was incorporated into the Medicines Regulation where appropriate.

Stakeholders were generally positive about the direction of the draft legislation and about the opportunity to provide comment. Many strongly supported the new real-time prescription monitoring provisions, the new approved persons provisions and the approach to licences and general approvals. There was also support for the new substance management plan policy.

AMAQ was generally supportive of the new legislation, in particular real-time prescription monitoring. However, AMAQ had some reservations about midwives and nurse practitioners being authorised to prescribe S8 medicines and about automatic recognition of scheduled medicines endorsements established by National Boards for optometrists and podiatrists. However, these scopes of practice will only occur in specific circumstances and have been endorsed by the appropriate National Boards. The amendments relating to suitably qualified midwives and nurse practitioners prescribing S8 medicines is only translating what is already in the Health (Drugs and Poisons) Regulation. No additional policy change has been made.

The Office of Best Practice Regulation assessed the entire medicines and poisons regulatory framework, in accordance with the Queensland Government Guide to Better Regulation and advised that no further regulatory impact analysis was required on the basis that the proposal is unlikely to lead to significant adverse impacts and should reduce overall regulatory requirements.