

# Medicines and Poisons Bill 2019

## Explanatory Notes

### Short title

The short title of the Bill is the *Medicines and Poisons Bill 2019* (Bill).

### Policy objectives and the reasons for them

Medicines and poisons are regulated in Queensland by the *Health Act 1937*, *Health (Drugs and Poisons) Regulation 1996* and *Health Regulation 1996*. The Health (Drugs and Poisons) Regulation provides a wide range of controls over the possession, supply, administration and other activities involving medicines and poisons listed in the Commonwealth *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard). The Poisons Standard is a Commonwealth instrument that classifies medicines and poisons into ‘schedules’ of substances from ‘Schedule 2’ (S2) through to ‘Schedule 10’ (S10). A substance is categorised into a schedule based on the level of regulatory control required to deal with the public health and safety risks associated with the substance. The Health Regulation imposes controls for manufacturing, advertising and labelling substances. The Health Regulation also sets out the requirements for dispensing substances at a pharmacy.

The *Pest Management Act 2001* and the *Pest Management Regulation 2003* regulate access to and use of poisons such as pesticides and fumigants. They also set licensing and competency requirements for persons who carry out pest management activities.

The Health Act is one of the oldest Acts on the statute book. The current framework is difficult to apply in practice, outdated and unnecessarily prescriptive. The framework is almost entirely contained in subordinate legislation. The Regulations, particularly the Health (Drugs and Poisons) Regulation, are complex, piecemeal and do not reflect contemporary drafting standards. For example, the Health (Drugs and Poisons) Regulation prescribes the exact measurements of bolts that are required when mounting cabinets or above-ground safes to store regulated drugs. These prescriptive requirements may not always be fit for purpose, such as when storing medicines securely in refrigeration, and may prevent more innovative and technologically advanced methods of safe storage. The medicines and poisons legislation have similar objectives and regulate some of the same scheduled substances for either therapeutic or non-therapeutic uses.

A new regulatory framework is needed to modernise and streamline the regulation of medicines and poisons, ensuring requirements are easier for industry and the community to understand and apply in practice.

The regulatory framework applies to persons carrying out regulated activities with regulated substances and will affect a broad range of stakeholders across industries as diverse as agriculture, health care, pest management and veterinary services, such as manufacturers and

wholesalers of regulated substances; licenced retailers of medicines and poisons; trained health professionals with an as-of-right authority to deal with specific medicines in certain environments, such as registered nurses in a prison and first aid providers; pest management technicians and primary producers carrying out pest management activities; and landholders with an approval to use regulated poisons. It also applies in a range of everyday settings including filling prescriptions at a pharmacy; receiving life-saving drugs in hospital; and enabling vulnerable people, such as children, those with a disability and the elderly, to receive the medicines they need. The scheme is not intended to regulate the everyday activities of laypersons or carers as long as they are dealing with regulated substances lawfully, for example, by filling a prescription lawfully prescribed by their doctor. The focus of the scheme is on regulating trained professionals and industry who require increased regulation and are sufficiently trained and experienced to know what is permitted under the scheme.

The purpose of this Bill is to repeal and replace the existing legislation with a new regulatory framework comprising the Medicines and Poisons Bill, Medicines and Poisons (Medicines) Regulation (Medicines Regulation) and Medicines and Poisons (Pest Management, Poisons and Other Regulated Substances) Regulation (Poisons Regulation).

The new regulatory framework:

- provides greater assurance to the community that the medicines, poisons and therapeutic goods they use are regulated by a modern, outcomes-focused framework that enhances public safety;
- ensures Queensland Health is better able to monitor and respond to health risks associated with inappropriate access to and use of, medicines and poisons. For example, the framework minimises the risk that medicines and poisons could be diverted for unlawful purposes by limiting who may supply medicines and poisons, introduces real-time prescription monitoring for particular medicines and enables the chief executive to make an emerging risk declaration to prevent substances that may pose a risk of injury or illness entering the marketplace until their safety has been determined;
- simplifies licensing requirements, for example, manufacturers with licences for multiple sites will be able to transition to a single licence for all sites, and employees will be able to be included in an employer's approval without the need to hold a separate approval;
- streamlines the requirements for prescribing medicinal cannabis in Queensland by enabling non-specialist medical practitioners to prescribe it without the need for approval from Queensland Health, eliminating duplication with the Commonwealth approval process;
- improves national uniformity, for example by recognising Commonwealth manufacturing licences under the *Therapeutic Goods Act 1989 (Cth)*, *Narcotic Drugs Act 1967 (Cth)* and *Agricultural and Veterinary Chemicals Code Act 1994 (Cth)*, and aligning key terminology with the Poisons Standard;
- provides certainty for medicines manufacturers by applying the Commonwealth Therapeutic Goods Act, ensuring that all therapeutic goods are manufactured to the same high standard; and
- includes no new or increased fees. The existing fee structure has been translated into the new framework and no new or additional fees will be payable, for example fees for primary producers who hold a licence or approval will not change.

## Achievement of policy objectives

The Bill repeals the Health Act, Pest Management Act and corresponding Regulations and replaces this suite of legislation with the Medicines and Poisons Bill and supporting Regulations.

The new regulatory framework has been developed following an extensive review of the existing legislation, which identified a number of emerging issues about the regulation of medicines and poisons. This review involved consultation with a wide range of industry stakeholders whose activities are regulated under the framework. The Medicines and Poisons framework will achieve a number of objectives, outlined below.

### **Modernised, streamlined framework**

#### *Minimising the number of authorities*

The Medicines and Poisons Bill will streamline authorities for a person or entity to perform a regulated activity with a regulated substance. Regulated substances include scheduled substances included in the Poisons Standard and pesticides and fumigants registered or permitted for use by the Australian Pesticides and Veterinary Medicines Authority.

An individual or entity may perform regulated activities with regulated substances if they hold an authority under the Bill, including a wholesale licence, retail licence, pest management licence, general approval or manufacturing licence (collectively known as substance authorities) or a manufacturing licence under Commonwealth legislation, for example, the Agricultural and Veterinary Chemicals Code Act, Narcotic Drugs Act or Therapeutic Goods Act.

Individuals or entities manufacturing or wholesaling regulated substances in Queensland, other than S5 and S6 substances, must hold a manufacturing or wholesaling licence under the Bill. A manufacturing licence also authorises the wholesale of goods manufactured under the licence. Individuals or entities who hold a manufacturing licence under Commonwealth legislation will not require an additional manufacturing or wholesaling licence in Queensland under the Bill.

Currently, manufacturers who manufacture across multiple sites are required to hold multiple licences. Under the Medicines and Poisons Bill, manufacturers who currently hold licences for multiple manufacturing or operational sites will be able to transition to one licence for all sites. This will streamline the licensing process, although a fee per site will still apply.

Individuals or entities who supply a regulated substance by wholesale will also be able to streamline their administrative processes. Currently, individuals or entities who supply medicines and poisons by wholesale from multiple sites hold multiple licences. Additionally, an individual representing a medicines wholesaler requires a wholesale representative licence. Under the Medicines and Poisons Bill, individuals or entities who supply by wholesale only require a single licence. Individuals working as a representative of a medicines wholesaler will be bound by their employer's manufacturing and/or wholesaling licence, rather than requiring their own individual licence as is the case under the Health Act. As a result, wholesale representatives will no longer be required to pay a fee for an individual licence. This may

provide a financial saving for medicines wholesalers and individuals who currently pay for licences for multiple representatives and sites.

Interstate wholesalers of medicines and interstate and international wholesale suppliers of poisons into Queensland will not require a wholesale licence under the Medicines and Poisons Bill. However, it is a requirement that interstate and international wholesalers who wish to supply regulated substances into Queensland must have an equivalent authority under their jurisdiction. Interstate and international wholesalers are also required to supply directly to their intended recipient and are not able to store regulated substances in Queensland without obtaining a wholesale licence or supplying their product to another entity that has a wholesale licence under Queensland legislation.

#### *'As-of-right' authorities*

The Health (Drugs and Poisons) Regulation and Pest Management Regulation grant authorities to classes of persons to perform specified activities with medicines and poisons, for example to possess, supply or administer a medicine or to persons using certain high-risk poisons for research or analysis. These authorities, generally known as 'as-of-right' authorities, are granted to members of groups identified by reference to registration status (such as a medical practitioner or pharmacist), position (such as a person in charge of a nursing home or engineering workshop, or a State analyst) or qualification (for example, a qualified ambulance officer, horticulturalist or metallurgist).

This broad model will be retained in the Medicines and Poisons framework, but will be significantly streamlined to assist authority holders and the general public to more easily understand the scope of each authority.

Under the Regulations, an 'approved person' will be authorised to carry out a regulated activity with a regulated substance because of their occupation, profession or the position they hold. Approved persons, for example, pharmacists and nurses using medicines in their work or primary producers using certain pesticides or fumigants on their own property, will not be required to apply for a licence or general approval under the Bill to carry out specific regulated activities. For each class of approved person, the Regulations will detail the permitted regulated activities and scope of practice for the relevant person, the medicines and poisons within that scope and any limits to the permitted regulated activities. For example, only a specialist medical practitioner may be authorised to prescribe a specific restricted medicine. The medicines and poisons scheme enables other prescribers to apply for a separate prescribing approval.

These authorities will be organised and presented according to the class of the authority holder, rather than being scattered throughout the substantive provisions as is the case under the Health (Drugs and Poisons) Regulation and Pest Management Regulation. Existing authorities will be translated into the relevant Regulation, with some minor changes to reflect established shifts in scope of practice.

#### *Prescribing approvals*

The Health (Drugs and Poisons) Regulation requires prescribers seeking to prescribe a controlled drug (referred to under the Bill as S8 medicines) and particular S4 medicines to a drug dependent person, to obtain an approval. With the introduction of real-time prescription

monitoring (details provided below under ‘Protecting the public from harm’), a prescribing approval will only be required for prescribers seeking to prescribe opioid replacement medicines. However, until the real-time prescription monitoring database is fully functioning, all prescribers will be required to apply to Queensland Health for approval to prescribe certain medicines to patients that they consider to be drug-dependent. These approvals to treat drug dependent patients will also be a type of prescribing approval.

Also, there are certain medicines that require prescribers to have specialist training or knowledge before they are able to use or prescribe the medicines. For these medicines (termed *restricted medicines*), the Medicines Regulation will specify a field of specialty practice or other qualifications that will make the prescriber an authorised prescriber for these medicines. For example, drugs for fertility treatment may be prescribed by specialists in obstetrics and gynaecology.

Prescribers who do not meet the defined criteria may apply to Queensland Health for a prescribing approval to treat patients with these medicines.

### *General approvals*

The Health (Drugs and Poisons) Regulation empowers the chief executive to grant case-by-case approvals to persons, authorising them to carry out specific activities, for example, authorising individual volunteers at the RSPCA to use an S4 veterinary medicine for the humane treatment of injured animals or authorising a researcher at a university to possess a controlled drug (S8) or dangerous poison (S7).

Some of these long-standing approvals will be converted into as-of-right authorities under the Medicines Regulation. In other cases, the new regulatory framework will continue to empower the chief executive to grant a case-by-case ‘general approval’.

Under the Bill, a general approval will authorise the approval holder to undertake a regulated activity with the regulated substance stated in the approval, under the conditions stated in the approval or as standard conditions stated in a Regulation.

For example, a general approval may authorise a person or an entity to:

- possess and/or administer a regulated substance to an animal for humane treatment;
- possess, supply and administer a regulated substance as part of a specialised health program such as a commercial immunisation program or palliative care;
- possess and/or supply a regulated substance for the purpose of healthcare in an isolated or remote area (e.g. first aid at a mine or an island resort);
- possess, supply and apply a poison (other than an S5 or S6) for teaching or research purposes;
- possess and apply a restricted S7 poison to kill invasive animals at a landholder’s property;
- or
- manufacture prohibited substances at a university for research purposes.

To streamline the approval process and give more flexibility and oversight of employees’ activities under the proposed scheme, entities such as universities, research facilities and local governments will be able to apply for a general approval to cover all individuals. Once the entity obtains a general approval, individuals will no longer be required to hold their own

approval. The entity will be responsible for ensuring the development of, and adherence to, adequate governance measures, policies and procedures, and training to manage the public health and safety risk associated with the regulated substance.

### *Monitoring and enforcement*

The Medicines and Poisons Bill introduces simplified and consistent offence provisions to replace more than 50 separate offences in the existing legislation relating to the manufacture, supply, possession and use of medicines and poisons.

The scheme is structured around persons dealing with regulated substances in the ‘authorised way’. Accordingly, a number of the offence provisions relate to a person not doing something in the authorised way.

The overarching offences include an offence to carry out, or direct another person to carry out, a regulated activity with a regulated substance if the person is not authorised, and offences to manufacture, possess or supply a regulated substance in an unauthorised way.

The offences in the scheme are distinct from existing offences under the Criminal Code and *Drugs Misuse Act 1986*. Noting the concept underpinning the scheme of the ‘authorised way’, specific offences are included in the Medicines and Poisons framework to ensure stakeholders are easily able to understand their obligations.

Under the framework, no offence will be committed if a person carries out the regulated activity in the ‘authorised way’, meaning they hold the necessary authority to carry out that activity. The Bill also provides limited exemptions from some offences, including where a person assists another person, such as a child, by supplying or administering a medicine that has been lawfully supplied for the therapeutic treatment of another person.

A person also does not commit an offence if authorised to carry out regulated activities under an emergency order. This may include circumstances where urgent action is needed to distribute medicines in response to the outbreak of an infectious disease, or to respond to a natural disaster which would otherwise jeopardise the safe storage of dangerous poisons.

Given the age of the existing legislation, the maximum penalties have been reviewed to better align with penalties under the Therapeutic Goods Act, Agricultural and Veterinary Chemicals Code Act and other comparable legislation in Queensland and interstate.

If an offence aligns directly to the Health (Drugs and Poisons) Regulation, the penalties remain the same under the Medicines and Poisons framework. However due to the restructuring of the scheme, where multiple offences were captured by a single new offence, it was necessary to set penalties consistent with key legislation in Queensland and other jurisdictions. Key offences such as clause 33 (Offence to manufacture medicines or hazardous poisons) have a maximum penalty set higher at 750 penalty units to reflect the potential seriousness of the offence and the number of offences this provision replaces in the existing legislation.

A number of lower level offences in the framework are considered appropriate for inclusion as infringement notice offences under the *State Penalties Enforcement Regulation 2014* (SPE Regulation). The inclusion of infringement notice offences will be considered further prior to

commencement of the scheme, in consultation with the Department of Justice and Attorney-General as custodians of the SPE Regulation.

### *Medicinal cannabis*

The provisions of the *Health and Other Legislation Amendment Act 2019* that did not commence on assent will be commenced by proclamation on 1 July 2019 and will repeal the *Public Health (Medicinal Cannabis) Act 2016* and amend the Health Act to significantly streamline the regulatory framework for prescribing medicinal cannabis in Queensland by allowing it to be regulated and treated the same as other S4 or S8 medicines.

Once the Health Act is repealed by the Medicines and Poisons Bill, the use of medicinal cannabis in Queensland will be authorised by the medicines and poisons framework in the Bill, provided the activity is authorised by the Therapeutic Goods Administration under the Commonwealth Therapeutic Goods Act.

The Medicines and Poisons Bill will further streamline the regulatory framework for prescribing medicinal cannabis in Queensland by enabling non-specialist medical practitioners to prescribe it without the need for approval from Queensland Health. This will eliminate duplication of the Commonwealth approval process and remove the potential for Queensland Health and the Therapeutic Goods Administration to reach different conclusions about applications for access to eligible patients.

## **Protecting the public from harm**

### *Real-time prescription monitoring*

The *National Drug Strategy 2017-2026*, released by the Commonwealth Department of Health in 2017, noted that implementation of real-time monitoring of prescription medicines such as pharmaceutical opioids could assist in reducing supply of illicit and illicitly used drugs. There was national agreement at the April 2018 Council of Australian Governments (COAG) Health Council meeting to support the implementation of a national real-time reporting solution.

The Office of the Health Ombudsman's 2016 report, *Undoing the knots constraining medicine regulation in Queensland*, was also strongly supportive of real-time prescription monitoring. The report noted that such a tool would have significant benefits for the effective and efficient monitoring of prescribing and dispensing of S8 medicines in Queensland and help to manage risks to the health and safety of the public.

The Health (Drugs and Poisons) Regulation contains existing requirements for prescribers to notify Queensland Health if treatment of a patient with a S8 medicine will exceed two months, and to obtain an approval from Queensland Health before treating a drug-dependent person with S8 medicines and certain S4 medicines. This approval process often takes place during a patient's consultation, which is time consuming for practitioners and patients. Queensland Health also incurs a significant regulatory cost to manage requests and manually record data.

The Health (Drugs and Poisons) Regulation also requires dispensers to report the dispensing of S8 medicines to Queensland Health. This reporting is done by pharmacists every seven days, but with the time taken to manually record and compile the information by Queensland Health, the information is generally up to 14 days out of date.

The Bill establishes a head of power for Queensland Health to implement a real-time prescription monitoring system, in accordance with the COAG agreement, to manage the use of dependence-forming medicines. The development and implementation of a real-time prescription monitoring system will aid clinical decision-making by allowing prescribers and dispensers access to real-time prescription and dispensing information before they prescribe or dispense certain substances.

The substances which will be monitored by the system ('monitored medicines') will be defined in the Medicines Regulation to include controlled drugs such as pharmaceutical opioids and other prescription-only medicines associated with abuse and drug-seeking such as sedatives, sleeping tablets and products that combine codeine with other medicines.

The system will allow Queensland Health, as the regulator, the ability to better monitor compliance with legislation and work with prescribers to better manage their patients' use of certain medicines.

Before prescribing or supplying a monitored medicine, prescribers will be required to check the monitored medicines database to see if the person has previously been prescribed or supplied a monitored medicine. Before dispensing or giving a treatment dose of a monitored medicine, dispensers will be required to check the database to see if the person has previously been prescribed or supplied a monitored medicine. Failure to check the database before taking one of these proposed actions will be subject to a maximum penalty of 20 penalty units.

The offence is not applicable if the prescriber or dispenser has a reasonable excuse or the proposed action happens in a situation prescribed by regulation to be exempt. The regulation may prescribe circumstances such as treatment of an injury in an emergency and circumstances where the patient is unlikely to be doctor shopping, such as pain relief for end-of-life care for terminal cancer.

The introduction of a real-time prescription monitoring system will provide life-saving benefits to patients, assistance for doctors when prescribing dependence-forming medicines, minimise over-prescription and reduce doctor shopping.

The Queensland database will leverage off the national solution being developed by the Commonwealth, the National Data Exchange (NDE). The NDE will capture the prescription dispensing event data from all states and territories. Under this arrangement, Queensland will have access to its own data, and the data of other States only upon agreement with the respective jurisdiction.

In addition to real-time monitoring of prescription medicines, recommendation 3.8 of the Queensland Organised Crime Commission of Inquiry Report (30 October 2015) provided that the Queensland Government should legislate to make Project STOP, a database for real-time reporting of over the counter sales of pseudoephedrine, mandatory for all pharmacies and pharmacists dispensing pseudoephedrine in Queensland, noting that this may be achieved by inserting a provision in the Health (Drugs and Poisons) Regulation. This recommendation will be reflected in the Medicines Regulation by requiring pharmacists to record sales of pseudoephedrine in a database that provides real-time information to other pharmacists in the state.

*Inclusion of pest management in the framework*

Based on evidence of harm to public health, the Medicines and Poisons framework applies to pest management businesses undertaking pest management activities in primary production. This will ensure safety of primary produce.

However, primary producers will continue to be able to use pesticides or fumigants in compliance with label instructions approved by the Australian Pesticides and Veterinary Medicines Authority.

*Emerging risk declarations and recall orders*

The Medicines and Poisons Bill will enable the chief executive to make:

- an emergency order;
- an emerging risk declaration;
- a recall order;
- a public warning.

An emergency order may be made to take immediate action to manage the risk of significant harm or illness, or emergency situations where powers are needed to effectively manage that risk. The order authorises regulated activities to be carried out with regulated substances in relation to an emergency as defined under the *Public Safety Preservation Act 1986*, a disaster situation under the *Disaster Management Act 2003*, a declared public health emergency under the *Public Health Act 2005*, a biosecurity event for which a biosecurity emergency order under the *Biosecurity Act 2014* applies or another public health event, such as an outbreak of a communicable disease or a severe weather event such as a cyclone.

An emerging risk declaration may be made if there is a belief that an unscheduled substance or device used to apply or administer a substance poses a risk of injury or illness. For example, this may apply to a sports supplement containing substances that have new evidence of harm to human health. The emerging risk declaration will state any conditions that apply to performing an activity for the substance or device, including:

- a substance must not be manufactured, sold or used in the State;
- a substance may only be used in a particular device or in a particular way;
- a device must not be used for administering or applying a substance;
- a substance must be disposed of in a particular way.

The inclusion of the emerging risk declaration powers will enable the chief executive to prevent substances that may pose a risk of injury or illness entering the marketplace until their safety can be determined or an alternative means of regulating the unsafe substance is implemented.

A recall order may be made if there is a risk of harm to persons or animals because of labelling, packaging, efficacy or other safety issues. For example, this may apply to hair dyes causing severe skin and scalp irritation due to incorrect formulation with a scheduled substance or metal cleaning products with high levels of the dangerous poison hydrofluoric acid contrary to labelled ingredients. Before making the recall order, the chief executive must advise the person responsible for the substance that they intend to make an order. Recall orders may be applied to substances or devices that are subject to an emerging risk declaration. To minimise overlap

of powers, a recall order is not made if the substance is regulated under the powers of another Act or Commonwealth law, for example the Therapeutic Goods Act, and those powers have been exercised, for example, by the Therapeutic Goods Administration.

A public warning may be issued in the public interest to warn or inform the public about any person or persons who have:

- contravened the Medicines and Poisons Act and against whom action is being taken; or
- committed any unlawful practices or offences against other relevant legislation.

If the chief executive makes an emerging risk declaration or a recall order, manufacturers, wholesalers and retailers will be required to comply with the requirements of the order. This may include stopping the manufacture or supply, recalling the substances from the end users, destroying the substances, relabelling or repackaging the product, and other measures to protect the public from harm. There may also be a requirement to publish warnings about the product.

### *Registers*

The Bill provides that Queensland Health must maintain registers relating to substance authorities, as well as administrative action taken in relation to substance authorities and authorisations. The registers may be published on Queensland Health's website. However, some confidential information such as personal information or information that may damage the commercial activities of a person must not be published unless the chief executive is satisfied publication is reasonably necessary to avoid a health risk and will not place a person at risk of harm.

The registers will enable people engaging with a licence or approval holder or an approved person to determine if the person holds the appropriate authority for the activity they are carrying out. The registers will allow, for example, a consumer to check that a pest management technician holds a current licence or a supplier of medicines to determine that a purchaser or a prescriber has the authority to purchase medicines or to prescribe a specific medicine.

### *Substance Management Plans*

Many of the prescriptive requirements contained in the Health (Drugs and Poisons) Regulation will be repealed and replaced with a new requirement in the Bill for certain substance authority holders to develop a substance management plan.

A substance management plan is a co-regulatory tool to assist substance authority holders to consider and manage known and foreseeable risks specific to regulated activities with regulated substances. The requirement for a substance management plan supports a risk-management system for regulated substances that is dynamic and proportionate to the risk. The scheme will be outcomes-focused and set minimum risk management, accountability and governance criteria that must be met by certain entities in their dealings with regulated substances.

Under the Regulations, an individual or entity that holds a manufacturing licence, wholesaling licence, prohibited substance general approval (if required as a condition of the approval) and other entities such as residential aged care facilities (RACF), community pharmacies, schools and hospitals, will be required to have a substance management plan before commencing any regulated activity with a regulated substance. These types of entities generally already have documented policies and procedures in place around regulated substances, for example existing

occupational health and safety management plans for some entities, as well as accreditation documentation that will contribute to the making of a substance management plan. The plan needs to be reviewed at least every five years, and at least every two years if the entity compounds medicines on the premises or prior to that time if an incident, such as theft or loss, involving a regulated substance has occurred.

The substance management plan must include measures for the:

- packaging, labelling, handling, storage, security, custody and transportation requirements of regulated substances;
- competency, training and supervision requirements of staff; and
- maintenance and reconciliation processes for purchasing regulated substances and the disposal mechanisms of the substances.

An entity will be required to have a ‘responsible person’ for making, implementing and reviewing the plan. The Medicines Regulation and Poisons Regulation will prescribe who the responsible person must be. For example, a community pharmacy’s responsible person is each pharmacist who owns the community pharmacy or for a place where medicine is manufactured under a manufacturing licence, the responsible person is the holder of the manufacturing licence.

Detailed requirements for substance management plans will be outlined by regulation and included in the relevant departmental standard relating to substance management plans. Entities will have one year after the Bill comes into force to comply with the substance management plan requirements. This will also give existing entities, who will be prescribed in the Medicines Regulation and Poisons Regulation as being a regulated place that is required to have a substance management plan, sufficient time to make their plan, so that their activities will not be interrupted. Queensland Health proposes to roll out a comprehensive communications strategy during implementation, including templates and sample substance management plans for different categories of entities, and ongoing information will be available to stakeholders. Stakeholders will also be advised that existing policies, procedures and accreditation documentation may form part, or all of their plan, thereby minimising any resource impacts.

#### *Persons subject to workplace health and safety laws*

The Bill enables a person to possess or apply an S7 poison, other than an S7 poison excluded by regulation, in the authorised way and in compliance with workplace health and safety laws. For example, a welder using hydrofluoric acid pickling paste or a land holder using the herbicide paraquat for killing weeds will be authorised to possess or apply the poison without an authority.

However, this does not apply to the industries prescribed in the Poisons Regulation. For example, a child care service can not possess or apply S7 poisons without an authority. This enables appropriate protection of public health while enabling unhindered use of scheduled high-risk poisons for industrial purposes.

#### *Acceptable Concentration for Tattoo and Permanent Makeup Ink Standard*

The Poisons Regulation will prescribe the *Acceptable Concentration for Tattoo and Permanent Makeup Ink Standard*, which is based on recommendations from the National Industrial Chemicals Notification and Assessment Scheme.

Prescribing this standard will minimise and prevent harm arising from products containing poisons at unsafe levels such as carcinogens in tattoo inks, through the implementation of minimum standards for product quality.

#### *Information sharing for public health and safety*

The Bill allows for the disclosure of confidential information in limited circumstances to an entity performing relevant functions or where it is necessary for the care of a patient. In part, this implements key recommendations from the Office of the Health Ombudsman report, *Undoing the knots constraining medicine regulation in Queensland*. When taken together with the public register provisions, these information-sharing provisions provide for a direct and responsive approach to managing health risks.

### **National Uniformity**

#### *National reforms*

The Bill supports a COAG commitment to adopt a nationally-consistent approach to the management of medicines, poisons and therapeutic goods. The Bill has been informed by a number of other national reforms, which enable it to more readily meet the challenges of new technology and emerging risks.

These include:

- the national consultation process conducted by the former National Coordinating Committee on Therapeutic Goods in relation to national consistency in poisons control, and the associated strategies to implement a national approach to poisons chemical controls detailed in the Decision Regulation Impact Statement;
- the *National Competition Review of Drugs, Poisons and Controlled Substances Legislation* (the Galbally Review), commissioned by COAG, which examined Australian state and territory legislation regulating medicines and poisons against national competition principles. The review recommended increasing national uniformity, improving efficiency and reducing the level of control where possible to improve the net benefit to the community. The Bill implements a recommendation to discontinue licences for wholesale representatives to authorise supply of medicines samples to doctors;
- the *Chemicals and Plastics Regulation Productivity Commission Research Report* (2008), which was commissioned to address the responsiveness of agencies at all levels of government in relation to setting opportunities for improved interaction between regulators across jurisdiction and streamlined Commonwealth assessment functions. It recommended that state and territory Governments:
  - adopt poisons scheduling decisions made by the Commonwealth Department of Health directly by reference, as published in the Poisons Standard; and
  - uniformly adopt regulatory controls for poisons through either a template or model approach, as published in the Poisons Standard.

#### *Adoption of Poisons Standard*

The Medicines and Poisons Bill continues to implement the Poisons Standard, improving national uniformity by adopting the schedules, parts and appendices by reference. The Medicines and Poisons scheme will reflect the current version of the Poisons Standard,

ensuring key regulatory controls governing the availability and accessibility of medicines and poisons in Queensland will continue to be consistent with those in other states and territories.

In addition, the Medicines and Poisons Bill includes a head of power to make regulations so that short-term gaps in the scheduling of a medicine or poison at the national level can be addressed by Queensland legislation if they arise in the future. This allows the legislation to quickly adapt to recognise substances that have become available in some way in the marketplace, but are yet to be scheduled. It allows for the Medicines and Poisons legislation to be responsive and to place interim restrictions on access and use, before the Commonwealth recognises the substance and its scheduling in the Poisons Standard. This is a flexible approach that will enhance public safety.

### *Terminology*

The terminology used in the Medicines and Poisons Bill and Regulations has been aligned with the Poisons Standard. The application of the Poisons Standard will align Queensland with other states and territories, and use of the same terminology will assist users of the legislation who also operate under the Commonwealth legislation.

### *National harmonisation of competency and training requirements for agricultural chemicals*

As part of the Medicines and Poisons framework, Queensland will be one of the first states to adopt the competencies proposed by the Harmonised Agvet Chemical Control of Use Task Group (HACCUT), for national consistency.

The Poisons Regulation will prescribe the *Competency requirements for approved persons undertaking regulated activities with poisons, pesticides and fumigants Standard*. These standards reflect the competencies proposed by HACCUT. Prescribing the name and date of the standard by Regulation will ensure that it may be updated on an ongoing basis to align with future national reviews of these competencies.

### *Recognising Commonwealth licences*

As noted above, under the Bill, individuals or entities who hold a manufacturing licence under Commonwealth legislation will not need a second, separate manufacturing licence. Scheduled medicines manufacturers licensed under the Commonwealth Therapeutic Goods Act or Narcotic Drugs Act and veterinary chemicals manufacturers under the Agricultural and Veterinary Chemicals Code Act will be authorised to manufacture those medicines in Queensland without the requirement of obtaining a Queensland manufacturing licence.

Medicines manufacturers licensed under the Commonwealth legislation will be authorised under the Medicines Regulation to wholesale goods manufactured under the Commonwealth legislation. This will remove the need for these manufacturers to obtain a second, separate wholesaling licence to undertake wholesaling activities in Queensland.

The recognition of manufacturing and wholesaling licences under Commonwealth legislation will provide uniformity between states and territories where these licences are already recognised. The recognition will also remove duplication and administrative burden for licence holders who are already licensed under Commonwealth legislation.

## Alternative ways of achieving policy objectives

The Bill was developed following an extensive review of the existing legislation. Alternatives to repealing and replacing the current legislation were considered, namely retaining the current legislation or significantly amending the current framework to modernise it. These options were not considered appropriate as the current legislative framework is not fit for purpose – it is outdated, difficult to apply and unnecessarily prescriptive.

The Galbally Review carried out an extensive review of the current legislative framework for medicines, poisons and therapeutic goods and identified duplication or overlap of the requirements of drugs, poisons and controlled substances legislation that increased compliance costs and reduced overall efficiency.

The current legislative framework creates barriers and extra costs for the government as the regulator and is complex and difficult for industry to understand. It increases compliance costs for industry, and by extension consumers, as it is not consistent with national and other state laws, such as the packaging and labelling requirements for chemicals, the Commonwealth Therapeutic Goods Act and the *Chemical Usage (Agricultural and Veterinary) Control Act 1988* (Cth), meaning industry has to comply with multiple regulatory schemes. There is also a lack of consistency with the regulatory schemes of other jurisdictions.

The Galbally Review concluded that there would be considerable savings to industry, government and consumers if a more consistent and uniform national approach was taken to regulating drugs, poisons and controlled substances in Australia.

Amending the current framework to modernise it would be a significant process due to its size and complexity and the age of the legislation. The amendments required would be significant and drafting would be constrained by the current structure of the legislation. The duplication between the Health Act, Health (Drugs and Poisons) Regulation and Health Regulation, and the Pest Management Act and Regulation would also not be addressed. The current duplication between the Health Regulation and the Commonwealth Therapeutic Goods Act would also continue.

The Bill represents a move away from highly prescriptive regulation to an outcomes-focused approach that aims to provide stakeholders with greater flexibility in the way in which compliance is achieved.

## Estimated cost for government 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 under 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, for example, 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.

The resources used to manage the existing regime will continue to be utilised under the new scheme, however the implementation of the Bill will incur one-off costs for the following:

- Queensland Health has committed to implementing an information and communication technology solution and required legislative changes to support the real-time prescription monitoring database for monitored medicines across Queensland by 2020. This is a complex and multifaceted program of work which includes developing and implementing a real-time reporting solution through a database that allows prescribers and dispensers direct visibility of a patient's prescription dispensing record of monitored medicines during consultation. The program of work will also include engagement and education strategies to support understanding and uptake of the database by end users such as prescribers and dispensers, policy reform and new standards in relation to safe prescribing monitored medicines. The program of work to implement the system will continue for three years and is funded from existing budget allocations.
- Upgrades to the licensing database will require significant reconfiguration of the system which will be met within existing budget allocation.
- Training and information sessions for stakeholders are required to inform them of the roll-out of the new regulatory regime and new compliance requirements. This will include training for authorised persons who will be undertaking monitoring and enforcement activities under the new legislative framework and for Queensland Health's licensing personnel responsible for administering the licensing system.
- Development of guidance material, compliance framework toolkits and other associated administrative material.

Development of these training and educational resources is an important process for supporting users to transition to the new legislation.

## **Consistency with fundamental legislative principles**

### **Overview**

The Bill has been drafted with regard to the fundamental legislative principles (FLPs) in section 4 of the *Legislative Standards Act 1992*.

However, a number of clauses in the Bill may potentially impact on particular FLPs. For example:

- The Bill establishes a new scheme to regulate medicines and poisons in Queensland which requires the inclusion of standard provisions that raise FLP issues such as: new offences; administrative powers of the chief executive to administer the scheme; powers of inspectors to enter and search premises and seize things; and information-sharing provisions to support compliance with the scheme and the establishment of a real-time prescription monitoring system.
- As the Bill provides for authorities to be granted under the scheme, a range of potential FLPs are raised, for example in relation to the chief executive's administrative power to

- impose suitability criteria and conditions on authority holders and consistency with natural justice in relation to changes to or cancellation of an authority.
- The Bill seeks to ensure that Queensland Health is better able to monitor and respond to health risks associated with inappropriate access to, and use of, medicines and poisons. Uncontrolled access to medicines and poisons presents significant risks to community public health. However, the Bill recognises that there are beneficial uses of such substances in medicine, industry and agriculture. The Bill allows the use of substances to be managed by harmonising with existing controls in other legislation at a State and national level, while protecting public health. To protect the public from harm associated with medicines and poisons, it is necessary to strike a balance between the rights of authority holders to use medicines and poisons and the rights of the community not to be endangered by these substances. For this reason, the Bill potentially departs from some FLPs to ensure the safety of Queenslanders is paramount. For example, the Bill enables the chief executive to keep and publish registers relating to administrative action and substance authorities and to consider whether a person is fit and proper to hold an authority, including a consideration of their criminal history.
  - As the scheme is highly technical and complex, it is necessary to prescribe a range of matters by regulation and to refer to a number of external documents, such as the Poisons Standard.

The potential breaches are discussed in further detail below and are considered justified to support the scheme. All potential breaches of FLPs have been carefully considered in framing the Bill and wherever possible, the impact of potential breaches has been minimised.

### **Rights and liberties of individuals - *Legislative Standards Act 1992*, section 4(2)(a)**

The Bill contains a number of clauses that potentially impact on the fundamental legislative principle that legislation must have sufficient regard to the rights and liberties of individuals. Potential breaches are discussed in detail below.

#### ***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 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.

Given the size and complexity of the scheme, the Bill contains administrative powers for the chief executive to support the operation and administration of the scheme. These powers are considered to be sufficiently defined and subject to appropriate review, as outlined below.

#### *Administrative powers*

##### **Power to make an emergency order**

Clause 58 (Chief executive may make emergency order) provides that the chief executive may make an emergency order authorising a person to carry out a regulated activity with a regulated substance in relation to a biosecurity event under the *Biosecurity Act 2014*, a disaster situation under the *Disaster Management Act 2003*, a declared public health emergency under the *Public*

*Health Act 2005*, an emergency under the *Public Safety Preservation Act 1986* or another event at a State or local level that poses a health risk, including an event that has the potential to cause human disease through exposure to infection. The power to make an emergency order is necessary to ensure the chief executive can take immediate action to manage the risk of significant harm or illness, or other risks associated with emergency situations.

For example, an emergency order may be required:

- during an outbreak of an infectious disease. The order would provide the ability for a vaccine or medicine to be easily and quickly distributed to treat the infection and help prevent further spread of the disease. In addition, an emergency order could allow for additional authorised persons, who may not ordinarily be authorised, to treat patients and administer the required substance.
- when there is a natural disaster and health or storage facilities are under threat of flooding, fire or other damage. The order may allow for variations to the authorised way of dealing with substances, such as different storage conditions, or creation of a temporary facility where health professionals may provide necessary care to the public.
- for the chief executive to authorise qualified persons who do not have a current pest management licence to spray mosquitoes following a flood event, due to the scale of the required spraying activity and the public health risk.
- to support a biosecurity emergency order made due to the presence of Asian honey bees which are declared prohibited matter under the Biosecurity Act. The chief executive could make an emergency order allowing suitable Department of Agriculture and Fisheries (DAF) employees without a pest management licence to use specified pesticides to respond to the biosecurity event in a timely manner.

This power is considered justified as the Bill places appropriate limits on when the order applies and under what circumstances, including that the order cannot be in place for more than three months. Subsection (2) sets out matters that must be included in the emergency order, including the event the order applies to; a description of the area the order relates to; the day the order starts and ends; the regulated activity with the regulated substance that may be carried out; the class of persons who may carry out the regulated activity; and any conditions applying to the regulated activity, including, for example, the circumstances in which a person may carry out the activity.

Clause 59 (Publication of emergency order) provides further safeguards, requiring the chief executive to take reasonable steps to ensure persons likely to be directly affected by the order are made aware of the order immediately after making it, and to publish the order on the Queensland Health website as soon as practicable, but no later than two business days after the order is made.

Given the emergency nature of these powers and the limited circumstances in which they would apply, these powers are not subject to administrative review.

#### Application process for substance authorities

The Bill provides for a range of different authorities to regulate persons or entities performing regulated activities with regulated substances. Substance authorities include a wholesale licence, retail licence, pest management licence, general approval or manufacturing licence. To support this framework, the Bill contains administrative powers relating to the application process for substance authorities.

Clause 69 (Duration) provides that the chief executive may decide the term of an authority. This is necessary because the chief executive requires the flexibility to decide the length of the term for each authority based on the activities that the authority allows, as different regulated activities have varying levels of risk. For example, substance authorities that are licences, such as manufacturing licences, will be annual licences while the duration of a general approval may change. The length of a general approval can vary as any requirements for governance or varying degrees of risk associated with the activities in the authority are taken into consideration when deciding the length of the term. For example, the chief executive may issue an authority for a shorter period than requested by the applicant due to the usage of new technology requiring closer regulation than established technology.

Clause 74 (Finalising a substance authority) provides that if a person stops being the holder of a substance authority, for example, if a manufacturing licence holder surrenders their licence, the chief executive may give the person a notice authorising the person to carry out a stated regulated activity with the regulated substance in a stated way for a stated period. For example, the chief executive may give a notice stating that a person who has surrendered a manufacturing licence for Schedule 7 (S7) poisons may store the poisons at the place where the poisons were manufactured for six months until they can be taken to a disposal facility. The person is taken to carry out the regulated activity with the regulated substance in the authorised way if the person complies with the notice. This power is sufficiently defined as it requires the chief executive to state in the notice the regulated activity the person is authorised to carry out, the way in which the person is authorised to carry out the activity, and the period in which the person is able to carry out the activity. This power is necessary to allow the chief executive to facilitate the safe disposal of medicines and poisons in circumstances where, for example, an authority holder is insolvent and a liquidator becomes responsible for any regulated substances held under the authority. The time-limited notice will permit the person named in the notice to lawfully possess and dispose of the substances.

Clause 87 (Further information request) provides that the chief executive may give an applicant for a substance authority a notice stating further information the chief executive reasonably considers is required from the applicant to decide the application. The notice may require the further information to be verified by statutory declaration. The power to give an information request is considered sufficiently defined as it must state the information to be provided and a reasonable period, of at least 30 days after the day the notice is given, for compliance with the notice.

This power is necessary to assist the chief executive to decide the application if insufficient information has been provided. It may be appropriate and necessary to request further information from an applicant to make a well-informed decision. For example, more information may be needed on the type and concentration of substances to be used, the proposed method of storage of the substance or about the premises where the regulated activity will be carried out. Additionally, this power could apply if the applicant has qualifications from an international jurisdiction and needs to provide evidence that they meet equivalent qualifications within Queensland's jurisdiction to be considered a fit and proper person to hold the authority. This power may also be applicable if a person's criminal history is relevant to the application. This power is justified due to the risks that are associated with substances that require an approved authority, and the need to consider all relevant information thoroughly before providing an individual with the authority.

Clause 89 (Period for deciding application) provides that the chief executive must decide an application for a substance authority on or before the final consideration day or by an agreed date decided under clause 88. The ‘final consideration day’ is defined in clause 86. Clause 89(4) provides that if the chief executive fails to decide the application by the day required under this clause, the chief executive is taken to have refused to grant the application. The power to decide an application within the timeframe provided by this clause is considered justified as it provides applicants with clear guidance on when their application will be decided and when their application is taken to have been refused. It also allows the chief executive a reasonable period of time to consider an application and make a decision.

### Administrative action

Clause 95 (Definitions for part) provides a definition for *administrative action*, which states that administrative action in relation to a substance authority means changing a condition of an authority or suspending an authority for a stated period or indefinitely, or cancelling a substance authority. This allows the chief executive to take administrative action in relation to substance authority holders and approved persons under the regulations.

This is considered justified to ensure the application of administrative action under the scheme is equitable, by applying it to all persons who are covered under substance authorities included in the Bill as well as to approved persons who hold authorities under a regulation. The list of approved persons in the regulations is extensive and each authority will have tailored specific limitations on what activities with regulated substances the authority allows.

Allowing administrative action for approved persons, by changing conditions or suspension of their authority under the regulations, will ensure that administrative action can be applied to all individuals dealing with regulated substances and not just limited to the authorities listed in the Bill. Clause 96, discussed below, sets out the grounds on which the chief executive may decide that administrative action is necessary and ensures that the power is appropriately defined. Clause 96 also provides an additional safeguard that the chief executive must not take administrative action unless the chief executive has first considered giving a compliance notice about the proposed administrative action.

### Emerging risk declarations

Chapter 5, Part 1, Division 1 of the Bill provides the chief executive with powers to make an emerging risk declaration. An emerging risk declaration may be made if there is a reasonable belief that an unscheduled substance or device used to apply or administer a substance poses a risk of injury or illness. For example, this may apply to a sports supplement containing substances that have new evidence of harm to human health. The inclusion of the emerging risk declaration powers will enable the chief executive to prevent substances that may pose a risk of injury or illness entering the marketplace until their safety can be determined.

Clause 111 (What is an *emerging risk declaration*) sets out that an emerging risk declaration is made by the chief executive declaring that a substance that is not a regulated substance must not be made, sold or used in the State, the substance may only be used with a particular device or in a particular way, a particular device must not be used with the substance, or the substance must be disposed of in a particular way. Failing to comply with an emerging risk declaration carries a maximum penalty of 500 penalty units (clause 116).

This power is considered to be sufficiently defined and subject to appropriate review, noting:

- Clause 112 (Making emerging risk declaration) sets limitations for when an emerging risk declaration may be made, providing that the chief executive may make an emerging risk declaration if they reasonably believe the substance is being made, sold or used in the State and there is an urgent need to regulate, or further regulate, the substance because of a health risk. Subsection (2) provides that the chief executive may not make a declaration in relation to a medical device under the *Therapeutic Goods Act 1989* (Cth);
- Clause 113 (Matters to be included in emerging risk declaration) sets out the matters that must be included in the declaration, including a description of the substance to which the declaration applies, and if the declaration relates to a device, a description of the device and either a description of the way the device may or may not be used with the substance, or a statement that the device must not be used with the substance. The declaration must also state any conditions that apply to carrying out an activity with the substance. Clause 113 also provides that the declaration may state a day on which it takes effect and a day on which it ends;
- Clause 114 (Publication of emerging risk declaration) requires the chief executive to publish the emerging risk declaration on the Queensland Health website and take reasonable steps to ensure that persons likely to be directly affected by the declaration are made aware of it, for example, by publishing media releases, advertising in newspapers or other publications, or contacting affected persons;
- Clause 115 (Effect and duration of emerging risk declaration) sets out that the declaration takes effect when it is published on the Queensland Health website or on a later date stated in the declaration. Clause 115(2) also sets out when the declaration ends, with the declaration able to be in effect for a maximum of three months, unless the chief executive decides to renew the declaration as outlined below. Clause 115 also provides that if a provision of the Act or a decision made under the Act is inconsistent with an emerging risk declaration, the declaration prevails to the extent of the inconsistency;
- Clause 117 (Renewal of emerging risk declaration) provides that before the declaration ends, the chief executive may renew the declaration by publishing a notice on the Queensland Health website. The chief executive may only renew the declaration if they believe that more time is required to allow the substance stated in the declaration to be prescribed under clauses 11, 12 or 13 as a medicine, poison or prohibited substance, for the substance stated in the declaration to be considered under the Commonwealth Therapeutic Goods Act for listing in the Poisons Standard, or for the device stated in the declaration to be registered as a medical device under the Commonwealth Therapeutic Goods Act. The chief executive must also believe that the substance, or use of the substance with a device should, in the meantime, continue to be regulated under the Act to prevent or minimise a health risk. In renewing the emerging risk declaration, the chief executive may decide to change any matter stated in the declaration if the chief executive considers the change reasonably necessary. For example, a change may be required if new information is obtained indicating that the public health risk is greater or lesser than the level originally determined, such as emergent evidence of harms being caused by the substance which require additional controls to be placed on who may deal with the substance. The notice for the renewal of the declaration must state the emerging risk declaration to which the renewal applies, the date the declaration ends, which is to be a maximum of three months from the date of publication of the renewal notice, and, if the chief executive decides to change a matter stated in the declaration, a brief statement of the change and the reasons for the change. The chief executive must take reasonable steps to ensure persons likely to be directly affected by the renewal of the declaration are made aware of the renewal;

- Clause 128 (Compensation for emerging risk declaration or recall order) provides that a person directly affected by an emerging risk declaration may apply to the chief executive for compensation. Clause 128 is discussed in more detail below.

### Recall orders

Chapter 5, Part 1, Division 2, Subdivision 1 provides for the chief executive to make recall orders. A recall order may be made if the chief executive considers a product containing a regulated substance poses a health risk. The recall order may be necessary because of labelling, packaging, efficacy or other safety issues. For example, this may apply to hair dyes causing severe skin and scalp irritation due to incorrect formulation with a scheduled substance or metal cleaning products with high levels of hydrofluoric acid contrary to labelled ingredients.

Clause 119 (Chief executive may make recall order) provides that the chief executive may make a written recall order that is directed to a responsible person who the chief executive believes is responsible for controlling the manufacture, possession or supply of the product. The recall order may require the responsible person to recall the product from manufacture, possession or supply. Failure of a responsible person to comply with a recall order without a reasonable excuse carries a maximum penalty of 500 penalty units (clause 125).

To minimise overlap of powers, a recall order is not made in relation to a regulated substance if the substance is regulated under another Act or Commonwealth law and those powers have been exercised for the recall of the substance, for example, by the Therapeutic Goods Administration (clause 118).

This power is considered to be sufficiently defined and subject to appropriate review, noting:

- Clause 120 (Notice required for making recall order) requires that before the chief executive makes a recall order, the chief executive must give the responsible person for the proposed recall order a notice. The notice must state that the chief executive intends to make a recall order, the terms of the proposed order, the reasons for making the proposed order, and that the person may give the chief executive written submissions within seven days about why the chief executive should not make the proposed order. The responsible person may give the chief executive written submissions about why the proposed recall order should not be made. However, if the chief executive considers the recall order must be made urgently to prevent a serious health risk to a person, they may make the order without providing the responsible person with a notice (clause 121 (Urgent recall order)). This is considered justified in situations where urgent action is required. For example, an urgent recall order may be needed if the label on a product containing hydrofluoric acid incorrectly stated the hydrofluoric acid concentration, and it contained a higher concentration likely to cause immediate injury to a person, or if a device to poison wild dogs was faulty and releasing cyanide into the environment. If an urgent recall order is made, the chief executive is required to give the responsible person a notice as soon as practicable, and no later than 48 hours, after the recall order is made, stating the terms of the order, the reasons for making the order and that the person may give the chief executive written submissions, within seven days after the notice is given, about why the chief executive should revoke the order. The responsible person may give the chief executive written submissions about why the recall order should be revoked.
- Clause 122 (Decision about recall order) provides that after considering any written submissions made under clause 120 by the responsible person for the proposed recall order, the chief executive must decide whether to make the order. After considering any written

submissions made under clause 121 by the responsible person for a recall order, the chief executive must decide whether to revoke the order. The chief executive is required to give the responsible person an information notice for these decisions.

- Clause 123 (Notifying public about recall order) requires the chief executive to publish information on the Queensland Health website that is sufficient to alert the public about the potential health risk identified in a recall order. The chief executive may publish the information in any other way the chief executive considers reasonably necessary to alert the public, for example by publishing media releases or advertising in newspapers or other publications.
- Clause 124 (Content of recall order) sets out what must be stated in a recall order, including the details of the product that is recalled under the order, the responsible person for the order, reasons for the recall of the product, what the responsible person must do to recall the product and the reasonable period for which the order is effective. The recall order may state the responsible person must do any of the following:
  - o stop the manufacture or supply of the product;
  - o take reasonable steps to recover the product from another person;
  - o isolate or dispose of the product;
  - o repackage or relabel the product; or
  - o publish warnings about the product.
- Clause 126 (Effect of recall order) states that:
  - o subject to clause 128, the chief executive is not liable for any costs incurred in complying with a recall order. However, clause 128 (Compensation for emerging risk declaration or recall order) allows the responsible person to apply to the chief executive for just and reasonable compensation if they suffered loss because of the order and there were insufficient grounds for making the order. If the chief executive refuses the application or pays less compensation than the amount sought, the chief executive must give the applicant a Queensland Civil and Administrative Tribunal (QCAT) information notice for the decision. Clause 202 provides that the person may apply to QCAT for a review of the decision about compensation under clause 128;
  - o the recall order remains in force for the period stated in the order, unless it is revoked by the chief executive.

### *Imposition of conditions on a licence or other statutory authority*

A number of provisions in the Bill provide for conditions to be imposed on persons or authority holders. This is necessary to support the operation of the scheme, given, for example, the range of different authorities granted under the scheme to regulate persons or entities performing regulated activities with regulated substances and the need to regulate these persons flexibly and to address risks appropriately and proportionally.

Relevant clauses are detailed below.

### Authorised activities

Clause 54 (Authorisation of prescribed classes of persons) provides that a regulation may prescribe a class of persons to carry out a regulated activity with a regulated substance. An *approved person* is a member of a class of persons prescribed by regulation for a regulated activity with a regulated substance for the class of persons. The approved person is authorised to carry out the regulated activity with the regulated substance. An authorisation made under this clause is the *approved person's authorisation*. The regulated activity for which the

approved person is prescribed may be limited by reference to the circumstances in which, or the purposes for which, the regulated activity may be carried out by the class of persons.

This is necessary given the range of approved persons and regulated activities required to be regulated under the scheme, which requires detailed requirements to be set out in the regulations for each class of approved person. For example, a requirement may be needed to:

- restrict the types of pesticides that can be used by a person constructing fences on a rural farm and placing a pesticide in the base of the fence post hole, and to impose relevant competencies for the person. These requirements may be necessary to ensure the person handles the pesticide appropriately, preventing pesticides entering the food supply and harming public health; or
- set the limited conditions under which dentists are able administer or prescribe Schedule 8 (S8) medicines to a patient. The conditions include restrictions on a dentist prescribing S8 medicines to the extent that they may not give a repeat prescription for the medicine or prescribe more than three days supply of the medicine, and set out the particular S8 medicines a dentist may administer or prescribe.

### Extended practice authorities

Clause 232 (Making extended practice authorities) provides that the chief executive may make a document, known as an extended practice authority (EPA), stating the places or circumstances in which an approved person may deal with a regulated substance; imposing conditions on dealing with a regulated substance; or requiring an approved person to hold particular qualifications or training to deal with a regulated substance. The chief executive may make an EPA by adopting another entity's code, guideline, protocol or standard, whether in whole or part. An EPA has effect in relation to an approved person if it applies to the approved person under a provision of a regulation. It is considered appropriate for an EPA to impose conditions as they contain detailed, clinical requirements such as patient criteria for exclusion, medication forms and routes of administration, and the required education and qualifications for practitioners working under them.

Appropriate safeguards are included in relation to the EPA provisions. In order to ensure that purposes of the Bill are met through people carrying out activities with medicines having the necessary competencies and health and safety risks being appropriately managed, subsection (3) provides that a regulation may prescribe matters the chief executive must consider before making an EPA. This will include matters such as the types of medicines to be dealt with, the service need to be met by the authority and how the risks associated with the medicines will be managed. Queensland Health has made a commitment to table any extrinsic material referenced in legislation in the Legislative Assembly, so the updated EPA will be tabled, providing the Legislative Assembly with an opportunity to consider the EPA and any conditions imposed under it.

### Emergency order

Clause 58 (Chief executive may make emergency order) provides that an emergency order may include conditions applying to the regulated activity, including the circumstances in which a person may carry out the activity.

Conditions may include requirements for storage, record keeping, reporting and disposal. For example, in the event of a natural disaster within a rural area, the usual facilities that store and

dispense regulated substances could be under threat or may no longer be accessible. This may require management for retrieval of the substances and subsequent orders for movement of substances in a secure and safe way, new temporary storage facilities, recording of stock retrieved and where they are stored, along with guidelines surrounding destruction of any damaged, or potentially damaged goods.

Conditions may also be required to limit the substances and persons subject to the order. For example, conditions may be required if the chief executive of DAF issues a biosecurity emergency order due to the presence of Asian honey bees, which are declared prohibited matter under the Biosecurity Act. To support DAF's activities, the chief executive of Queensland Health could issue an emergency order allowing suitable DAF employees to use specified pesticides without a pest management licence to respond to the biosecurity event in a timely manner. In this instance, limiting the type of pesticide and defining which DAF employees would be suitable to respond to the biosecurity event may be necessary. Pest management technicians require numerous competencies to safely handle a range of pesticides. By limiting the activity to a limited number of pesticides, employees who may not have completed these competencies would only be required to be familiar with particular pesticides and labels, reducing the risk of improper application of the pesticides.

The imposition of conditions is considered justified as the Bill clearly defines when the order applies and under what circumstances. Clause 58(2) sets out matters that must be included in the emergency order and requires that the order be in place for no longer than three months. Clause 59 (Publication of emergency order) requires the chief executive to take reasonable steps to ensure persons likely to be directly affected by the order are made aware of the order immediately after making it, and to publish the order on the Queensland Health website as soon as practicable, but no later than two business days after the order is made.

### Substance authorities

Chapter 3, Part 2, Division 1 provides that the chief executive may grant a range of licences and approvals under the Act, known as substance authorities. Substance authorities include manufacturing licences, wholesale licences, retail licences, pest management licences, prescribing approvals and general approvals. Division 3 (Duration and conditions of substance authorities) sets out the conditions that may apply to those authorities. Clause 70 (Conditions) provides that a substance authority is subject to a standard condition prescribed by regulation to apply to the substance authority, and any additional conditions decided by the chief executive. If the chief executive decides to change a standard condition, the substance authority is subject to the changed condition instead of the standard condition. It is considered appropriate to prescribe standard conditions by regulation noting the range of substance authorities that standard conditions will need to be stipulated for, the detailed nature of such conditions, and the need to respond flexibly if changes are required in future. For example, the changing environment created by the internet and electronic transactions means that businesses may change the way that they deal with, sell and distribute medicines in future. It is considered appropriate for the chief executive to have the ability to change a standard condition noting that flexibility is required to ensure that conditions are tailored appropriately to the type of authority. Clause 71 (Failure to comply with substance authority conditions) provides that it is an offence for a substance authority holder not to comply with the conditions of the authority without a reasonable excuse. This offence carries a maximum penalty of 200 penalty units.

Clause 76 (Deciding initial application) provides that the chief executive must decide whether or not to grant an initial application for a substance authority. The chief executive may decide to impose additional conditions or change a standard condition if it is reasonably necessary. For example, an entity engaging volunteers to euthanise injured wildlife may be required to engage a veterinary surgeon to train and assess the competency of those volunteers to safely administer the medicine used for euthanasia. The entity may also be required to develop a protocol on the use of the euthanasia agent, including disposal of carcasses containing the substance and the substance itself. This example is not proposed to be covered by standard conditions in the Poisons Regulation. These additional conditions would be necessary to mitigate the public health and safety risk of this activity. Additional or changed conditions may also be required on a case-by-case basis if a general approval is granted for a unique application such as a research proposal, to protect public health due to the diversity and unpredictable application, of poisons for research. The power to impose conditions is considered to be sufficiently defined. If the chief executive decides to grant an application without imposing additional conditions or changing any standard conditions, clause 77 provides that they must give the applicant a notice stating that the substance authority is granted, the day the decision takes effect and that the standard conditions apply to the authority. If the chief executive decides to grant the application subject to additional conditions or changes to any standard conditions, or decides to refuse to grant the application, the chief executive must give the applicant an information notice for the decision, which is subject to internal review under clause 198. An internal review decision relating to the initial application may then be subject to external review by QCAT under clause 202.

#### Emerging risk declaration

Clause 113 (Matters to be included in emerging risk declaration) sets out the matters that must be included in an emerging risk declaration, including any conditions that apply to carrying out an activity with the substance.

As outlined above, the power to make an emerging risk declaration is considered appropriate.

The inclusion of conditions in a declaration is appropriate so that the emerging risk can be managed flexibly. For example, if a new substance entering the market has been identified as posing an unacceptable public health risk due to its toxicological properties, specific conditions would be required to manage those risks. It is not possible to predict what public health threats an emerging risk will present. Therefore, it is necessary to have the ability to impose conditions on a case-by-case basis.

#### *Imposition of suitability, eligibility and similar criteria*

A number of clauses impose criteria on authority holders. This is necessary to support the operation of the scheme given the need to determine the suitability of persons or entities to hold authorities under the Act and to deal with regulated substances, as this is critical to ensuring the health and safety of the public. Clauses that impose criteria are considered below.

#### Fit and proper person requirement

Clause 76 (Deciding initial application) provides that in deciding whether or not to grant the initial application for a substance authority, the chief executive may have regard to a range of matters including whether a relevant person is a fit and proper person for the substance

authority applied for and whether the place at which the regulated activity is proposed to be carried out is suitable for the activity. In considering whether a relevant person is a fit and proper person, the chief executive may seek criminal history information about the person under clause 216.

This is also relevant in relation to:

- amendment applications under clause 79 (Deciding amendment application), which provides that in deciding whether or not to grant an amendment application, the chief executive may have regard to the conditions of the authority and any changes to the matters considered by the chief executive when the substance authority was granted;
- renewal applications under clause 83 (Deciding renewal application), which provides that in deciding whether or not to grant a renewal application, the chief executive may have regard to the conditions of the authority and any changes to the matters considered by the chief executive when the authority was granted. If the chief executive decides to grant the renewal application, the chief executive may also decide to impose additional conditions or change a condition of the substance authority, if the chief executive is satisfied the action is reasonable necessary.

Clause 96 (Grounds for taking action) provides that if the chief executive believes a relevant person is not a fit and proper person, this is grounds for the chief executive to take administrative action in relation to an authority.

The power of the chief executive to consider whether a person is a fit and proper person in deciding an application or in relation to administrative action may be seen to breach the FLP that rights and liberties, or obligations, should be dependent on administrative power only if the power is sufficiently defined and subject to appropriate review because the consideration of other relevant matters may be subjectively applied.

Determining whether an applicant is a fit and proper person to hold an authority is necessary to ensure the integrity of the decision-making process and provide confidence to the community that substance authority holders are being managed appropriately.

It is appropriate for the chief executive to determine if an applicant has the resources and competencies required to undertake the regulated activity. For example, if the manufacturer of an S7 poison is not suitably qualified, they may not possess the scientific knowledge required to safely manufacture and supply the substance without endangering the community.

Providing discretion allows the chief executive to have regard to matters including the person's skills, experience, qualifications and knowledge relevant to the regulated activity and regulated substance to which the application relates, whether the person has committed any relevant offences, whether the person engages or has engaged in conduct that risks, or is likely to risk, a regulated substance being used for a purpose that is unlawful, whether the person has the means to carry out the regulated activity to which the application relates, including financial resources and access to suitable staff and materials, and any conditions or other limitations placed on a practitioner's registration, or disciplinary action taken against the practitioner, under practitioner law.

This discretion is appropriate because the chief executive considers a broad range of applications for various types of substance authorities. There are a large number of circumstances that are relevant to a person being inappropriate to hold an authority and it would

not be possible to provide for every circumstance in legislation. For example, Queensland Health may require that an applicant for a general approval provide clinical protocols for the activities proposed to be performed under the approval in order to assess the applicant's clinical governance. To balance the exercise of this power, the chief executive's decision is subject to internal review and external review by QCAT. The imposition of criteria in these provisions is therefore considered justified.

#### Health assessment for pest management licences

Clause 90 (Health assessment for pest management licences) provides that for an application for a pest management licence, the chief executive may ask the applicant to undergo a health assessment by a medical practitioner of their physical and mental health. The chief executive may then have regard to the health assessment in considering the application for a pest management licence under clause 76. This may be appropriate if, for example, a person applying for a pest management licence will be required to work in enclosed spaces, as a person with a permanent back injury may not be physically able to access a ceiling space to effectively undertake pest control activities. The provision is also necessary because some pesticides such as organophosphate substances may cause neurological effects such as blurring of vision and loss of muscle control, which could impact on the health of occupiers of premises being treated by the pest management technician and particularly the pest management technician themselves. Exposure to some pesticides may also result in neurological effects that cause mental health issues affecting the applicant's ability to effectively carry out pest control work. A health assessment may be requested based on feedback from customers or other pest management technicians. Action may be required to prevent further deterioration in a technician's health. The provision is also necessary as technicians may have unsupervised access to domestic residences and other sensitive locations, and it is important to ensure that appropriate people are granted a licence to protect the health and safety of the public.

This power is considered to be sufficiently defined. Subsection (3) provides that the chief executive must give the applicant a notice stating the reason for requesting the health assessment, the name of a particular medical practitioner, or the qualifications of a medical practitioner, who may conduct the assessment, and the reasonable day by which the assessment must be done. The assessment conducted by the medical practitioner must include a written report stating the practitioner's findings about the applicant's mental and physical health in relation to carrying out the type of regulated activity to which the application relates. An applicant who fails to give the written report to the chief executive by the day mentioned in subsection (3)(c), without a reasonable excuse, is taken to have withdrawn their application.

The power to ask for a health assessment is subject to appropriate review and safeguards. As noted above, the chief executive's decision about whether to grant, amend or renew a substance authority is subject to internal review and external review by QCAT. Clause 210 (Health assessment not admissible) provides that a report about a person's health assessment done under clause 90 is not admissible as evidence in a legal proceeding, other than an internal or external review proceeding relating to the report. Subsection (3) provides that a person cannot be compelled to produce the report, or give evidence about the report or its contents, in a proceeding, other than a review proceeding relating to the report. These requirements do not apply if the person to whom the report relates consents to the report being admitted, produced or given as evidence.

A range of Queensland Acts specify that a decision-maker may require a health assessment as part of the approval process, including under the *Architects Act 2002* (Part 2A), *Education (Queensland College of Teachers) Act 2005* (sections 119A and 119B), and the *Health Practitioner Regulation National Law Act 2009* (Schedule, Part 8, Division 9).

***Is the legislation consistent with principles of natural justice?***

Section 4(3)(b) of the Legislative Standards Act states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation is consistent with principles of natural justice.

As the scheme provides for the granting of various authorities for a person or entity to perform a regulated activity with a regulated substance, a range of provisions are included in the Bill that relate to changing or cancelling an authority, administrative action, and review and appeals, and may be seen to impact on the principles of natural justice.

These provisions are considered necessary to support the operation of the scheme and support the administrative powers under the Bill.

***Right to be heard***

Certain provisions in the Bill could be viewed as depriving a person of a right, interest or expectation of a benefit and be seen to infringe upon the principles of natural justice. These clauses are detailed below.

**Notification of changes affecting substance authority**

Clause 73 (Changes affecting substance authority) applies if a substance authority holder notifies the chief executive of a change in circumstances in relation to the substance authority.

The chief executive may require the holder to apply to amend the authority in a stated way, or apply for a new substance authority, by a stated reasonable day. The chief executive must give the holder an information notice for this request. The provision is considered justified given the authority holder is provided with notice of the chief executive's request and an opportunity to amend their authority or apply for a new authority, rather than the authority being immediately cancelled without the person being heard.

If the holder does not comply with the notice before the stated day, or they make an application for a new authority, the substance authority is cancelled. If the holder was required to apply for a new authority, the cancellation of the existing authority takes effect on the day the decision for the new application is made. The cancellation of the authority is considered appropriate because it is only undertaken after a clear process has been followed. The process includes the holder being given an information notice stating what the holder is required to do, and only if the holder does not comply with the notice by the stated day, or the application for a new authority is decided, is the original authority cancelled.

This provision is considered justified as the chief executive is required to take certain information into consideration when approving an authority. This is to ensure those authorised to deal with regulated substances are capable of doing so safely. If this information changes, it is appropriate for the chief executive to consider whether the approval is still justified and the

authority holder may deal with the substance safely, or whether variations to the conditions of the authority should be made.

For example, if a manufacturing supervisor under an entity manufacturing licence changes, the chief executive would need to reassess whether the new manufacturing supervisor holds the necessary qualifications to supervise the manufacture of substances. The qualifications required of a manufacturing supervisor ensure that they have appropriate scientific knowledge to manufacture substances safely, produce a product of a high quality, and to dispose of by-products appropriately. If the manufacturing supervisor was not appropriately qualified, there is a risk that substances would be made available to the public that are not fit for purpose and may be harmful to health.

### Administrative action

Chapter 4, Part 3 (Administrative action) of the Bill sets out the process for administrative action under the framework. These provisions are required noting the range of authorities granted under the scheme and the need to regulate authority holders to ensure that risks to public health and safety are identified and appropriately dealt with. The ability to take administrative action under the Bill is considered justified, as relevant persons are given an adequate opportunity to present their case to the decision maker.

Administrative action in relation to an authority includes changes to conditions of a substance authority or approved person's authorisation under a regulation, suspension of a substance authority or approved person's authorisation under a regulation for a stated period or indefinitely, or cancellation of a substance authority. For example, an approved person's authorisation under a regulation that permits a medical practitioner to prescribe may be varied so that the authorisation does not apply to certain medicines, such as S8 medicines.

Clause 96 (Grounds for taking action) ensures that the criteria for taking administrative action is sufficiently defined, as it sets out the grounds on which the chief executive may take administrative action for an authority. The chief executive may take administrative action if they reasonably believe:

- a relevant person for an authority has contravened a requirement under the Act or a corresponding law;
- administrative action is reasonably necessary to prevent or minimise a health risk;
- a relevant person for the authority is not a fit and proper person; or
- a relevant person for the authority made a materially false or misleading representation to obtain the authority.

The chief executive may take administrative action only if they have considered giving a compliance notice to the person about the matter to which the proposed administrative action relates.

Clause 97 (Show cause notice before taking action) clearly defines the circumstances in which the chief executive must give an authority holder a show cause notice before taking administrative action and the matters required to be included in the notice. The chief executive must give the authority holder a show cause notice if they are proposing to take administrative action in relation to an authority. The clause provides that the show cause notice must state the following:

- that the chief executive proposes to take administrative action;

- the proposed administrative action, including whether it applies to all regulated activities with regulated substances to which the authority relates or a particular regulated activity or regulated substance;
- the reasons for the proposed administrative action;
- that the authority holder may give the chief executive a written response to the show cause notice within a stated period of at least 21 days (the *show cause period*).

The show cause period provides the authority holder with an adequate opportunity to present their case to the decision maker, with clause 98 (Chief executive must consider response) providing that the chief executive must consider the written response before deciding whether or not to take the proposed administrative action stated in the show cause notice.

Clause 99 (Decision not to take administrative action) provides that if the chief executive decides not to take the proposed administrative action stated in the show cause notice, the chief executive must give the holder a notice stating the decision.

Clause 100 (Decision to take administrative action) clearly sets out when the chief executive may take administrative action and what the chief executive can decide to do. A decision can be made about administrative action if:

- the show cause period has ended;
- the chief executive has considered any written response from the authority holder; and
- the chief executive believes there is a ground for taking administrative action.

The chief executive may decide to take the administrative action stated in the show cause notice or to take other administrative action that is less onerous. If the chief executive decides to take administrative action to suspend the authority indefinitely or change the conditions of the authority, they must also decide the review day for the administrative action. The term 'review day' is defined in clause 95. The chief executive must give the authority holder an information notice for these decisions. The administrative action takes effect on the day stated in the information notice. The day stated in the information notice must not be earlier than the day the notice is given to the holder.

Clause 102 (Immediate administrative action) provides that the chief executive may decide to take administrative action in relation to an authority on a ground mentioned in clause 96(1) without giving the authority holder a show cause notice if they consider it reasonably necessary because there is an urgent need to prevent a serious health risk to any person, including the authority holder. If the chief executive decides to take administrative action to suspend an authority indefinitely or change the conditions of an authority, the chief executive must also decide the review day for the administrative action. The chief executive is required to give the holder an information notice for their decisions. The administrative action takes effect on the day stated in the information notice. The day stated in the information notice must not be earlier than the day the notice is given to the holder.

This power is justified noting the high bar for immediate administrative action – the chief executive is required to consider immediate administrative action is reasonably necessary because there is an urgent need to prevent a serious health risk to any person. For example, if a pest management technician was found to be storing pesticides in food or drink containers, there would be a risk to the health of the technician and any other person who may have access to their pesticide containers. The chief executive may choose to immediately suspend the technician's licence for a stated period to prevent the technician from taking pesticides in these

containers to a work site, and to allow the technician this time period to resolve the issue. The chief executive may also take immediate administrative action to suspend a health practitioner's authority to deal with a medicine if an action by the practitioner has resulted in significant harm to a patient they are treating, and it is necessary to investigate whether the practitioner remains a suitable person to hold the authority.

If the chief executive decides to take administrative action under clause 100 or 102, they must give the authority holder an information notice. This means that the chief executive's decisions under these clauses are subject to internal review. An affected person may apply to QCAT for external review if a decision on an application for internal review of the decision has been made.

Clause 103 (Agreed administrative action) provides that the chief executive may take administrative action in relation to an authority, other than cancellation of the authority, if a relevant person for the authority to whom the action applies agrees to the action being taken. However, if the authority is a substance authority, the chief executive may take the administrative action only if the holder of the authority also agrees to the action. The chief executive is required to give the holder a notice stating the terms of the agreed administrative action and the review day that has been agreed by the relevant person. The administrative action takes effect on the day stated in the notice. The day stated in the notice must not be earlier than the day the notice is given to the holder.

### Compliance notices

Chapter 4, Part 4 (Compliance notices) sets out the process for compliance notices to be given under the framework.

Clause 108 (Giving a compliance notice) provides that the chief executive or an inspector may give a person a compliance notice requiring the person to rectify the matter if they reasonably believe:

- the person has contravened a provision of the Act in circumstances that make it likely the contravention will continue or be repeated;
- a matter relating to the contravention is reasonably capable of being rectified; and
- it is appropriate to give the person an opportunity to rectify the matter.

Failing to comply with a compliance notice without a reasonable excuse carries a maximum penalty of 200 penalty units (clause 110).

Clause 109 (Content of compliance notice) clearly defines the matters to be included in a compliance notice, providing that a notice must state the following matters:

- the chief executive or inspector believes the person has contravened a provision of the Act in circumstances that make it likely the contravention will continue or be repeated;
- the provision the chief executive or inspector believes has been contravened;
- briefly, how it is believed the provision has been contravened;
- the matter the chief executive or inspector believes is reasonably capable of being rectified;
- the reasonable steps the person must take to rectify the matter;
- the stated reasonable period within which these steps must be taken, having regard to any health risks posed by the contravention; and
- it is an offence to fail to comply with the compliance notice without a reasonable excuse.

The compliance notice provisions are considered to be consistent with the principles of natural justice as they provide clear criteria for when the chief executive or an inspector may give a compliance notice and provide the person with an opportunity to rectify the matter. For example, a compliance notice may be used for an approval holder who is required to keep a substance management plan but has not reviewed the plan after reporting an incident. The fact that an incident occurred means that the current plan was not sufficient to prevent the incident from occurring and that a review is required. Without the review, the incident may be likely to occur again and the contravention is easily rectified by the authority holder undertaking the review.

Another example of the use of a compliance notice might be if an inspector identifies that a substance management plan does not address a risk about safe custody of a regulated substance sufficiently by identifying, and having introduced, measures to mitigate the risk. There may have been no incidents of loss or theft of the regulated substance, but a risk gap has been identified by the inspector on review of the substance management plan. As there has not been an intentional breach, a compliance notice may be appropriate to provide an opportunity for the entity to rectify the matter. This provides natural justice and would also serve as an educational tool.

### *Procedural fairness*

The Bill contains a number of clauses that relate to procedural fairness. Matters to be considered in relation to procedural fairness include whether a person who is the subject of the decision will be provided with adequate notice of when any hearing will take place, adequate notice of any allegation being considered, adequate notice of any particular requirements of the decision-maker and a reasonable opportunity to present the person's case and respond to any adverse material. Relevant clauses are detailed below.

### Public warnings

Clause 127 (Statement of warning) provides that the Minister, chief executive or chief health officer (a *senior administrator*) may make a public statement identifying and giving warnings or information about any of the following matters:

- contraventions of the Act that have resulted in notification action being taken and the persons who committed the contraventions. 'Notification action' is defined in clause 127(6) as giving a compliance notice, making a recall order, taking immediate administrative action under clause 102 or giving a show cause notice under Chapter 4, Part 3;
- practices regulated under a relevant law that, in the reasonable opinion of the senior administrator, are unlawful. 'Relevant law' is also defined in clause 127(6) and means the Act, the *Agricultural and Veterinary Chemicals (Queensland) Act 1994*, the *Agricultural Chemicals Distribution Control Act 1966* or the *Chemical Usage (Agricultural and Veterinary) Control Act 1988*;
- offences committed against a relevant law and the persons who committed the offences.

The statement may identify particular contraventions, practices, offences and persons. However, the senior administrator must not make a statement unless satisfied it is in the public interest to do so, and a public statement or warning has not been made, or is not about to be made, under another Act or process that is more appropriate in the circumstances. The making of the public statement is in the public interest if the senior administrator is satisfied the statement is reasonably necessary to prevent or minimise a health risk in relation to a regulated

substance. No liability is incurred by the State for the making of, or for anything done for the purpose of making, a public statement under the clause in good faith.

The publication of alleged contraventions of the Act may not be seen to afford individuals procedural fairness, particularly where parties are identified. This potential FLP breach is considered justified on the basis that publication is restricted to matters that are in the public interest which may include, but are not limited to, preventing or minimising a health risk. As the senior administrator is required to be satisfied that publication is in the public interest, the circumstances covered by this clause are inherently serious and with potentially serious public health consequences. For example, a public warning about a contravention by a manufacturer involving a widely used regulated substance, or product containing a regulated substance, may avert a widespread health issue with significant repercussions.

Similar provisions have been included in other Queensland legislation, including section 231 of the *Motor Dealers and Chattel Auctioneers Act 2014*, section 230 of the *Property Occupations Act 2014*, section 145 of the *Debt Collectors (Field Agents and Collection Agents) Act 2014*, section 148 of the *Agents Financial Administration Act 2014* and section 93 of the *Tourism Services Act 2003*.

Given the significance of this power to make a public statement and to address related FLP issues, this power is not able to be delegated by the chief executive (see clause 238 (Delegation by chief executive)). This means the power is only able to be exercised by the Minister, chief executive or chief health officer.

### Review provisions

Chapter 6 of the Bill provides for review of decisions. These provisions ensure natural justice for persons affected by decisions made under the scheme, setting out the processes for internal and external review of a decision.

The internal review provisions include:

- Clause 197 (Review process must start with internal review), which provides that an affected person may not apply to QCAT for review of an original decision (being a decision made under the Act, other than a decision to seize or forfeit a thing), unless the person has first applied for an internal review of the decision, and the application has been decided or is taken to have been decided, under this division. Clause 197 does not apply to a decision about compensation under clause 128, which may immediately be the subject of an external review to QCAT;
- Clause 198 (Who may apply for internal review), which states that an affected person for an original decision may apply to the chief executive for an internal review. A person who is entitled to be given an information notice for an original decision but has not yet received one may ask the chief executive for that notice. However, the chief executive's failure to give such notice does not limit or otherwise affect the person's right to apply for a review of the decision;
- Clause 199 (Requirements for application), which requires an internal review application to be in the approved form and supported by enough information to enable the chief executive to decide the application. The application must be made within 14 days after the applicant is given the information notice, however the chief executive may at any time extend the time for making the internal review application. If the person has not been given an information notice, the application must be made within 28 days after the day the person

becomes aware of the decision. The application does not affect the operation of the decision or prevent the decision being implemented;

- Clause 200 (Internal review), which provides that the chief executive must conduct an internal review of an original decision within 28 days of receiving an internal review application. The chief executive must review the original decision, and decide whether to confirm the original decision, amend the decision or substitute another decision. The chief executive must give the affected person a QCAT information notice for the decision. The chief executive and the affected person may, before the 28 days is over, agree to a longer period for the chief executive to comply with subsection (1). Unless the original decision was made by the chief executive personally, the application must be dealt with by a person who did not make the original decision and who holds a more senior office than the person who made the original decision. The power under section 27A of the *Acts Interpretation Act 1954* to delegate functions does not alter this provision. If the chief executive does not give the affected person a QCAT information notice within 28 days, or the agreed longer period, the chief executive is taken to confirm the original decision;
- Clause 201 (QCAT may stay operation of original decision), which states an affected person for an original decision may immediately apply to QCAT for a stay of the operation of the decision. The application may be made at any time within the application period for an internal review of the original decision. QCAT may make an order staying the operation of the original decision only if it considers the order is desirable having regard to the interests of any person whose interests may be affected, any submission made by the entity that made the original decision and the public interest. Clause 201 sets out other matters of detail about how QCAT deals with the stay of a decision made under the Act.

The external review provisions include:

- Clause 202 (Applying for external review), which provides that a person given or entitled to be given a QCAT information notice may apply to QCAT for a review of an internal review decision or a decision about compensation under clause 128. Section 22(3) of the *Queensland Civil and Administrative Tribunal Act 2009* allows QCAT to stay the operation of an internal review decision, either on application or its own initiative;
- Clause 203 (Appealing seizure or forfeiture decision), which provides that a person who is given an information notice for a decision of the chief executive to seize or forfeit a thing may appeal the decision to a Magistrates Court. The appeal is started by filing a notice of appeal with the registrar of the court. The notice of appeal must state fully the grounds of the appeal. The appeal does not affect the operation of the decision to seize or forfeit a thing or prevent the decision being implemented. Clause 203 sets out other matters of procedural detail;
- Clause 204 (Staying operation of decision), which provides that a person who appeals a seizure or forfeiture decision may apply to the court for a stay of the operation of the decision. The court may, by order, grant a stay of the property decision to ensure the effectiveness of the appeal. The stay may be given on conditions the court considers appropriate. The stay operates for the period decided by the court, however this period must not extend past the time when the court decides the appeal;
- Clause 205 (Powers of court on appeal), which provides that, in deciding an appeal against the property decision, the court has the same powers as the chief executive in making the decision, is not bound by the rules of evidence and must comply with natural justice. The appeal is by way of rehearing. The court may confirm the property decision, substitute another decision or set the decision aside and return the matter to the chief executive with directions the court considers appropriate;

- Clause 206 (Effect of court's decision on appeal), which states that, if the court substitutes another decision for the property decision, the substituted decision is taken to be a decision of the chief executive, and the chief executive may give effect to the substituted decision as if it were their original decision and no application for review or appeal had been made. If the court sets aside the property decision and returns the matter to the chief executive with directions, and the chief executive makes a new decision in accordance with the directions, the new decision is not subject to any further review or appeal under this part.

These comprehensive provisions about review of decisions and appeals ensure that administrative decisions made under the Act are subject to appropriate review.

***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.

Clause 238 (Delegation by chief executive) specifies that the chief executive may delegate their functions and powers under the Act to an appropriately qualified person who is a health service employee or public service employee. The inclusion of this delegation power is justified as there are a range of administrative powers under the Act, and it would be impractical for the chief executive to exercise day-to-day functions under the Act personally. Before making an instrument of delegation, the chief executive will consider all circumstances including the nature of the power, its consequences and whether its use requires particular expertise or experience when deciding on the appropriate delegates. The clause also includes the limitation that the delegate must be a health service employee or public service employee, which ensures delegates are subject to appropriate governance and accountability.

The powers under clause 127 (Statement of warning) are exempt from this clause. This is an appropriate safeguard noting the serious nature of this power.

***Does the legislation provide for the reversal of the onus of proof in criminal proceedings without adequate justification?***

Section 4(3)(d) of the Legislative Standards Act provides that whether legislation has sufficient regard to rights and liberties of individuals depends on whether the legislation does not reverse the onus of proof in criminal proceedings without adequate justification. The Bill includes a number of provisions that may be seen to reverse the onus of proof. The former Scrutiny of Legislation Committee has noted that generally, reversal of the onus of proof in criminal proceedings is opposed, but that justification for the reversal is sometimes found in situations where the matter that is the subject of proof by the defendant is peculiarly within their knowledge and would be extremely difficult, or very expensive, for the State to prove. Relevant clauses are considered below.

**Executive officer may be taken to have committed offence**

Clause 214 (Executive officer may be taken to have committed offence) states that if a corporation commits an offence against a serious offence provision, each executive officer of the corporation is taken to have also committed the offence if they authorised or permitted the

corporation's conduct constituting the offence, or they were knowingly concerned, either directly or indirectly, in the corporation's conduct. 'Serious offence provision' is defined in subsection (4). Proceedings may be conducted against an executive officer, and they may be convicted of the offence, whether or not a corporation has also been proceeded against or convicted for the offence. However, this does not affect the liability of the corporation for the offence, or the liability of any person for the offence under chapter 2 of the Criminal Code.

This provision is considered justified as the executive officer is taken to have committed the offence only where they authorised or permitted the corporation's conduct or were, directly or indirectly, knowingly concerned in the conduct. This is not considered a reverse onus of proof, as the State would have the burden of proving that the officer authorised or permitted the conduct, or was knowingly concerned in it. The Council of Australian Governments (COAG) guidelines, *Personal liability for corporate fault – guidelines for applying the COAG principles*, provide that this type of provision is not objectionable in principle, as it holds officers liable as an accessory where they were personally and directly complicit. This type of provision requires the prosecution to prove that the individual knew the essential facts that constitute the corporate offence, and through their own act or omission, was a participant in that offence.

This provision is based on a similar provision in section 153ZN of the Health Act. Although the Health Act provision applied to any offence committed by a corporation under that Act, clause 214 narrows the scope of the provision by only applying it to particular serious offences. The serious offences covered by the clause include, for example, an executive officer of an entity that holds an authority allowing the entity to dispose of waste in a way that may be more cost-effective to the corporation, but exposes the public to a regulated substance, resulting in adverse health effects, or where a corporate applicant for a licence to manufacture medicines stated in the application that a person proposed to supervise the manufacturing of medicines under the licence has certain experience in manufacturing that the person does not have.

Given that the controls placed on the carrying out of regulated activities with regulated substances under the Bill are aimed at protecting the health and safety of the public, it is appropriate that an executive officer, who is in a position to influence the conduct of the corporation, be required to ensure that the corporation complies with the legislation. The provisions are therefore warranted to ensure that there is effective accountability at a corporate level.

A similar provision is contained in a range of other Acts, including section 143 of the *Private Health Facilities Act 1999*, section 205A of the *Radiation Safety Act 1999* and section 57 of the *Transport Operations (Road Use Management) Act 1995*.

### Evidentiary provisions

Chapter 6, Part 2, Division 1 of the Bill sets out evidentiary presumptions applicable to legal proceedings under the Act. The presumptions are:

- that a certificate purporting to be signed by the chief executive stating a range of matters is evidence of the matter, for example, that a stated document is a departmental standard; or a document that states that on a stated day, or for a stated period, a substance authority was or was not in force (clause 208);

- that a particular substance is a regulated substance of the same type as a regulated substance commonly supplied under the same name, description or labelling as the particular substance (clause 209).

These provisions are considered appropriate to remove an unnecessary administrative burden for the prosecution to prove administrative, technical and scientific matters that are unlikely to be in dispute in proceedings. This makes efficient use of a court's time and streamlines proceedings. Similar evidentiary provisions appear in other Acts, such as sections 267 and 268 of the *Hospital and Health Boards Act 2011*, sections 67 and 68 of the *Cross River Rail Delivery Authority Act 2016* and section 120 and 120A of the *Transport Operations (Road Use Management) Act*.

Clause 209 (Evidence of regulated substance) is considered justified as the Poisons Standard and assessments undertaken by the Australian Pesticides and Veterinary Medicines Authority (APVMA) contain very specific labelling requirements for regulated substances to manage public health risk associated with their use. There is therefore an expectation that businesses will be truthful in the labelling of their products to avoid public health risk or misleading users regarding the efficacy of their product. The evidence provision allows the identity of the substance to be inferred without needing to analyse every container of the substance subject to the legal proceeding.

***Power to enter premises, and search for or seize documents or other property, only with a warrant issued by a judge or other judicial officer***

Section 4(3)(e) of the Legislative Standards Act states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation confers power to enter premises, and search for or seize documents or other property, only with a warrant issued by a judge or other judicial officer.

*Inspectors' functions and powers*

Chapter 5 (Monitoring and enforcement), parts 2 to 5 provide for inspectors' functions and powers. Specific clauses are discussed in detail below.

To address the FLP concerns with inspectors' powers, the Office of the Queensland Parliamentary Counsel's FLP Notebook provides that current Queensland drafting practice established by precedent to achieve consistency with FLPs includes the following:

- an inspector must be issued with official identification documents and, when the inspector is exercising a power, the inspector must produce them to any person against whom the power is being exercised;
- entry of any premises without consent is strictly controlled through requirements for warrants and limitation of circumstance;
- entry without consent into anywhere a person lives requires the highest justification;
- the powers that may be exercised, particularly on entry of premises, must be specified as far as practical, and justifiable in proportion to the interference in rights and liberties involved;
- if it is an offence to obstruct or fail to obey, help, or provide information to an inspector, reasonable excuse must be provided as a defence;
- property must not be interfered with or seized without particular justification;

- if property may be seized, the circumstances of its return must be specified and the circumstances must be fair, and the owner must be permitted reasonable access to it while it is seized; and
- if property is damaged, provision must be made for notice to be given to the owner of property and for payment of compensation unless there is particular justification for not providing compensation.

Generally, the inspectors' powers in the Bill are consistent with these principles, contain appropriate safeguards and are considered necessary to support the effective and transparent exercise of inspectors' powers for monitoring, compliance and enforcement of the Act.

Safeguards include:

- Clause 135 (Issue of identity card) provides that the chief executive must issue an identity card to each inspector, and that the card must contain a recent photo of the inspector, a copy of their signature, identify the person as an inspector under the Act, and state an expiry date for the card. Clause 136 (Production or display of identity card) provides that in exercising a power in relation to a person in the person's presence, an inspector must produce their identity card for the person's inspection before exercising the power, or have the identity card displayed so it is clearly visible to the person when exercising the power. Subsection (2) provides that if it is not practicable to comply with these requirements, the inspector must produce the identity card for the person's inspection at the first reasonable opportunity;
- clause 182 (Duty to avoid inconvenience and minimise damage) provides if an inspector exercises a power, they must take all reasonable steps to cause as little inconvenience, and do as little damage, as possible;
- clause 183 (Notice of damage) provides that if an inspector damages something when exercising a power, they must give notice of the damage to the owner of the thing;
- clause 184 (Compensation for exercise of powers generally) provides a person may claim compensation from the State if they incur loss because of the exercise of a power by an inspector;
- the appeal provisions in Chapter 6, Part 1, Division 5 (Appeals), which provide a person may appeal a property decision to seize or forfeit a thing under the Act to a Magistrates Court.

### *Entry procedure*

Clause 140 (General power to enter places) provides that an inspector may enter a place if:

- an occupier at the place consents to the entry;
- it is a public place and entry is made when the place is open to the public;
- the entry is authorised under a warrant;
- it is a professional practice place of a person authorised under the Act and the entry is made when the place is open for carrying on business or otherwise open for entry;
- it is an authorised place that is required to be open for inspection as a condition of the authorisation of the place; or
- a compliance notice or recall order has been given to a person and the inspector needs to check whether the notice or order has been complied with (clause 141) and the inspector has made a reasonable attempt to locate an occupier of the place and obtain their consent to the entry (clause 146).

Clause 140 is largely consistent with standard inspector powers and appropriate safeguards have been included in relation to the general power to enter places. For example:

- if the entry is by way of consent from the occupier:
  - the inspector must explain the purpose of the entry, including the powers intended to be exercised, and advise the occupier that they are not required to consent, that consent may be given subject to conditions and may be withdrawn at any time (clause 144),
  - the power is subject to any conditions of the consent and ceases if the consent is withdrawn (clause 140(3)),
  - the inspector may ask the occupier to sign an acknowledgement of the consent stating, for example, the purpose of the entry and powers to be exercised, the day and time of consent and any conditions of the consent (clause 145);
- if the entry is authorised under a warrant:
  - the power is subject to the terms of the warrant (clause 140(5)),
  - entry procedures under clause 152 (Entry procedure) must be complied with if there is an occupier of the place, for example, the inspector must identify themselves by producing their identity card, give the person a copy of the warrant and give the person an opportunity to allow the inspector immediate entry without the use of force, or make a reasonable attempt to do these things. The inspector is not required to comply with these requirements if they reasonably believe that entry to the place without compliance with these requirements is needed to ensure the execution of the warrant is not frustrated. The inclusion of such a power is justified on the basis that the issue of a warrant can only be made by a magistrate (see clause 147), and only if the magistrate is satisfied there are reasonable grounds for suspecting a particular thing or activity that may provide evidence of an offence against the Act exists at the place (see clause 148).

In relation to clause 145 (Consent acknowledgement), if the occupier signs a consent acknowledgement, the inspector must give the occupier a copy of the signed acknowledgement as soon as practicable and no later than one business day. There may be instances where an inspector has determined there is a need to seek entry, for example to seize a substance that may pose a threat to public health and safety, and is granted entry by the occupier. The inspector may handwrite an acknowledgement of consent for the occupier to sign. As the acknowledgement of consent is handwritten and signed by the occupier, it may not be possible to provide a copy of it to the occupier until the inspector returns to their office and can make a copy. This might occur, for example, if an inspector has observed something suspicious but they do not have a book with carbon copy paper on them. It may also occur in remote areas that do not have mobile phone coverage. One means used by inspectors due to advances in technology is to photograph the signed acknowledgement of consent with their mobile phone and either text or email the photograph to the occupier. This would not be possible to do immediately in an area that is not serviced with adequate mobile phone coverage.

In some cases, it may be in the interests of public health and safety, to gain entry to premises with consent, without giving a copy of a signed consent acknowledgement. For example, it may be preferable to complete the acknowledgement of consent after the entry, rather than risk losing access to a dangerous substance by returning later and risking that the substance may be moved or evidence lost.

It may also be preferable to give a copy of a signed acknowledgement of consent other than via a carbon copy produced at the time. Carbon copies are often difficult to read and the ink may not be visible in the long-term. Also, an occupier may deny that a copy of a signed acknowledgement of consent was given to them. However, if an inspector sends a copy by text

or email, this provides better proof that the inspector gave the occupier a copy of the acknowledgement. The ability to use these methods may not be available to the inspector immediately, and it may have to wait until the inspector returns to their office or reaches an area with mobile phone coverage. Therefore, enabling a copy of the consent acknowledgement to be given within one business day is an appropriate departure from the standard provision. The Bill ensures that investigations are not put at risk, allows better, more modern means of providing a copy of the signed acknowledgement of consent to be used by inspectors and also provides a better evidence trail.

A similar provision is included in section 34(5) of the *Tobacco and Other Smoking Products Act 1998*, which provides that an authorised person must promptly give a copy of a consent acknowledgement to the occupier.

Appropriate safeguards are included in relation to the consent acknowledgement, including under clause 145(4) that if an issue arises in a legal proceeding about whether the occupier consented to the entry and the acknowledgement is not produced in evidence, the onus is on the person relying on the lawfulness of the entry (that is, the inspector) to prove the occupier consented.

Under clause 140 an inspector has the power to enter a professional practice place, an authorised place or a place that is subject to a compliance notice or recall order. This is subject to the safeguard that the power does not authorise entry to a part of the place where a person resides (see clause 140(2)). The power to enter is necessary to ensure compliance in professional practices and protect the health and safety of the public, particularly in instances where a compliance notice or recall order have been made, as these places and/or persons have been associated with conduct that is known to risk public health.

For example, a compliance notice may have been given to a wholesaler where storage of controlled drugs is insufficient to prevent a theft, which may lead to the illegal availability of drugs of dependence. This may be easily rectified by the entity taking additional security measures, such as installing a safe or putting a restricted access, passcode lock on a storage door. The inspector may decide that the situation can be addressed by giving a compliance notice requiring the stated increase in security. It would be important for the inspector to be able to access the business premises at a later date to check if the changes required in the compliance notice had been made. Similarly, if a recall order has been given, the chief executive may order a licensed manufacturer to cease the production of a particular medicine if the production included the labelling of the medicine with incorrect information. An inspector would need to gain entry to the business premises at a later date to ensure all the medicine to which the recall order applied had been removed for destruction, or had been repacked or relabelled.

For a professional practice place or an authorised place, the Bill provides authority for a person to undertake a regulated activity, and there is an expectation that the activity would be subject to regulatory oversight as part of routine compliance activities. The power of entry is only allowed while the place is open for carrying on business or otherwise open (see clause 140(d)) and allows the inspector an opportunity to assess the normal operations of the business, for example a poisons manufacturer. Without these powers, inspectors would not be able to make on-the-spot inspections to collect evidence and avoid the possibility of evidence being destroyed, in order to enforce the Act.

In relation to the power to enter if a compliance notice or recall order has been given:

- clause 141 specifies that the inspector may enter at reasonable times to check compliance;
- clause 146 provides that an inspector must, before entering a place under clause 141, make a reasonable attempt to locate an occupier of the place and obtain the occupier's consent to the entry. If the inspector subsequently finds an occupier present at the place after being unable to locate an occupier, or the occupier refused to consent to the entry, the inspector must make reasonable attempts to produce their identity card for the occupier's inspection and inform the occupier of the reason for entering the place, and that the inspector is authorised under this Act to enter the place without the permission of the occupier. If the inspector enters the place after being unable to locate an occupier, they must leave a notice in a conspicuous position and in a reasonably secure way. The notice must state the date and time of the entry and information about the reason for entering the place and that the inspector is authorised to enter the place without permission.

### *Stopping or moving vehicles*

The Bill contains powers for inspectors to stop or move vehicles (see Chapter 5, Part 4, Division 1). These provisions apply if an inspector reasonably suspects, or is aware, that a thing in or on a vehicle may provide evidence of the commission of an offence against the Act (clause 153). This power is considered justified because until the vehicle is stopped or moved to a safe location, it may not be possible to properly inspect the vehicle for offences against the Act. For example, an inspector may notice liquid leaking from the back of a pest management vehicle which they suspect is a pesticide. Until the vehicle is stopped, an inspector would not be able to verify if it is a pesticide and if it was being stored appropriately in the vehicle. These provisions are also required, for example, where an inspector reasonably suspects scheduled substances are being transported by vehicle by a person who is not authorised to possess them. This may be because the goods are stolen, or Australian Customs may have alerted Queensland Health about a vehicle they are seeking that may contain an illegally imported scheduled substance. The powers may also be needed if a person is suspected of having removed documents or evidence from business premises and the inspector reasonably suspects they are in a vehicle of the business owner. A number of other Acts include a threshold of reasonable suspicion for the power to stop or move vehicles, including section 286 of the Biosecurity Act, sections 33 to 36 of the *Fair Trading Inspectors Act 2014* and section 84E of the *Forestry Act 1959*.

Clause 154 (Power to stop or move) provides inspectors with a power to direct a person to stop, move or not move a vehicle if the inspector reasonably suspects, or is aware, that a thing in or on a vehicle may provide evidence of the commission of an offence against the Act. Failure to comply with a direction given under clause 154 without a reasonable excuse carries a maximum penalty of 50 penalty units (see clause 156).

This power is considered justified noting that when giving a direction to move or not move a stopped vehicle, the inspector must give the person an offence warning for the direction (see clause 154(3)). If the vehicle is moving, clause 155 requires the inspector to clearly identify they are exercising powers, for example by using a loudhailer or sign. Once the vehicle stops, the inspector must immediately produce their identity card for inspection.

### *General powers after entering places*

The Bill provides for general powers of inspectors after entering places where entry is by consent, authorised under a warrant, to a professional practice place that is open for carrying

on business or otherwise open for entry, or to an authorised place that is required to be open for inspection as a condition of the authorisation of the place (see Chapter 5, Part 4, Division 2). These powers support inspectors' ability to undertake monitoring and compliance activities under the scheme.

Clause 158 (General powers) provides that an inspector may search, inspect, examine, film, take a thing for examination, place an identifying mark, take an extract or copy from a document, produce an image from an electronic document and remain at the place for the time necessary to achieve the purpose of the entry. Subsection (3) provides that if the inspector takes a document from the place to copy it, they must return it to the place as soon as practicable. Subsection (4) provides that if the inspector takes an article or device from the place that is reasonably capable of producing a document from an electronic document, they must produce the document and return the article or device to the place as soon as practicable.

Clause 159 (Power to require reasonable help) provides that the inspector may make a 'help requirement' of an occupier or person at the place to give the inspector reasonable help to exercise a general power, including, for example, to produce a document or give information. Failing to comply with a help requirement without a reasonable excuse carries a maximum penalty of 50 penalty units (clause 160). This power is justified as it enables the inspector to carry out their duties. Appropriate safeguards have been included, as the inspector must give the person an offence warning for the help requirement (clause 159(2)) and a person may have a reasonable excuse for not complying. It is a reasonable excuse not to comply with a help requirement if complying might tend to incriminate the individual or expose them to a penalty (clause 160(2)). However, the reasonable excuse does not apply if a document or information that is the subject of the help requirement is required to be held or kept by the person under the Act (clause 160(3)). Further justification about issues related to self-incrimination is provided below.

### *Seizure and forfeiture*

The Bill includes powers to allow an inspector to seize evidence or property (see Chapter 5, Part 4, Division 3). These powers are necessary to ensure enforcement of the scheme noting that these types of powers improve public health and safety by, for example, halting dangerous processes, securing dangerous substances, or ensuring evidence is not lost so that prosecutions may be undertaken. For example, if a retailer was selling a sports supplement containing a regulated substance that is harmful to human health, and the inspector was not able to seize the product, the retailer could continue to sell the product, exposing the public to health risks, or death, caused by the substance.

Clause 161 (Seizing evidence at a place that may be entered without consent or warrant) allows an inspector who enters a place without the consent of an occupier and without a warrant to seize a thing, based on a 'reasonable suspicion' that the thing is evidence of an offence against the Act. Clause 162 (Seizing evidence at a place that may be entered only with consent or warrant) allows an inspector who is authorised to enter a place with the consent of an occupier or a warrant to seize a thing if they reasonably suspect the thing is evidence of an offence against the Act and the seizure is consistent with the purpose of entry. The inspector may also seize anything else at the place if the inspector reasonably suspects the thing is evidence of an offence against the Act and the seizure is necessary to prevent the thing being hidden, lost or stolen, or if the inspector reasonably suspects the thing has just been used in committing an offence against the Act.

The equivalent Health Act provisions (sections 153A and 153B) and Pest Management Act provisions (sections 72 and 73) required the inspector to have a reasonable belief that the thing is evidence of an offence. It is considered that the threshold of 'reasonable suspicion' under the Bill is justified because it may be critical for public health and safety to seize evidence of an offence against the Act. For example, it may be vital that a dangerous substance is seized to prevent it from being distributed, or to prevent a person who is in illegal possession of a dangerous substance from disposing of that substance (for example a dangerous poison) so as to get rid of evidence, and the disposal method might prove dangerous to the environment and/or human health. An inspector may be unable to determine exactly what a substance is or contains on first inspection, with most substances requiring analysis before an inspector is able to reasonably believe it is or contains a particular substance. Therefore, at the time of seizure, it is generally only possible for an inspector to have a reasonable suspicion based on the ingredients listed on the label or information from similar products.

A threshold of reasonable belief requires the inspector to believe the thing is evidence of an offence on grounds that are reasonable in the circumstances. A reasonable belief requires knowledge of facts, although an inspector may not be in possession of all of the facts when monitoring compliance with the Bill. For example, to form a reasonable belief that a container of clear liquid is cyanide, the inspector would be required to test the liquid by taking a sample and arranging for it to be analysed in a laboratory by the State Forensic and Scientific Services (FSS) or a contracted scientific analysis service. This causes practical difficulties for inspectors, as it is not possible to carry out testing of the evidence without first seizing it, as the facilities used to test these types of substances are not mobile. Without the ability to seize a thing based on reasonable suspicion, the potentially harmful substance would remain in the possession of its owner and potentially be available to the public.

Although the reasonable belief threshold requires a basis in fact, a threshold of reasonable suspicion allows an inspector to suspect the thing is evidence on grounds that are reasonable in the circumstances and that would also seem reasonable to others. This would enable an inspector to form a reasonable suspicion based on a range of factors such as there being no labels on liquids, signs of removal of documentation, labels or invoices in foreign languages, the volume or storage method of a substance which may obscure the ability to obtain sufficient facts, complaints made to Queensland Health by the public about health-related side effects or efficacy of substances or missing entries in registers, for example the S8 and prohibited substance register. A reasonable suspicion threshold is appropriate in a medicines and poisons context because of the nature of the substances being regulated. Firstly, it is often impossible to gather facts required to hold a reasonable belief because the substances may not be identifiable by observation alone. Frequently, scientific analysis is required, and this can only be done through seizing the substance. Secondly, for regulated substances, there may be a danger of significant public or environmental harm if the suspected substance is not seized.

Therefore, requiring an inspector to hold a reasonable suspicion that the thing is evidence of an offence against the Act is considered an appropriate threshold, noting the significant potential public health and safety and environmental ramifications from failing to enforce the framework and the impracticalities associated with meeting the reasonable belief threshold. Allowing an inspector to seize a thing on the basis of reasonable suspicion will improve effective enforcement of the scheme by preventing persons from removing or destroying the thing that may be evidence for an offence against the Act.

A number of other Acts include a threshold of reasonable suspicion for seizure of things, including the Forestry Act (section 18(1)(ga)(i)), *Major Events Act 2014* (section 54), *Mental Health Act 2016* (section 403), Public Health Act (section 157ZD) and *Police Powers and Responsibilities Act 2000* (sections 53A, 135(4)(f), 157(1)(h), 196, 603).

Clause 163 (Seizure of property subject to security) provides an inspector may seize and exercise powers relating to a thing, despite a lien or other security over the thing claimed by another person. The seizure does not affect the other person's claim to the lien or other security against a person other than the inspector or a person acting under the authority of the inspector. This power is necessary as the entity may not own the equipment or substance at the place due to contractual or leasing arrangements. The seizure of the equipment or substance does not cancel the entity's financial responsibility under other agreements or transfer financial responsibility to the State. This is a standard provision used in Acts containing provisions about inspectors' powers (for example, section 43 of the Fair Trading Inspectors Act). It is appropriate that an inspector should not be prevented from seizing property just because a security interest or a lien has been taken over the property. Also, subsection (2) provides that a security interest in personal property is not affected by seizure of that property by an inspector. The person holding a security interest retains their interest in the property. The Bill does not affect or undermine the protections afforded by the *Personal Property Securities Act 2009* (Cth).

Clause 164 (Power to secure seized thing) provides an inspector may leave a seized thing at the place of seizure and take reasonable action to restrict access to it. To restrict access to the thing, the inspector may seal the thing or the entrance to the place of seizure, and mark the thing or place to show that access is restricted; make equipment inoperable or require the person in control of the place or thing to undertake these measures to restrict access to the thing. Failure to comply with a requirement to restrict access without a reasonable excuse carries a maximum penalty of 50 penalty units (see clause 165). For example, in tracing the origin of a medicine that has been supplied in an unauthorised way to a person, an inspector may discover premises containing a significant amount of a scheduled medicine that the occupier of the premises is not authorised to possess. To prevent the substance being removed from the premises or being made available to the public, the inspector may restrict access by placing a padlock on each entry point until arrangements can be made to transport the substance from the premises. This action can help protect the public from any further risk of harm.

Appropriate safeguards are included in relation to the inspectors' powers to seize things:

- clause 167 (Receipt and information notice for seized thing) provides an inspector must, as soon as practicable after seizing the thing, give the owner a receipt for the thing that generally describes the thing, its condition and an information notice about the decision to seize it. The inspector may delay giving the receipt and information notice if they reasonably suspect giving them may frustrate or otherwise hinder an investigation. The threshold of reasonable suspicion is included in a range of other legislation including the *Health Ombudsman Act 2013* (section 218), Hospital and Health Boards Act (section 235(5)) and Mental Health Act (section 586(5)). This is justified as the delay may only be for so long as the inspector continues to have a reasonable suspicion and remains in the vicinity of the place where the thing was seized to keep it under observation;
- clause 168 (Access to seized thing) provides until the seized thing is forfeited or returned, the inspector must allow the owner of the thing to inspect it at any reasonable time and from time to time. The inspector must allow the owner to copy a document free of charge;

- clause 169 (Return of seized thing) provides that if a seized thing is not forfeited, transferred or subject to a disposal order, as soon as the chief executive stops being satisfied there are reasonable grounds for retaining the seized thing, the chief executive must return it to its owner. If the thing is not returned to its owner within three months of being seized, the owner may apply to the chief executive for its return.
- clause 203 (Appealing seizure or forfeiture decision) provides that a person who is given an information notice for a decision of the chief executive to seize a thing may appeal the decision to a Magistrates Court.

The Bill includes powers relating to forfeiture and disposal of seized things (see Chapter 5, Part 4, Division 3, Subdivisions 4 and 5 and Division 4). These powers are necessary to ensure that things that are evidence of an offence against the Bill and could be potentially harmful or inappropriate for continued use can be dealt with appropriately. For example, a tattoo ink that has been seized and found to contain high concentrations of amines, which are carcinogenic to humans when injected into the skin, should not be returned to a tattoo parlour, but destroyed, so there is no risk related to its continued use. Another example would be if a regulated medicine is seized and it has not been made by a licensed manufacturer. In these circumstances, it would be appropriate for the seized medicine to be forfeited to the State and disposed of in the correct manner, for example by sending it to an approved entity for disposal. Due to the method of manufacture, the medicine may not accord with what it is labelled to be, for example the strength of the medication may be excessive, posing a danger to anyone taking the medicine. Another example might be a manufacturing plant may not have complied with the *PIC/S Guide to Good Manufacturing Practice for Medicinal Products* (PE009-13, 01 January 2017), which, except for Annexes 4, 5 and 14, has legal force in Australia and is available at: <https://www.tga.gov.au/publication/manufacturing-principles-medicinal-products>. This may have resulted in the medicine being contaminated and therefore not safe to take, even if taken in accordance with the label. This may cause a public health and safety risk.

Clause 170 (Forfeiture by chief executive decision) permits the chief executive to decide a seized thing is forfeited to the State if an inspector cannot find its owner after making reasonable inquiries, cannot return it to the owner after making reasonable efforts or reasonably believes it is necessary to keep the thing to prevent it from being used to commit the offence for which it was seized. Clause 171 (Information notice about forfeiture decision) provides that an information notice must be given to the owner of the forfeited item. If an owner cannot be found, an information notice must be left in a conspicuous position and in a reasonably secure way at the place where the thing was seized.

Clause 203 (Appealing seizure or forfeiture decision) provides that a person who is given an information notice for a decision of the chief executive to forfeit a thing may appeal the decision to a Magistrates Court.

Clause 172 (When thing becomes property of the State) provides a thing becomes property of the State if it is forfeited to the State, or the owner and the State agree in writing to transfer ownership to the State. Clause 173 (How property may be dealt with) provides that if a thing becomes the property of the State under clause 172, the chief executive may deal with the thing as they consider appropriate, including destroying it or giving it away.

Clause 174 (Disposal order) provides that a court may make a disposal order authorising the disposal of anything owned by a person convicted of an offence under the Act, that was either

the subject of, or used to commit, the offence. A disposal order may also be made in relation to another thing the court considers likely to be used by the person or another person in committing a further offence against the Act.

*Powers to require production of documents and information*

The Bill includes powers to require production of documents and information (see Chapter 5, Part 4, Division 5).

Clause 175 (Power to require name and address) provides an inspector with the power to require a person to state their name and residential address. This power is applicable if the inspector finds the person committing an offence against the Act, in circumstances that lead the inspector to reasonably suspect the person has just committed an offence against the Act or the inspector has information that leads the inspector to reasonably suspect an offence has just been committed. The reasonable suspicion threshold is included for name and address powers across a range of Acts. Failure to comply with the requirement without a reasonable excuse carries a maximum penalty of 50 penalty units (clause 176). This power is justified as in order to effectively undertake compliance with the scheme, inspectors require correct information about persons found to be committing, or suspected of committing, an offence. Appropriate safeguards are included, with the inspector required to give the person an offence warning for the requirement.

Clause 177 (Power to require production of document) provides an inspector may require a person to make available for inspection or produce a document required to be kept by the person under the Act or a document given to the person under the Act. The inspector may keep the document to copy it. If the inspector copies the document, they may require the person responsible for keeping the document to certify the copy as a true copy. These powers are justified as in order to effectively undertake compliance with the scheme, inspectors require access to documents kept under the Act. Appropriate safeguards are included, with the inspector required to return the document to the person as soon as practicable after copying it. Similar powers are found in the *Transport Operations (Road Use Management) Act 1995* (section 49) and *Transport Operations (Passenger Transport) Act 1994* (section 126M).

Clause 178 (Offence to contravene document production requirement) provides it is an offence with a maximum penalty of 50 penalty units for a person to fail to comply with a document production requirement unless the person has a reasonable excuse. It is not a reasonable excuse for a person to fail to comply with a document production requirement on the basis that complying with the requirement might tend to incriminate the person or expose the person to a penalty. However, a limited immunity applies under clause 188 against the future use of the information or document.

Clause 179 (Offence to contravene document certification requirement) provides it is an offence with a maximum penalty of 50 penalty units to fail to comply with a document certification requirement unless the person has a reasonable excuse. It is not a reasonable excuse for a person to fail to comply with a document certification requirement on the basis that complying with the requirement might tend to incriminate the person or expose the person to a penalty. However, a limited immunity applies under clause 188 against the future use of the information or document.

Clause 180 (Power to require information) provides that an inspector may require a person to provide information to the inspector related to an offence by a stated reasonable time. This power applies if the inspector reasonably believes an offence against the Act has been committed and the person may be able to give information about the offence. As above, this power is required to ensure inspectors can undertake enforcement of the scheme by having access to relevant information. The failure to comply with this requirement without a reasonable excuse carries a penalty of 50 penalty units (clause 181). It is a reasonable excuse not to give the information if giving it might tend to incriminate the individual or expose them to a penalty. It is appropriate to include this safeguard for information provided to an inspector in accordance with the general principle that legislation should provide protection against self-incrimination. This safeguard is not included in relation to document production and certification noting that where a person is required to keep a document under legislation, it is appropriate to waive the benefit of the self-incrimination rule in relation to that document.

Similar powers to require information or production of documents are included in a range of Acts, including sections 120 and 323 of the Biosecurity Act, section 154 of the *Coal Mining Safety and Health Act 1999*, section 107 of the *Drugs Misuse Act 1986*, sections 85 and 466 of the *Environmental Protection Act 1994*, section 199 of the Food Act, and sections 126M and 129 of the *Transport Operations (Passenger Transport) Act 1994*. The current Pest Management Act also contains a power to require production of documents in section 85.

***Does the legislation provide appropriate protection against self-incrimination?***

Section 4(3)(f) of the Legislative Standards Act provides that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether it provides appropriate protection against self-incrimination.

Clause 178 (Offence to contravene document production requirement) and clause 179 (Offence to contravene document certification requirement) provide that it is not a reasonable excuse for a person to fail to comply with a document production or document certification requirement on the basis that complying with the requirement might tend to incriminate the person or expose the person to a penalty.

The former Scrutiny of Legislation Committee considered that it may be easier to justify the abrogation of the privilege against self-incrimination if a person is required to produce documents required to be issued or kept under an Act. Similarly, the Queensland Law Reform Commission, in its 2004 report, *The Abrogation of the Privilege Against Self-Incrimination*, noted that by participating in a statutory scheme, such as through obtaining a licence or other form of registration, a person has, as a condition of participation, accepted the enforcement provisions and waived the benefit of the privilege against self-incrimination. The Commission also observed that to allow a claim of privilege in relation to records of this type would thwart the purpose of the legislation, since it would facilitate a failure to keep the records, or their destruction or falsification, with little fear of detection.

The documents required to be produced under clauses 178 and 179 are documents given to the person under the Act or documents required to be kept under the Act, so they fall directly within the categories of documents identified by the Scrutiny Committee and Law Reform Commission, as outlined above.

Without cooperation by the person who has been given or is required to keep a document under the Act, it would not be possible for the inspector to gather relevant information by alternative means. For example:

- each authority holder who is required to keep a substance management plan will have a plan that outlines the management of foreseeable risks for their industry and premises, or an authority holder who is required to keep an S8 medicines register or a poisons register will have entries in the register that are unique to their dealings with the substances.
- Queensland Health inspectors may require information from a document such as a prescription from a pharmacy, where that prescription is suspected of having been dispensed incorrectly or may not be compliant. The prescription is only able to be retrieved from the pharmacy as the individual is unlikely to have it once they have received the prescribed substance. The purpose of the prescription as evidence is to confirm whether the substance has been dispensed correctly or is compliant with the requirement and that the pharmacist has dispensed in the authorised way or if an authorised prescriber has prescribed in the authorised way.

This potential breach is considered justified as the provisions enable inspectors to enforce the framework - if they were not able to request documentation on the grounds it might incriminate, their enforcement capability would be compromised.

If inspectors are not able to obtain such documents on the grounds that the authority holder may self-incriminate themselves, an inspector would not be able to identify and act on non-compliance with the person's conditions of authority. Compromising enforcement capability for an individual's right to protect oneself against self-incrimination could have serious ramifications to wider public health and safety. For example:

- if an approval holder who is authorised to deal with a prohibited substance had not been maintaining their S8 medicines register or a poisons register, there is risk of diversion of S8 and prohibited substances, which can result in serious harm to human health.
- a doctor may be asked to provide a document such as the S8 medicine register for an investigation. The investigators would require a certified copy of the register for the investigation as evidence and would need to see the original register to determine whether any breaches have occurred. The purpose of having a certified version of the document is so that the copy can be used for the ongoing investigation while the doctor continues to use their original version, enabling the doctor to continue to practise, albeit in a potentially restricted way. If the doctor does not provide this document as required, it could hinder the investigation and allow them to practise for a longer term, posing a public health risk.

An appropriate safeguard is provided in clause 188 (Evidential immunity for individuals complying with particular requirements), which states that evidence of the information or document given under clauses 159 (Power to require reasonable help) or 177 (Power to require production of document), and other evidence directly or indirectly derived from the information or document, is not admissible against the individual in any proceeding to the extent it tends to incriminate the individual, or expose the individual to a penalty, in the proceeding.

***Does the legislation adversely affect rights and liberties, or impose obligations, retrospectively?***

Section 4(3)(g) of the Legislative Standards Act provides that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation does not adversely affect rights and liberties, or impose obligations, retrospectively.

Clause 225 (Information recorded in database) provides that a regulation may prescribe information that must be recorded by the chief executive in the monitored medicines database. The prescribed information may include information obtained under the repealed Health Act before the commencement of the clause, despite the purpose for which the information was obtained or created. This clause may be seen to breach section 4(3)(g) of the Legislative Standards Act. It is necessary to include information obtained under the Health Act noting that upon the database becoming operational, information regarding Queensland Opioid Treatment Program patients will be transferred for those who are currently on the program, along with information relating to patients who were previously on the program. This is considered justified as a patient's history of drug dependence is a strong predictor of a patient relapsing into drug seeking behaviour. Current and past admission into the opioid treatment program is relevant to ongoing clinical management for promoting safe practices for therapeutic use of monitored medicines.

Clause 281 (Procedure until monitored medicines database operational) sets out transitional arrangements to deal with the application of the monitored medicines database provisions until the monitored medicines database is operational. During the transition period, that is, between commencement of the transitional provision and a day prescribed by regulation as the day the database is fully operational, a person will not be subject to relevant offence provisions (clauses 41 and 226), and sections 84(2)-(10), 84A(3) and (4), 120, 122, 213 and 213A of the *Health (Drugs and Poisons) Regulation 1996*, which provide for approvals for the treatment of drug dependent persons, continue to apply as they did immediately before commencement of the legislative framework.

Section 84 of the Health (Drugs and Poisons) Regulation applies to a dispenser who dispenses a controlled drug on a paper prescription or administers or supplies a controlled drug on a written instruction. The section provides that the dispenser must record particular information when dispensing, administering or supplying a controlled drug and send the chief executive the prescription or information.

Section 84A of the Health (Drugs and Poisons) Regulation applies to a dispenser who dispenses a controlled drug on an electronic prescription. The section provides that the dispenser must send the chief executive the electronic prescription and must immediately give the chief executive written notice if they are asked to dispense more of a controlled drug or more frequently than appears to be reasonably necessary.

Section 120 of the Health (Drugs and Poisons) Regulation applies where a doctor or nurse practitioner treats a patient with a controlled drug for more than two months, or reasonably suspects a patient has been treated with a controlled drug by another doctor or nurse practitioner for more than two months and intends to use a controlled drug in the treatment of a patient. The doctor or nurse practitioner is required to immediately give the chief executive a written report about the circumstances of the patient's treatment. The chief executive may ask for additional information about the treatment of the patient.

Section 122 and 213 of the Health (Drugs and Poisons) Regulation state that a relevant practitioner must not dispense, prescribe, administer or supply a controlled drug or restricted drug of dependency if they reasonably believe a person is a drug dependent person. Section 213A states that a dentist must not dispense, prescribe, administer or supply a restricted drug of dependency if they reasonably believe a person is a drug dependent person.

Clause 281 provides that the clause does not prevent a person complying with the Act to the extent practicable if the database is able to be used during the transition period. This will allow prescribers and dispensers to begin familiarising themselves with the system during the transition period. Relevant offences for misusing the database will apply during the transition period.

Clause 281 is necessary to ensure that if the monitored medicines database is not operational by the commencement of the legislative framework, prescribers and dispensers continue to have access to the current information telephone line that advises prescribers who call the line about controlled drugs dispensed for patients. For example, prescribers may call to check whether a patient is part of the Queensland Opioid Treatment Program before the monitored medicines database is operational. Clause 281 does not have retrospective application, but rather continues the effect of existing provisions for a transitional period, until the new provisions become operational.

Clause 282 (Transitional regulation-making power) provides that a regulation may make provision of a saving or transitional nature about any matter for which it is necessary to make provision to allow or facilitate the doing of anything to achieve the transition from the Health Act or the Pest Management Act to this Act, and for which this Act does not make provision or sufficient provision. The clause provides that a transitional regulation may have retrospective operation to a day that is not earlier than the day on which clause 282 commences.

Clause 282 may be seen to breach section 4(3)(g) of the Legislative Standards Act as it provides a head of power for a transitional regulation which may have retrospective operation. This is appropriate as the retrospective operation can only be to a day that is not earlier than the day on which clause 282 commences. Although the Bill provides for a range of transitional issues, it is possible that unanticipated matters may arise given the complexity of transitioning to the new Bill. The inclusion of such a power will ensure that any transitional issues that have not been identified during the drafting of the provisions can be quickly addressed to ensure individuals' rights are not adversely affected.

A similar transitional provision has been included in a range of other Acts, including repealed section 86 of the *Ambulance Service Act 1991*, repealed section 9A of the Health Practitioner Regulation National Law Act and repealed section 202 of the Transport Operations (Road Use Management) Act.

***Does the legislation confer immunity from proceeding or prosecution without adequate justification?***

Section 4(3)(h) of the Legislative Standards Act provides that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation does not confer immunity from proceeding or prosecution without adequate justification.

The former Scrutiny of Legislation Committee stated that one of the fundamental principles of the law is that everyone is equal before the law and should be fully liable for one's acts or omissions. However, the Committee recognised that the conferral of immunity is appropriate in certain situations, such as to persons carrying out statutory functions.

Clause 49 (State officers and helpers) provides state officers do not commit an offence against the Act only because the State officer carries out the officer's functions or exercises the

officer's powers. The conferral of immunity on these persons is appropriate given their enforcement role under the Act, noting the Scrutiny of Legislation Committee's position.

Clause 50 (Persons authorised under other laws) provides a person who has an approval, licence, permission or other authority under another Act or a law of the Commonwealth that permits the person to do something in Queensland that is, or involves, carrying out a regulated activity with a regulated substance (a related authority) is taken to not have committed an offence against the Act to the extent the person acts under the related authority. This provision ensures that where a person has an equivalent authority under another Act, for example, an approval under the *Work Health and Safety Act 2011* to possess a restricted carcinogen that is also a restricted S7 poison, this would be considered equivalent to an approval under this Act for the substance. The conferral of immunity on these persons is justified noting they are authorised under another Act to carry out a regulated activity and that prosecuting them for an offence under the Medicines and Poisons Act would not be in accordance with the policy intent of the framework.

Clause 188 (Evidential immunity for individuals complying with particular requirements) provides that evidence of the information or document given under clauses 159 (Power to require reasonable help) or 177 (Power to require production of document) and other evidence directly or indirectly derived from the information or document, is not admissible against the individual in any proceeding to the extent it tends to incriminate the individual, or expose the individual to a penalty, in the proceeding. This provision is justified as it is included as a safeguard against the potential FLP in clauses 178 and 179 relating to self-incrimination.

***Does the legislation in all other respects have sufficient regard to the rights and liberties of individuals?***

A number of FLP issues not specifically contained in the Legislative Standards Act are discussed below.

***Right to privacy***

The right to privacy, the disclosure of private or confidential information, doctor-patient confidentiality, and privacy and confidentiality issues have generally been identified by the former Scrutiny of Legislation Committee as relevant to consideration of whether legislation has sufficient regard to individuals' rights and liberties.

The Bill contains a range of provisions that may be seen to infringe upon the privacy of individuals, including provisions relating to collection and storage of personal information, confidentiality requirements, establishment of the monitored medicines database and keeping and publishing of registers. These provisions are considered to be justified as adequate safeguards are in place and the provisions enable the operation of the Act and protect the health and safety of the public. In addition, information that is shared may also assist relevant compliance entities to undertake well-informed and comprehensive investigations into activities that may endanger the health and safety of the public. The inability of Queensland Health to provide this information may cause a public health risk if not addressed appropriately through compliance orders or prosecution.

### Confidentiality provisions

Chapter 7, Part 2 of the Bill (Confidentiality) sets out the confidentiality requirements for the framework, including where disclosure is permissible. The inclusion of these provisions is necessary to ensure that information that has become known to the administrator of the Act in the course of performing their functions is kept confidential and disclosed in permitted circumstances only. The term ‘administrator’ is defined in clause 219 of the Bill.

Clause 220 (Confidentiality of information) provides it is an offence with a maximum penalty of 50 penalty units for an administrator to directly or indirectly disclose confidential information or criminal history information to another person unless the disclosure is permitted under the Medicines and Poisons Act, if the disclosure is otherwise required or permitted by law, if the person to whom the information relates consents to the disclosure or the disclosure is in a form that does not identify the person to whom the information relates.

Disclosure of confidential information is permitted in the circumstances outlined below.

### Entities performing relevant functions

Clause 221 (Disclosure of information to entities performing relevant functions) provides that an administrator may disclose confidential information to particular entities if satisfied that the provision of the confidential information is necessary for the entity to exercise its functions and the confidential information will be collected, stored, and used by the entity in a way that protects the privacy of the persons to whom the information relates from unjustified intrusion.

An administrator may disclose confidential information to a health ombudsman official; a coroner investigating a death under the *Coroners Act 2003*; the chief executive of the department in which the Food Act or the *Food Production (Safety) Act 2000* is administered; a law enforcement agency for the purpose of detecting, investigating, preventing or prosecuting an offence in relation to a regulated substance; the Australian Health Practitioner Regulation Agency (AHPRA) or a National Health Practitioner Board; the APVMA for performing its functions under the *Agricultural and Veterinary Chemicals Act 1994* (Cth) or the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth); the Secretary performing their functions under the Commonwealth Therapeutic Goods Act or the *Therapeutic Goods Act 2019* (Qld) which is proposed to be enacted through the Therapeutic Goods Bill 2019; a corresponding law entity (that is, an entity of the Commonwealth or another State that administers, or performs functions in relation to, a corresponding law); or another entity of the Commonwealth or another State performing its functions relating to a practitioner law, the management of health and safety risks in public places and workplaces or the importation or exportation of goods or substances into or from Australia.

The regulation of medicines and poisons involves a range of different entities. These entities require information from Queensland Health to enable them to exercise their functions effectively, especially as the information collected by Queensland Health may form the core evidentiary basis of their investigations or action. Queensland Health collects and has immediate access to information that another entity may not have access to or be able to collect and store. For example, Queensland Health is able to provide a coroner with prescribing patterns of practitioners if it is relevant to an investigation. There are also circumstances where Queensland Health needs to provide the APVMA with information on inspections or notify them of a business supplying unregistered pesticides, or to notify the Health Department in

another state or territory of compliance actions being taken against a Queensland licensed pest management technician seeking registration in the other jurisdiction.

The Health Ombudsman's 2016 Investigation report, *Undoing the knots constraining medicine regulation in Queensland*, noted that building and maintaining effective and efficient partnerships is a core requirement of any complex regulatory framework and that there is a lack of information-sharing between agencies that deal with many interrelated matters each year. The Health Ombudsman recommended that Queensland Health explore changes to legislation to improve the ability of agencies involved in S8 medicine management to share relevant and confidential information to improve the timeliness of risk mitigation strategies to ensure health and safety of the public. Clause 221 has been included in the Bill partly in response to implementing the Health Ombudsman's recommendation.

Clause 221 is justified to enable information-sharing between appropriate entities for the purpose of administering the scheme. The provision may also be used to support the operation of the monitored medicines database and corresponding databases in other jurisdictions, as it will allow Queensland Health to disclose information through the National Data Exchange, which will underpin the monitored medicines database. The information in the database will be used to promote safe practices for supplying, prescribing and dispensing regulated substances.

Appropriate safeguards have been included in the provision. The administrator may only disclose confidential information to the entity if satisfied that the disclosure is reasonably necessary for the entity to exercise its functions, and the information will be collected, stored, and used by the entity in a way that protects the privacy of the persons to whom the information relates from unjustified intrusion. The entities listed under clause 221 are established by either the State, Territory or Commonwealth Governments and are bound under relevant legislation such as the *Public Service Act 2008* and *Information Privacy Act 2009* or equivalent State, Territory or Commonwealth legislation. These entities are also subject to their own respective legislation which outlines the requirements for collection, storage and use of confidential information provided to them. An example is section 17 (Disclosure of confidential information to coroner) of the Coroners Act, which provides that a coroner may only disclose information obtained under the section for a purpose connected with the investigation being conducted by the coroner.

### Therapeutic treatment

Clause 222 (Disclosure for therapeutic treatment of person) provides that an administrator may disclose confidential information to a health practitioner if the health practitioner is providing therapeutic treatment to the person to whom the information relates and the disclosure is reasonably necessary for the treatment of the person.

This provision is justified as it balances the individual's right to privacy with the need to ensure appropriate information-sharing to enable the therapeutic treatment of a person. For example, Queensland Health may need to disclose confidential information to a pharmacist who is authorised to dispense a regulated substance and needs to clarify or confirm that the prescriber is authorised to prescribe that substance. This would also be applicable in situations where a doctor may contact Queensland Health in relation to a patient's methadone treatment to prevent instances of doctor shopping. Appropriate safeguards are included. The information must be necessary for the therapeutic treatment or health care of an individual. Also, a registered health

practitioner to whom the administrator discloses the information is subject to the Health Practitioner Regulation National Law, which contains provisions regarding the application of the *Privacy Act 1988* (Cth) and the disclosure and confidentiality of information.

### Requests for information

Clause 223 (Requests by chief executive for information) provides the chief executive may by way of a notice, direct the head of a public sector unit to give information to the chief executive within a stated reasonable time. The request may be made if the chief executive considers the public sector unit has information, including confidential information, that is reasonably necessary to carry out the chief executive's functions under the Act, and to urgently prevent a health risk in relation to a substance.

The head of the public sector unit must comply with the notice unless they reasonably considers the disclosure of the information would prejudice the investigation of a contravention, or possible contravention, of a law; prejudice the effectiveness of a lawful method or procedure for preventing, detecting, investigating or otherwise dealing with a contravention or possible contravention of a law; or would endanger a person's life or physical safety. The *head* of a public sector unit is defined to mean the chief executive of the unit.

This provision is justified as the public sector unit may have been notified of an incident that has associated public health impacts. For example, the Department of Environment and Science may be investigating an environmental chemical spill and be unable to issue a public warning due to the status of their investigation. The chief executive could request details of the spill so that a timely health warning can be issued.

There are instances when Queensland Health may require further information for a variety of activities that are within scope such as investigations, amendments to EPAs and the creation of emergency orders. For example, DAF conducts compliance investigations for animal stock feed manufacturers under the Agricultural and Veterinary Chemicals (Queensland) Act, which records information on the manufacturing practices and ingredients used. This information may be useful to Queensland Health for instances of contamination or traces of an illegal substance being used and action needing to be taken.

Appropriate safeguards are included, with the chief executive and public sector unit required to ensure the information provided relates only to the chief executive's functions under the Act, and to the extent possible, that the privacy of the person to whom the information relates is protected from unjustified intrusion. Depending on the nature of the request for information, this may require personal information that may identify an individual to be removed and that only relevant data is provided. An additional safeguard is included, with the public sector unit not required to comply with the notice if it reasonably considers the disclosure would fall within one of the categories outlined above.

### Monitored medicines database

Chapter 7, Part 3, Division 1 (Monitored medicines database) provides for the establishment of the monitored medicines database and requirements relating to information recorded on the database. These provisions may be seen to breach individuals' right to privacy by providing for the recording of information, including personal information, in the database, and providing people with access to information contained in the database. These concerns have been

balanced against the need to protect and promote the health of the public and are considered justified. The establishment of a real-time prescription monitoring system will aid clinical decision-making by allowing prescribers and dispensers access to real-time prescription and dispensing information before they prescribe or dispense dependence-forming medicines.

Clause 224 (Chief executive to keep database) provides the chief executive must keep the monitored medicines database to record information about the prescription and supply of monitored medicines. The clause sets out the purposes of keeping the database, including to promote safe practices for the therapeutic use of monitored medicines and reduce community harm caused by them, and to enable particular health practitioners to access the database to record and review information for the therapeutic treatment of persons.

Clause 225 (Information recorded in database) provides that a regulation may prescribe the information that must be recorded on the database by the chief executive. The information may include personal information; information obtained under the repealed Health Act before the commencement of the clause, despite the purpose for which the information was obtained or created; and information obtained under a law of another jurisdiction for a purpose mentioned in clause 224.

This is necessary to ensure the effective administration of the database. The system will only be effective for its intended therapeutic use and the promotion of safe supply, prescribing and dispensing, if users have access to relevant information, including a patient's personal information.

It is necessary to include information obtained under the Health Act, noting that (upon the database becoming operational), information regarding Queensland Opioid Treatment Program patients will be transferred for those who are currently on the program, along with information relating to patients who were previously on the program. This is considered justified as a patient's history of drug dependence is a strong predictor of a patient relapsing into drug seeking behaviour. Current and past admission into the opioid treatment program is relevant to ongoing clinical management for promoting safe practices for therapeutic use of monitored medicines.

The inclusion of information obtained under other jurisdictions' medicines and poisons legislation is necessary to give effect to the benefits from the proposed National Data Exchange. The National Data Exchange will capture the prescription dispensing event data from all States and Territories. Under this arrangement, Queensland will have access to its own data, and the data of other States only upon agreement with the respective jurisdiction. The inclusion of all dispensing events for a person will allow a prescriber or dispenser to view all access to monitored medicines for people who travel across State borders seeking prescriptions for monitored medicines. People who doctor shop have been found to travel from town to town up the eastern coast of Australia or between regional centres in western Queensland and New South Wales.

Clause 226 (Giving information) provides that an information provider must give the chief executive the information at the time, and in the way, prescribed by regulation, unless they have a reasonable excuse. It is an offence with a maximum penalty of 100 penalty units for a person to fail to give the chief executive the information. This offence is included to ensure that prescribers and dispensers provide relevant patient information for inclusion in the database. As noted above, this is necessary to ensure the database is effective, as the system

will only be of therapeutic use if users have access to relevant information. For example, to promote safe practices for the therapeutic use of monitored medicines, prescribers and dispensers need visibility of a patient's complete monitored medicines dispensing history, to help inform clinical decision-making. Compelling dispensers to provide this information to the chief executive (i.e. into the monitored medicines database) allows this visibility.

Clause 227 (Use of information) provides that the chief executive may disclose information in the database to a user by giving them the information or giving the user electronic access to the database. The chief executive may disclose the information to the user only for a purpose prescribed by regulation for the user. The purposes for which particular users will be granted access to the database or given information from the database will include providing electronic access to prescribers and dispensers who are treating individual patients, access to database administrators for the purpose of system improvement and maintenance, and access to the Health Ombudsman to support its functions. This provision will enable the operation of the database by ensuring that patient information relating to monitored medicines is recorded and checked by prescribers and dispensers in accordance with the scheme. Clause 41 (Restrictions for monitored medicines) requires prescribers and dispensers to check the database before prescribing, supplying, dispensing or giving a treatment dose of a monitored medicine to a person.

Granting users access to and use of the database is justified to support the operation of the scheme and to implement the Health Ombudsman's recommendation in the 2016 Investigation report, *Undoing the knots constraining medicine regulation in Queensland*, to introduce a real-time prescription monitoring system. It is also justified to support the implementation of recommendation I(a) of the Coroners Court of Queensland Findings of Inquest into the deaths of William John House, Vanessa Joan White, Jodie Anne Smith and Daniel Keith Milne, delivered in 2018. The report recommended Queensland Health urgently consider and determine how a real-time prescription monitoring system could be implemented in Queensland at the earliest opportunity.

Granting users access to the database is also strongly advocated for by peak medical, pharmacy and consumer bodies, including the Australian Medical Association, the Pharmaceutical Society of Australia, the Pharmacy Guild of Australia, the Royal Australian College of General Practitioners, Consumers Health Forum of Australia and others. Appropriate safeguards have been included in the Bill, with prescribers and dispensers bound by their professional obligations in relation to confidentiality of patient information. Apart from the automated 'upload' of dispensing data by dispensers, the monitored medicines database will be read-only for prescribers and dispensers. It is intended they will be unable to record information in the database.

The chief executive may also impose a condition on a user for accessing or using information from the database if the condition is consistent with a purpose mentioned in clause 224 or prescribed by regulation for the user under this clause. Offences will be included in the scheme to prevent misuse of the database.

### Registers

Chapter 7, Part 3, Division 2 (Registers) provides for the chief executive to keep and publish registers relating to substance authorities, as well as administrative action taken in relation to substance authorities and authorisations.

The intent of these provisions is to enable people engaging with a licence or approval holder or an approved person to determine if the person holds the appropriate authority for the activity they are carrying out. For example, the registers will allow a consumer to check that a pest management technician holds a current licence or a supplier of medicines to determine that a purchaser or a prescriber has the authority to purchase medicines or to prescribe a specific medicine.

Clause 229 (Content of administrative action register) provides that the administrative action register must contain the name of the person and a brief description of the administrative action taken in relation to the person.

Clause 230 (Content of substance authority register) provides that the substance authority register must contain the following information about each substance authority:

- the identification number allocated to the authority;
- the name of the holder or, if the holder trades as a business, the holder's business or trading name and the name of the person responsible for overseeing or supervising the regulated activity authorised under the authority;
- the type of authority or regulated activity authorised under the authority;
- the term of the authority and the day the authority ends;
- the postcode of the place where the regulated activity under the authority will be carried out.

Clause 231 (Publishing registers) provides that the chief executive may publish the administrative action register and the substance authority register on the Queensland Health website.

These provisions may be seen to breach individuals' right to privacy by providing for the recording and publishing of information relating to substance authorities and administrative action. These concerns have been balanced against the need to protect and promote the health of the public and are considered justified. If Queensland Health has issued an authority to undertake a regulated activity, consumers and members of the public would have an expectation of regulatory oversight. The registers enable the public to verify that authority holders are authorised to undertake the activity, and whether any administrative action has been taken in relation to the authority holder. The purpose of the registers is to provide transparency and public assurance. For example, if a member of the public is concerned about whether their health practitioner is legitimate and able to provide or administer a particular substance, they can confirm this through the substance authority register. Similarly, a dispenser can confirm whether a prescriber is still authorised to prescribe a regulated substance, especially if they have been told that the prescriber is under investigation. The purpose of the registers is similar in nature and intent to the public national registers under section 222 of the Health Practitioner Regulation National Law (Queensland).

Appropriate safeguards are included. The chief executive must not include confidential information on a public register unless the chief executive is satisfied that the inclusion of the confidential information is reasonably necessary to avoid a health risk and the inclusion of the confidential information will not place a person at risk of harm. Also, the chief executive must remove information about administrative action from the public register if the administrative action no longer has effect.

### Health assessment

Clause 90 (Health assessment for pest management licences) of the Bill provides the chief executive may ask an applicant applying for a pest management licence to undergo a health assessment by a medical practitioner of their physical and mental health, and may have regard to the health assessment when deciding whether or not to grant, amend or renew an application. This may be appropriate where, for example, a person applying for a pest management licence will be required to work in enclosed spaces.

The inclusion of such an administrative power has been justified above, but this provision may also be seen to breach individuals' right to privacy, by requiring pest management licence applicants to undergo an assessment of their physical and mental health and allowing this information to be used in deciding the application.

This provision is justified as it is a discretionary power only and would not be used for every pest management licence application, but only if the chief executive considers it is required. For example, a person applying for a pest management licence will be required to work in enclosed spaces. A person with a permanent back injury may not be physically able to access a ceiling space to effectively undertake pest control activities. The provision is also justified because some pesticides such as organophosphate substances may cause neurological effects such as blurring of vision and loss of muscle control, which could impact on the health of occupiers of premises being treated by the pest management technician and particularly the pest management technician themselves. An existing power to require an applicant to undergo a health assessment is included in section 15 of the Pest Management Act.

Appropriate safeguards are included, with clause 210 (Health assessment not admissible) providing that a report about a person's health assessment done under clause 90 is not admissible as evidence in a legal proceeding, other than a review proceeding relating to the report. Subsection (3) provides that a person cannot be compelled to produce the report, or give evidence about the report or its contents, in a proceeding, other than a review proceeding relating to the report. This ensures that the health assessment remains private and confidential other than for use by the chief executive in deciding the person's application for a licence.

### *New offence provisions*

The inclusion of new offences in a legislative scheme have generally been identified as relevant to the consideration of whether legislation has sufficient regard to individuals' rights and liberties. New offences are required to be appropriate and reasonable in light of the conduct that constitutes the offence. Penalties are required to be consistent and proportionate to the offence.

The Medicines and Poisons Bill establishes several key offences to replace more than 50 separate offences in the existing legislation relating to the manufacture, supply, possession and use of medicines and poisons.

Given the age of the existing legislation, the maximum penalties have been reviewed to better align with penalties under the Commonwealth Therapeutic Goods Act and Agricultural and Veterinary Chemicals Code Act, and other comparable legislation in Queensland and interstate.

Where an offence aligns directly to the Health (Drugs and Poisons) Regulation, the penalties remain the same under the Medicines and Poisons framework. However, due to the restructuring of the scheme, where a series of specific offences are covered by a single new offence, it was necessary for penalties to be consistent with key legislation in Queensland and other jurisdictions. Key offences such as clause 33 (Offence to manufacture medicines or hazardous poisons), have a high maximum penalty to reflect the seriousness of the conduct to which it applies, the significant consequences for public health and safety of breaches, and the fact it is designed to cover a number of different scenarios.

### The authorised way

One of the fundamental structures underpinning the scheme is that persons must deal with regulated substances in the ‘authorised way’. Clause 31 (Meaning of *authorised way*) provides that a person carries out a regulated activity with a regulated substance in the authorised way if the person is authorised under clause 54(4), 57 or 62 of the Act to carry out the regulated activity with the regulated substance, the person complies with any requirement prescribed under section 91(1) for carrying out the regulated activity with the regulated substance and the person complies with any substance management plan that applies to the person.

This approach enables trained professionals to undertake their professional practice obligations without needing to list every authorised action in the legislation, with these professionals being sufficiently experienced and highly trained to know what the authorised way is when referring to particular activities. Accordingly, a number of the offence provisions relate to a person not doing something in the authorised way.

### General offences

The following are key offences under the Bill.

Clause 32 (Offence to deal with prohibited substances) provides that it is an offence to deal with prohibited substances unless the person deals with the substance in the authorised way or has a reasonable excuse. This offence carries a maximum penalty of 750 penalty units. This offence is considered appropriate and reasonable because prohibited substances, which include substances such as heroin and cocaine, are highly subject to abuse and misuse and pose a significant risk to public health, given that if misused, they are known to cause serious illness and death in humans. There are legitimate uses for these substances, such as in medical research and for calibrating machinery used by pathology laboratories for drug testing. However, the substances have a high value on the illicit drug market. The penalties for not complying with, for example, the storage and record-keeping requirements for these substances, should be high to act as a deterrent to aberrant behaviour. The sale, supply or use of other substances is prohibited because of their known dangerous properties such as being carcinogenic or toxic to tissues, skin or eyes.

Although the maximum penalty of 750 penalty units is high, it is considered proportionate to the offence noting the seriousness of the offence and the potential harm. The significant penalty is considered necessary to ensure a person takes responsibility for preventing and minimising the risks associated with their activities and the adverse effects their activities may cause. It reflects the principle that those who are responsible for posing a risk should manage the risk. A penalty of 750 penalty units is included in section 24 of the Biosecurity Act, section 32 of

the *Explosives Act 1999* and section 31 of the *Mining and Quarrying Safety and Health Act 1999*.

Clause 33 (Offence to manufacture medicines or hazardous poisons) provides that it is an offence to manufacture a medicine or hazardous poison unless the person manufactures the medicine or poison in the authorised way or has a reasonable excuse. This offence also carries a maximum penalty of 750 penalty units. This offence is considered appropriate and reasonable in light of the potential for widespread public harm if manufactured products do not meet appropriate safety and quality requirements. Manufacturers who do not comply with relevant manufacturing principles, or who do not have adequate facilities for the steps that they perform in manufacturing, place consumers of their products at significant risk of harm if the products they make are not fit for use. A recent meningitis outbreak in the United States that resulted in injury to 800 individuals and 76 deaths, exemplifies the potential for widespread significant harms to be caused by unsafe manufacturing practices. This outbreak was traced back to steroid injections that were contaminated with a fungus because their manufacturer had used improper sterilisation techniques. Similarly, product labelling is an important step in the manufacturing process where errors, such as labelling one product as another or omitting safety warnings, have led to significant harms to individuals and to the general public. Furthermore, inappropriate or unsafe manufacturing processes present a significant risk to public health and safety if they contribute to antimicrobial resistance or otherwise cause environmental contamination.

Although the maximum penalty of 750 penalty units is high, it is considered proportionate noting the seriousness of the offence. Similar offences, also carrying a penalty of 750 penalty units, are included in, for example section 104C of the *Fire and Emergency Services Act 1990*, section 34 of the *Coal Mining Safety and Health Act* and section 168B of the *Liquor Act 1992*. As manufacturing for medicines and poisons is the first step in the supply chain, any error or contamination has the potential for harm for many end users. As such, the penalty is considered commensurate with the public health and safety risks of unauthorised or improper manufacturing of medicines or hazardous poisons.

Clause 34 (Offence to buy or possess S4 or S8 medicines or hazardous poisons) provides that it is an offence to buy or possess an S4 or S8 medicine or hazardous poison unless the person buys or possesses the medicine or poison in the authorised way or has a reasonable excuse. The offence does not apply to a person who is given an S4 or S8 medicine lawfully supplied for the therapeutic treatment of someone else or an animal, and temporarily possesses the medicine until it is needed for the treatment.

This offence would capture possession of substances without authority, that may have a range of public health implications. For example, the misuse of S4 and S8 medicines, some of which can be subject to abuse and physical or psychological dependence, can cause harm to individuals. It would present significant risks to public health and safety and undermine the integrity of the health system if it were possible to possess these medicines without appropriate authorisation. In addition, the scheme imposes storage and record-keeping requirements for substances, for example, mandating the use of child-proof packaging and storage out of public access. This offence covers non-compliance with these important safety requirements. The offence also covers possession of hazardous poisons without authority. For example, it would apply to a person in possession of an S7 hazardous poison without authority who intends to dispose of it in a public water source. This offence allows for a proactive approach to protecting public health, as the person may be charged with possession prior to negatively impacting

public health. It is also intended to cover situations where a home owner purchases schedule 7 poisons on the internet to avoid supply restrictions in Australia.

This offence carries a maximum penalty of 200 penalty units. The penalty is considered proportionate to the offence noting the seriousness of the conduct it applies to. Similar offences, also carrying a penalty of 200 penalty units, are included in, for example section 733 of the *Petroleum and Gas (Production and Safety) Act 2004*.

Clause 35 (Offence to supply medicines or hazardous poisons) provides that it is an offence to supply a medicine or hazardous poison to someone else unless the supplier lawfully possesses the medicine or poisons and supplies it in the authorised way or has a reasonable excuse. This offence would apply to a person supplying substances to another person in an unlawful way, such as a pharmacist selling large quantities of pseudoephedrine tablets to a person where such a drug may be used to make methamphetamine (also known as ‘ice’) or selling a medicine to a person who did not know how to use it safely because, for example, no instructions for use were provided.

If a substance is supplied to a person who is not authorised to possess it, the person may not have the skills or knowledge to handle the substance in a safe way. If this is the case, the supplier is placing this person and potentially the wider public at risk. For example, this could apply to a retailer who supplies hydrofluoric acid, a S7 poison, to a person who is not authorised to possess a S7 poison. The person does not have knowledge or experience with using the poison and applies it incorrectly (for example, does not dilute the poison), impacting the health of themselves and anyone who comes in contact with the poison. Hydrofluoric acid readily penetrates intact skin causing tissue destruction and frequently death if medical treatment is not immediately available. This offence would also apply to the holder of a licence to sell by wholesale who does not take reasonable steps to determine that the person to whom they are supplying a substance is authorised to possess the substance. For example, this could apply to sedative medicines or opioid medicines that might be diverted for illicit use.

For the purposes of the offence, the quantity of the medicine or poison supplied, whether or not the supplier and the recipient are in the same place when the medicine or poison is supplied and whether or not the medicine or poison is supplied by indirect means are considered immaterial. This is intended to cover internet sales where the supplier or someone facilitating the supply is located in Queensland. A person in Queensland may accept the order and payment for a substance to be supplied from overseas directly to the customer. The quantity supplied is considered immaterial as different substances may have effects on public health at various quantities or concentrations. This offence carries a maximum penalty of 500 penalty units. Although the maximum penalty of 500 penalty units is high, it is considered proportionate to the offence noting the seriousness of the conduct it applies to. Similar offences, also carrying a penalty of 500 penalty units, are included in, for example the Public Health Act.

As noted above, the penalties for these offences are considered justified and proportionate noting the seriousness of the offences. Imposing general obligations to carry out activities in the authorised way promotes individual responsibility by persons authorised under the scheme and is underpinned by the principle that these professionals are sufficiently experienced and highly trained to know what the authorised way is for particular activities. A high maximum penalty allows a court to determine the appropriate penalty applying to the most serious cases, while allowing discretion to apply a lower penalty for offences involving less serious breaches.

The above offences contain appropriate safeguards:

- An offence is not committed if the act is undertaken in the authorised way. As noted above, the medicines and poisons framework is structured around persons carrying out regulated activities with regulated substances in the authorised way. This enables trained professionals to undertake their professional practice obligations without needing to list every authorised action in the legislation. If the authorised way for undertaking a particular activity is followed, no offence is committed. For example, if a pharmacist dispenses a medicine which is labelled for a person in accordance with a lawful prescription from a medical practitioner, no offence is committed.
- An offence is not committed if the person has a reasonable excuse. For example, clause 32 provides that a person must not deal with a prohibited substance unless they have a reasonable excuse. This may apply for example, if a person becomes the executor for the estate of a substance authority holder who has died. A pharmacist may also have a reasonable excuse if he or she has dispensed a medicine on a prescription which is later found to be fraudulent. Noting the general terms of the obligations under these offences, which is necessary to capture the range of activities regulated under the scheme, the inclusion of a reasonable excuse as a defence ensures that a person has the opportunity to demonstrate why they did not do something in the authorised way.

### Medicines offences

The Bill includes a number of offences specific to medicines.

Clause 36 (Offence to administer medicines), which carries a maximum penalty of 200 penalty units and clause 37 (Offence to supply or administer animal medicines to humans), which carries a maximum penalty of 100 penalty units, provide that an offence is committed when administering medicines or administering or supplying animal medicines to humans unless the person undertakes the action in the authorised way or has a reasonable excuse. This is similar to the approach taken for the general offences outlined above. It is a reasonable excuse, for example, for a person to use animal medicine on a person under clause 37(3) if no other medicine is available to treat a human disease.

Other medicines offences include:

- Clause 38 (Offence to prescribe or make standing orders) provides it is an offence to prescribe or make a standing order for a medicine unless the person does it in the authorised way or has a reasonable excuse. This offence carries a maximum penalty of 200 penalty units.
- Clause 39 (Unlawfully buying diversion-risk medicines) provides it is an offence to use a document the person has unlawfully prepared, or knows has been unlawfully prepared, to buy a diversion-risk medicine. This offence carries a maximum penalty of 100 penalty units. It is also an offence for a person to give a statement to someone who is authorised to prescribe or supply a diversion-risk medicine that the person knows is false or misleading, or omits anything without which the statement is false or misleading. This offence carries a maximum penalty of 100 penalty units.
- Clause 40 (Offences for self-prescribing or self-administering high-risk medicines) provides it is an offence to self-prescribe or self-administer high-risk medicines, without a reasonable excuse. This offence carries a maximum penalty of 100 penalty units.
- Clause 41 (Restrictions for monitored medicines) requires prescribers and dispensers to check the database before prescribing, supplying, dispensing or giving a treatment dose of

a monitored medicine to a person. A maximum penalty of 20 penalty units applies for non-compliance with these requirements.

Clause 42 (Offence to dispose of waste from S8 medicine) provides it is an offence to dispose of waste from an S8 medicine unless the person disposes of the waste by giving it to an appropriate person, disposes of the waste in the authorised way or has a reasonable excuse.

The unsafe disposal of waste from regulated substances may pose a risk to public health and safety if, for example, the waste contaminates the environment or, in the case of substances that have a high value on the illicit drug market, the waste comes into the possession of an unauthorised person. Improper disposal may allow a person to collect residual amounts of hazardous poisons from used containers and use it for unauthorised dealings. This offence carries a maximum penalty of 200 penalty units. The maximum penalty of 200 penalty units is considered proportionate to the offence noting the seriousness of the conduct it applies to. Similar offences, also carrying a penalty of 200 penalty unit, are included in, for example section 296 and 297 of the *Waste Reduction and Recycling Act 2011*.

#### Poisons and pest management offences

The Bill also includes a number of offences specific to poisons and pest management:

- Clause 43 (Offence to apply poisons) provides it is an offence to apply a poison unless the person does it in the authorised way, applies the poison in accordance with the approved label or has a reasonable excuse. This offence carries a maximum penalty of 200 penalty units.
- Clause 44 (Offence to carry out pest management activities) provides it is an offence to carry out pest management activities unless the activity is carried out in the authorised way or there is a reasonable excuse. This offence carries a maximum penalty of 200 penalty units.
- Clause 45 (Offence to offer to carry out pest management activities if unauthorised) provides a person must not offer to carry out a pest management activity for a pest management business unless the person has a pest management licence, or the person employs someone else with a pest management licence to carry out the pest management activity. This offence carries a maximum penalty of 200 penalty units.
- Clause 46 (Offence to require or permit unauthorised persons to carry out pest management activities) provides a manager must not permit or require another person who they know is not authorised to carry out a pest management activity to do so unless the manager has a reasonable excuse. This offence carries a maximum penalty of 200 penalty units.

Poisons, pesticides and fumigants pose a risk to human health if not used appropriately. The inclusion of offences relating to poisons and pest management is necessary to ensure that substances are used safely and effectively and do not cause harm. As with the general offences, these offences include safeguards of carrying out the activity in the authorised way. A number of the clauses also include a reasonable excuse defence.

Clause 47 (Offence to dispose of waste from hazardous poison, pesticide or fumigant) provides it is an offence to dispose of waste from a hazardous poison, pesticide or fumigant unless the person disposes of the waste in the authorised way or has a reasonable excuse.

As noted above in relation to clause 42, the unsafe disposal of waste from regulated substances may pose a risk to public health and safety. This offence carries a maximum penalty of 200

penalty units. The maximum penalty of 200 penalty units is considered proportionate to the offence noting the seriousness of the conduct it applies to. As noted above, similar offences, also carrying a penalty of 200 penalty unit, are included in, for example section 296 and 297 of the Waste Reduction and Recycling Act.

### Miscellaneous offences

- Clause 48 (Offence for giving or keeping false, misleading or incomplete information and records) provides it is an offence to give false, misleading or incomplete information. This offence is necessary to ensure the scheme can be administered appropriately, with correct record keeping central to this. This offence carries a maximum penalty of 50 penalty units.
- Clause 71 (Failure to comply with substance authority conditions) provides it is an offence to fail to comply with the conditions of a substance authority, without a reasonable excuse. This offence carries a maximum penalty of 200 penalty units.
- Clause 93 (Requirements for substance management plan) provides at subsection (1) that it is an offence for a responsible person to fail to make a substance management plan for a regulated place before any dealing happens at the place. This offence carries a maximum penalty of 250 penalty units. Clause 93(2) provides that a substance management plan must state particular matters, including the day the plan starts, the location of the place, the dealings and regulated substances to which it applies, the persons at the place whom it applies, and address the matters prescribed by regulation. It is an offence not to comply with these requirements, with a maximum penalty of 250 penalty units. It is a defence to the offence if the responsible person took reasonable steps to comply. The penalty of 250 penalty units is intended to ensure that entities implement a substance management plan for a regulated substance. The proposed penalty is proportionate and relevant to the provision as the plan is a pivotal risk management tool that all entities must comply with in relation to regulated substances. The plan will set out how known and foreseeable risks associated with carrying out a regulated activity with a regulated substance should be managed, for example, situations where the substance is compromised or used in inappropriate ways.
- Clause 94 (Compliance with substance management plan) provides that it is an offence for a person to fail to comply with a substance management plan, unless the person has a reasonable excuse. This offence carries a maximum penalty of 200 penalty units.
- Clause 110 (Failure to comply with compliance notice) provides it is an offence to fail to comply with a compliance notice, unless the person has a reasonable excuse. This offence carries a maximum penalty of 200 penalty units.
- Clause 116 (Failure to comply with emerging risk declaration) provides it is an offence to fail to comply with an emerging risk declaration, unless the person has a reasonable excuse. This offence carries a maximum penalty of 500 penalty units.
- Clause 125 (Failure to comply with recall order) provides it is an offence to fail to comply with a recall order, unless the person has a reasonable excuse. This offence carries a maximum penalty of 500 penalty units.
- Clause 137 (Return of identity card) provides it is an offence for a person to fail to return their identity card to the chief executive within 21 days after their office as an inspector ends. This offence carries a maximum penalty of 20 penalty units.
- Clause 156 (Failure to comply with direction) provides it is an offence for a person to fail to comply with a direction, unless the person has a reasonable excuse. This offence carries a maximum penalty of 50 penalty units.
- Clause 160 (Offence to contravene help requirement) provides it is an offence to fail to comply with a help requirement, unless the person has a reasonable excuse. This offence

- carries a maximum penalty of 50 penalty units. Clause 159 (Power to require reasonable help) requires the inspector to give the person an offence warning for the help requirement.
- Clause 165 (Offence to contravene other seizure requirement) provides it is an offence to fail to comply with a seizure requirement. This offence carries a maximum penalty of 50 penalty units.
  - Clause 166 (Offence to interfere) provides it is an offence to interfere with a seized thing or a restricted place, unless the person has a reasonable excuse. This offence carries a maximum penalty of 100 penalty units.
  - Clause 176 (Offence to contravene personal details requirement) provides it is an offence to fail to comply with a personal details requirement, unless the person has a reasonable excuse. This offence carries a maximum penalty of 50 penalty units.
  - Clause 178 (Offence to contravene document production requirement) provides it is an offence to fail to comply with a document production requirement, unless the person has a reasonable excuse. This offence carries a maximum penalty of 50 penalty units.
  - Clause 179 (Offence to contravene document certification requirement) provides it is an offence to fail to comply with a document certification requirement, unless the person has a reasonable excuse. This offence carries a maximum penalty of 50 penalty units.
  - Clause 181 (Offence to contravene information requirement) provides it is an offence to fail to comply with an information requirement, unless the person has a reasonable excuse. This offence carries a maximum penalty of 50 penalty units.
  - Clause 185 (Giving inspector false or misleading information) provides it is an offence to give an inspection false or misleading information. This offence carries a maximum penalty of 50 penalty units.
  - Clause 186 (Obstructing inspector) provides it is an offence to obstruct an inspector exercising a power, unless the person has a reasonable excuse. This offence carries a maximum penalty of 100 penalty units.
  - Clause 187 (Impersonating inspector) provides it is an offence to impersonate an inspector. This offence carries a maximum penalty of 100 penalty units.
  - Clause 217 (Changes in criminal history must be disclosed) provides it is an offence for a person to fail to give notice of changes in criminal history, within 14 days after the conviction. This offence carries a maximum penalty of 100 penalty units.
  - Clause 220 (Confidentiality of information) provides it is an offence to disclose confidential information or criminal history information to another person, unless the disclosure is permitted. This offence carries a maximum penalty of 50 penalty units.
  - Clause 226 (Giving information) provides it is an offence to fail to give the chief executive prescribed information at the time and in the way prescribed by regulation. This offence carries a maximum penalty of 100 penalty units.

### *Criminal history*

Clause 216 (Criminal history report) provides that the chief executive may ask the police commissioner for a written report about the criminal history of a person, when considering if the person is a fit and proper person in relation to a substance authority, or whether to take administrative action in relation to the person.

Clause 215 (Exceptions to criminal history disclosure requirements) provides that the *Criminal Law (Rehabilitation of Offenders) Act 1986* does not apply to a request, disclosure or notification made in relation to an individual's criminal history under Chapter 7, Part 1. The *Criminal Law (Rehabilitation of Offenders) Act* provides that an individual does not have to

disclose a conviction for which the rehabilitation period has expired and not revived, except in limited circumstances.

Clause 217 (Changes in criminal history must be disclosed) applies if the chief executive has obtained a criminal history report about a person, the person is later convicted of an indictable offence, and at the time of the conviction the person is an approved person or a relevant person for a substance authority. The clause requires the person to, within 14 days after the conviction, give notice of the conviction to the chief executive, unless the person has a reasonable excuse. Failing to comply with this requirement carries a maximum penalty of 100 penalty units.

These provisions may be regarded as adversely affecting an individual's privacy in relation to their personal information, particularly as the scope of these provisions includes spent convictions.

The scope of the criminal history provisions is considered justified due to the need to ensure that appropriate people are granted and hold a substance authority, noting the seriousness of harm that can be caused by the substances involved and the need to protect the safety of the public. The effective mitigation of public health and safety risks relies on authorised persons performing regulated activities in the way specified in the Bill and regulations. A person's criminal history is relevant to determining whether the person is a fit and proper person. By ensuring only appropriate people are authorised to deal with certain substances, the risk of diversion and/or inappropriate use of substances can be mitigated. Additionally, for pest management licensing, where technicians may have unsupervised access to domestic residences and other sensitive locations, relevant criminal history may be considered to protect the health and safety of the public. The provisions will enable the chief executive to have a more complete picture of the criminal history of an applicant, including information about convictions which may indicate a pattern of behaviour that may compromise the ability of a person to hold a substance authority and deal with regulated substances appropriately. Provisions of this nature are not uncommon in occupational regulation legislation where for public health and safety reasons, the integrity of applicants must be rigorously assessed.

It should be noted that while the proposed provisions allow the chief executive to take a person's criminal history into account when deciding if a person is fit and proper to hold a substance authority, the existence of a criminal history does not necessarily exclude a person from applying for, or holding, a substance authority. A person's criminal history is just one factor that the chief executive may consider, to the extent that it is relevant, when deciding if a person is a fit and proper person to hold a substance authority.

The Bill also contains appropriate safeguards to protect the interests of individuals whose criminal history is obtained. Clause 216(2)(b) requires a person's written consent before the chief executive may request the written criminal history report of a person. Clause 218 requires the destruction of the criminal history information as soon as practicable once it is no longer needed for the purpose it was given, while clause 220 ensures that a person's criminal history information is kept confidential by preventing the unlawful disclosure of a person's criminal history. Non-compliance with this requirement carries a penalty of 50 penalty units.

### **Institution of Parliament - Legislative Standards Act 1992, section 4(2)(b)**

The Bill contains a number of clauses that potentially impact on the fundamental legislative principle that legislation must have sufficient regard to the institution of Parliament. Potential breaches are discussed in detail below.

#### ***Does the legislation sufficiently subject the exercise of a delegated legislative power to the scrutiny of the Legislative Assembly?***

Section 4(4)(b) of the Legislative Standards Act provides that whether a Bill has sufficient regard to the institution of Parliament depends on whether the Bill sufficiently subjects the exercise of a delegated legislative power to the scrutiny of the Legislative Assembly.

The Bill includes references to a range of external documents. These provisions potentially impact on the fundamental legislative principle that legislation must have sufficient regard to the institution of Parliament. Reference to external documents throughout the framework is considered justified noting the detailed, technical and clinical nature of the matters contained in the external documents, and the flexibility this provides the scheme to remain up to date with current practices and requirements. If the matters referenced in external documents were contained in the Bill or regulations, they would regularly be out of date and not reflect changing practices, substances and activities.

Specific clauses are considered in more detail below.

#### **References to the Poisons Standard**

The Bill includes a number of references to the *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard). Clause 9 (Relationship with Poisons Standard) provides that words and expressions defined in the Poisons Standard and used in the Medicines and Poisons Act have the same meaning, to the extent the context permits. Subsection (4) provides that for the Medicines and Poisons Act, a schedule of the Poisons Standard applies to a substance in particular circumstances.

Relevant definitions for the Bill then refer to the Poisons Standard:

- Clause 10 (Meaning of *substance*) provides that a substance may be described by reference to the Poisons Standard, as well as to codes, guidelines, protocols or other standards;
- Clause 11 (Meaning of *medicine*) provides that a *medicine* is a substance to which particular schedules of the Poisons Standard apply;
- Clause 12 (Meaning of *poison*) provides that a *poison* is a substance, other than a fumigant or pesticide, to which particular schedules of the Poisons Standard apply;
- Clause 13 (Meaning of *prohibited substance*) provides that a *prohibited substance* is a substance to which particular schedules of the Poisons Standard apply;
- Clause 15 (Meaning of *S7 substance*) provides that an *S7 substance* is an S7 poison, fumigant or pesticide containing a substance to which Schedule 7 of the Poisons Standard applies;
- Clause 16 (Meaning of *hazardous poison*) provides that a *hazardous poison* is an S7 substance or a medicine treated as a poison under clause 12(2).

It is necessary to refer to the Poisons Standard in defining relevant terms under the Bill as the Standard is fundamental to the entire scheme. The Poisons Standard is a Commonwealth legislative instrument that classifies medicines and poisons into ‘schedules’ of substances from ‘Schedule 2’ through to ‘Schedule 10’. A substance is categorised into a schedule based on the level of regulatory control required to deal with the public health and safety risks of the substance. As a legislative instrument, the Poisons Standard is published on the Federal Register of Legislation (<https://www.legislation.gov.au/>). The Poisons Standard is regularly reviewed, and updated approximately three times a year following extensive committee meetings and decision-making processes regarding classification, which are outlined in more detail below.

The purpose of the Poisons Standard is to provide a means by which nationally uniform scheduling of substances can occur, which can be applied in the legislation of all Australian jurisdictions, usually by referral in each jurisdiction’s medicines and poisons legislation. The intention of classifying medicines and poisons into schedules allows for the setting of different levels of control for the availability of substances included in each schedule. Although the Poisons Standard is a Commonwealth instrument, there is state and territory input into scheduling decisions. The Scheduling Policy Framework is the national policy around restricting access to medicines and poisons. The Australian Health Ministers’ Advisory Council (AHMAC) is responsible for the framework and the framework must be endorsed by all states and territories.

There are two advisory committees, the Advisory Committee on Medicines Scheduling and the Advisory Committee on Chemicals Scheduling to advise the Commonwealth decision-maker, the Secretary of the Commonwealth Department of Health. Each state and territory is entitled to nominate a member on each of the committees. The Advisory Committees advise and make recommendations to the Commonwealth decision-maker on the level of access that should apply to each substance, that is, the schedule in which the substance should be included. An acknowledgment of the technical and specialised nature of scheduling medicines and poisons is that members nominated by states and territories are nominated on the basis of their knowledge, expertise and experience, rather than being merely representative. It is appropriate to rely on the scheduling decisions reflected in the Poisons Standard because it utilises the combined knowledge of national experts in a committee setting.

Although the scheduling level for substances is achieved through the Poisons Standard through this expert and rigorous assessment process, the regulation of how those substances are made available and used is a decision for the Parliament of each jurisdiction. It is at this State Parliamentary level that Queensland’s decision-making is applied as to who may be authorised for each schedule class, and in what circumstances. The Medicines and Poisons Bill establishes the types of authorised activities with scheduled substances, the authorised way substances can be used, types of substance authorities, and a head of power for the regulation to authorise classes of approved persons.

In addition to the technical and expert requirements needed for determining scheduling of substances, the Medicines and Poisons legislation would not keep pace with changes to the Poisons Standard if the legislation required amendment each time the Poisons Standard changed. As outlined above, AHMAC has responsibility for scheduling policy and regulatory controls set out in the Poisons Standard. The Poisons Standard provides for national uniformity and consistency, which provides certainty to industry, particularly for those that work across

jurisdictions. As a Commonwealth legislative instrument, the latest version of the Poisons Standard is always available on the Federal Register of Legislation.

#### Australian Pesticides and Veterinary Medicines Authority

Similarly, clause 14 (Meaning of *fumigant* and *pesticide*) provides that a *fumigant* and a *pesticide* are substances approved for use by the APVMA. The APVMA is the Australian Government statutory agency responsible for the management and regulation of all agricultural and veterinary chemical products in Australia. Assessment and registration of agricultural and veterinary chemicals has been delegated to APVMA by all states in the interest of national consistency and uniformity. In Queensland, the *Agricultural and Veterinary Chemicals (Queensland) Act 1994* confers powers on the APVMA and applies the code set out in the *Agricultural and Veterinary Chemicals Code Act (Cth)*, known as the AgVet Code. Pesticides and fumigants are regularly added to publicly available APVMA databases as they are approved by the APVMA. The databases can be accessed from the APVMA website at <https://apvma.gov.au/node/10831>.

It is therefore appropriate to refer to substances approved for use by the APVMA in defining *fumigant* and *pesticide* for the purposes of the scheme, rather than prescribing the substances in the Medicines and Poisons scheme. Prescribing the substances directly would duplicate the work of the APVMA and result in the legislation not keeping pace with changes made by the APVMA.

#### Clinical trials

Clause 52 (Clinical trials) provides a limited-circumstance exemption from offence provisions of the Medicines and Poisons Act for a person who is undertaking a regulated activity with a regulated substance as part of a clinical trial of a scheduled medicine, where the clinical trial has been approved by a human research ethics committee (HREC), and where the person is acting in accordance with a protocol or guideline approved for the human clinical trial by the committee.

Under clause 52(1), the persons to whom the exemption applies are defined by reference to clinical trials approved by a HREC. Subsection (3) defines *human research ethics committee* as a committee registered with the National Health and Medical Research Council (NHMRC) and operating in accordance with the human research guidelines issued under section 10 of the *National Health and Medical Research Council Act 1992 (Cth)* (NHMRC Act).

The NHMRC is a statutory entity established under section 5B of the NHMRC Act. It has various functions including a key role in public health research, medical research and ethical issues relating to health. Under section 10 of the NHMRC Act, the chief executive officer (CEO) of the NHMRC must issue guidelines for the conduct of medical research involving humans. To fulfil this requirement, the NHMRC has issued the National Statement on Ethical Conduct in Human Research (National Statement). The National Statement is available at <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>. All clinical trials in Australia must comply with the National Statement and HRECs have a responsibility for ensuring this is the case. When registering, the HREC must provide documentary evidence that demonstrates that it meets those requirements.

Defining the application of the clause in this way is considered appropriate, because an approved HREC is considered the only appropriate group of persons capable of approving a

clinical trial, under guidelines established by the NHRMC, which is the statutory body to administer the processes for approving and monitoring clinical trials. In all Australian jurisdictions, a clinical trial is only authorised to commence by the public health regulator upon approval by the responsible HREC. The NHMRC approves and registers the HREC, which approves and monitors the clinical trial and the governance by the trial sponsor, if there is one. It would not be appropriate for clinical trials to be approved outside of this legislative framework. To do so would place the research outside of the accepted system and invalidate it.

Clause 52(2) provides that a person does not commit an offence against the Bill to the extent that the person acts in accordance with any protocol or guidelines approved for the human clinical trial by the HREC. The HREC plays a key role in reviewing and monitoring clinical trials, with the National Statement requiring review of all clinical trials by a HREC, and setting out the HREC's responsibilities. The Therapeutic Goods Administration requires all clinical trials involving 'unapproved' therapeutic goods (e.g. scheduled medicines used 'off label') to be conducted in accordance with legislative requirements, the principles underpinning the World Medical Association's Declaration of Helsinki – *Ethical Principles for Medical Research Involving Human Subjects*, the National Statement and the relevant Good Clinical Practice guideline.

It is also appropriate that the clause 52 sub-delegates to external documents, as they form the basis for federal regulation and HREC oversight, and are developed or approved by the peak oversight body, the NHMRC. Guidelines issued by the CEO of the NHMRC must be developed by the NHMRC or, in the case of human research guidelines, be developed by the Australian Health Ethics Committee (section 9 of the NHMRC Act). Human research guidelines issued by the CEO must be tabled in each of the Houses of Parliament of the Commonwealth of Australia, and are therefore accessible to the public. The developed guidelines are co-developed with contribution by the State of Queensland through Queensland Health. The NHMRC must, by law, have the chief medical officer of Queensland as a member. Section 20 of the NHMRC Act provides that the chief medical officer for each jurisdiction must be a member of the NHMRC, along with other persons with medical, ethics, public health research and medical research expertise. The guidelines are the definitive guide for conducting a clinical trial and must be followed in accordance with the therapeutic goods legislation. The Guideline for Good Clinical Practice is available to download at <https://www.tga.gov.au/publication/note-guidance-good-clinical-practice>. Australian clinical trials using therapeutic goods are regulated by the therapeutic goods legislation.

Examples of clinical trials that use a regulated substance, might include trials of new models of care, or a new treatment protocol such as a new dosing regimen. For example, in a randomised, placebo controlled clinical trial related to administering multiple doses of a corticosteroid to an expectant mother at imminent risk of premature delivery rather than a single dose, the trial may occur in a hospital setting with the medicine administered by a person authorised to do so, but the exemption from offence may relate to labelling of the medicine, particularly where a placebo is also involved. Such examples demonstrate the limited application of the exemption provided by clause 52, for select circumstances that are otherwise regulated by strict controls. In all cases, the exemption only applies to the extent that the person is acting in accordance with any protocol or guidelines that have been approved for the clinical trial by the HREC.

This subdelegation is also considered appropriate noting the transparency that is provided through the notification scheme administered by the Therapeutic Goods Administration, and

registration of the trial. Clinical trials must be registered with the Australian and New Zealand Clinical Trials Registry, with registration providing an additional level of scrutiny and transparency that is also publicly available. The NHMRC explains registration as “the process whereby key details about the design, conduct and administration of planned clinical trials are made available on a publicly accessible database known as a clinical trial registry. In Australia, registration must occur before enrolment of the first participant (prospective trial registration is now widely accepted as an essential part of an overall strategy for improving research transparency). The World Health Organization’s (WHO’s) International Clinical Trials Registry Platform notes that the Declaration of Helsinki now explicitly states that ‘every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.’...In Australia, the Australian and New Zealand Clinical Trials Registry is one of the Primary Registries in the WHO Registry Network.” The National Statement requires “researchers must register the project as a clinical trial on a publicly accessible register complying with international standards (see information on the International Clinical Trials Registry Platform on the WHO website) before the recruitment of the first participant”.

With the layers of protection of public health and safety, especially for trial participants, provided by Commonwealth legislation, additional approvals and the transparency afforded by registration, additional oversight through further approvals being required by Queensland would provide a degree of over-regulation of clinical trials, with the additional regulatory burden adding no benefit. It would also create delays for the commencement of clinical trials. The Therapeutic Goods Administration promotes the aims of the Clinical Trial Notification Scheme as being to “provide considerable benefits by providing the momentum to research, developing new therapeutic goods locally and facilitating early patient access to new therapeutic developments.” Adding an unnecessary layer of regulation to the scheme by requiring further approvals through Queensland’s Medicines and Poisons legislation would not support those aims. For these reasons, it is considered appropriate to define clinical trials as those approved by a HREC and to sub-delegate to protocols or guidelines approved by the committee in providing safeguards for a limited exemption from offences under the Act.

#### References to stated code, guideline, protocol or standard

A number of clauses in the Bill provide that conditions or requirements may prescribed by reference to a stated code, guideline, protocol or standard.

Clause 10 (Meaning of *substance*) provides that a substance may be described by reference to the Poisons Standard, as well as to codes, guidelines, protocols or other standards. Reference to codes, guidelines, protocols or other standards are necessary for when the Poisons Standard scheduling needs to be updated as a matter of urgency. Given the lengthy timeframes of the scheduling process to introduce substances or make amendments to schedules of substances, there are circumstances where it is more appropriate to refer to a code, guideline, protocol or other standard. While reference to the Poisons Standard provides for a high degree of national uniformity, additional reference to a code, guideline, protocol or other standard provides for a means by which Queensland is not restricted to Commonwealth law, but may exercise a prerogative to further refine how a substance may be described by referring to the technical code, guideline, protocol or standard.

Such codes, guidelines, protocols or standard may be made by Queensland Health or by external agencies such as the World Health Organization or European Chemicals Agency.

Relevant codes, guidelines, protocols and standards are currently referenced in the Health (Drugs and Poisons) Regulation, for example, the Poisons Standard; Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8; the Optometry Guidelines (*Guidelines for use of scheduled medicines* made by the Optometry Board of Australia established under the Health Practitioner Regulation National Law) and the clinical practice protocol approved by the Queensland Ambulance Service.

All documents of this type referred to in the legislation would be made available publicly on the Queensland Health website, and would also be proactively distributed as needed.

References to external documents would depend on the chemical and the type of emerging risk, but may include references to guidelines and assessment reports available from organisations such as the US Agency for Toxic Substances and Disease Registry and the US Centers for Disease Control and Prevention or under international programs such as the International Programme on Chemical Safety INCHEM, which provides a single consolidated collection of chemical safety information from intergovernmental organisations.

This approach provides flexibility for dealing with emerging public health risks relating to new or innovative use of medicines and poisons. Due to the technical nature of these documents and revisions as new information becomes available, it is inappropriate to include such detail in the Bill.

Clause 54 (Authorisation of prescribed classes of persons) provides that requirements for approved persons can be prescribed by regulation. These requirements may include that an approved person complies with an EPA, code, guideline, protocol or standard. The ability to prescribe requirements to be placed on an approved person by regulation allows for timely responses to changes in use of scheduled substances, or changes to protocols and ensures the most up-to-date and safe procedures are adopted by persons authorised to use scheduled substances. For example, an Aboriginal and Torres Strait Islander health practitioner will have an additional requirement to comply with an EPA under the Medicines Regulation, which will prescribe the permitted scheduled substances and the protocols around using them. The EPAs will be published and publicly available on the Queensland Health website. The protocols will be contained in the Primary Clinical Care Manual, which is also available through the Queensland Health website and is available as a published document. The codes, guidelines, protocols or standards referenced by the regulation may be made by Queensland or by external agencies and may include documents such as the 'National guideline for retail storage of schedule 6 and schedule 7 poisons' made by AHMAC in relation to retail storage of S6 and S7 poisons, available at <https://www.tga.gov.au/publication/national-guideline-retail-storage-schedule-6-and-schedule-7-poisons>.

Some standards produced by standard setting bodies such as Standards Australia can be purchased through a website. The purchase of these standards is justified due to their technical nature and standards being necessary for the operation of the business. For example, pest management technicians who undertake termite management as part of their business should have a copy, or access to a copy of the Building Code of Australia. Australian standards are available from the Standards Australia website at <https://infostore.saiglobal.com/store/default.aspx>

Clause 70 (Conditions) provides that a regulation may prescribe standard conditions for a substance authority by reference to a code, guideline, protocol or standard, including a

departmental standard. The conditions may include operational details and requirements for the holder of a substance authority, for example, a condition may take the form of a standard that outlines how a manufacturer should test batches of regulated substances during manufacturing or when the holder of a substance authority must advise the chief executive of changes to the substance holder's circumstances. The content of the standard conditions includes extensive technical details for substance authority holders that is updated regularly to give effect to best practice, changes in industry and feedback from users. When making or amending a standard containing standard conditions, relevant individuals or organisations with expertise in, or experience of, the matters under consideration will be consulted. A copy of each standard made by the chief executive will be published on the Queensland Health website. Providing clinical, manufacturing and pest management details in an extrinsic document will enable the legislation to be streamlined and accessible, with technical information to provide guidance and allow flexibility on activities that require detailed information in external instruments.

### Extended practice authorities

Clause 232 (Making extended practice authorities) provides that the chief executive may make an EPA stating the places and circumstances in which an approved person may deal with a regulated substance; imposing conditions on dealing with a regulated substance; or requiring an approved person to hold particular qualifications or training to deal with a regulated substance. EPAs are similar to Drug Therapy Protocols, which are currently used for similar purposes in the Health (Drugs and Poisons) Regulation.

The ability for the chief executive to make an EPA that sits outside the Medicines and Poisons legislation is justified noting the detailed and clinical nature of the information contained in the EPA. Each EPA may contain a list of regulated substances that a relevant person will be able to administer, in what dose form, and for what length of time.

For example, an EPA for an Indigenous Health Worker – Isolated Practice Area might include in its opioid analgesics protocol limitations for a scheduled substance such as morphine sulfate pentahydrate to be administered through two approved routes of administration, being intramuscular or subcutaneous, with restrictions and conditions that supply is not permitted.

These protocols are of a clinical nature based on the most up-to-date health and medicine information and decision-making. It also allows for timely amendments to accepted protocols, including the introduction of new medicines available, new or revised treatment regimens with existing medicines, or the unavailability of medicines listed in the protocol. An example of the immediate need for an amendment might be if a medicine becomes unavailable. While there are systems in place for the reporting of low stocks of medicines, including worldwide shortages, there are times that some medicines may still become unavailable within a short timeframe that would not provide a sufficient lead time for a regulation amendment. To ensure continuity of care, or prevent the spread of disease, it may be necessary to amend an EPA to include a replacement medicine as part of the treatment protocol for a particular disease, for example tuberculosis.

Appropriate safeguards are included in the scheme for the use of EPAs. A key purpose of the Bill is to ensure people carrying out activities with medicines have the necessary competencies and that health and safety risks are appropriately managed, the Medicines Regulation will provide criteria the chief executive must consider before making an EPA. These criteria include

the nature of the dealings, for example, whether it should be a single instance of administration only or include supply, the types of medicines permitted, the service needs to be met by the authority and the benefits for the community served by the authority, how the risks associated with the medicines will be managed, the frequency with which the authority itself should be reviewed, and, in cases where the authorised person is managed by an entity, what the governance capability of the entity is.

An EPA made by the chief executive does not take effect until it is approved by regulation, with the name and date of the relevant EPA to be prescribed by regulation. Each time an EPA is updated, a regulation amendment will be required to prescribe the new name and date, and will be tabled in the Legislative Assembly. This will provide the Legislative Assembly with an opportunity for appropriate scrutiny of the EPA. As is currently done now with Drug Therapy Protocols under the Health (Drugs and Poisons) Regulation, EPAs will also be published on the Queensland Health website.

### Standards

Chapter 7, Part 4 (Extended practice authorities and departmental standards) provides at clause 233 (Making departmental standards) that the chief executive may make a standard about carrying out a regulated activity with a regulated substance and other matters relating to the purposes and administration of the Act.

Departmental standards will address issues such as substance management plans, storage of regulated substances, safe use of poisons for wild dog control, user competency requirements for specific regulated activities, recording systems for the sale of S3 pseudoephedrine, the use of electronic medication management and ordering systems, prescription, supply and administration of medicines in specific circumstances, such as treating drug dependent persons, and ensuring product quality.

The departmental standards will provide task-specific guidance for professions and industries that perform regulated activities with regulated substances. Due to the technical and scientific nature of the regulated activities and substances that evolve with best practice and consultation, it is not considered appropriate or possible for the content of the departmental standards to be included in the legislation.

This subdelegation to departmental standards is considered justified as appropriate safeguards are included that ensure the Legislative Assembly has sufficient scrutiny of the instruments.

For example:

- Clause 233(4) provides that a departmental standard takes effect in relation to a person, if it applies to the person under a provision of a regulation. Each standard made under the Bill will be prescribed in a regulation, with its name and date, to ensure transparency. Each time a standard is updated, a regulation amendment will be required to prescribe the new name and date, and the updated standard will be tabled in the Legislative Assembly. This will provide the Legislative Assembly with an opportunity for appropriate scrutiny of each standard.
- Clause 234 (Consultation about departmental standards) provides the chief executive, before making a standard, must consult with entities that are proposed to be subject to the standard or have expertise about the matters proposed to be dealt with by the standard.

- Clause 236 (Availability of extended practice authorities and standards) provides that the chief executive must publish each approved departmental standard free of charge on the Queensland Health website.

Clauses that refer to a specific departmental standard to be made under the Bill are discussed below.

Clause 76 (Deciding initial application) sets out the matters the chief executive may have regard to when deciding whether or not to grant an application for a substance authority. Clause 76(3) provides that if a departmental standard has been approved about the training and competency requirements for a person carrying out a regulated activity with a regulated substance (a *competency standard*), and an application for a substance authority relates to matters stated in the competency standard, the chief executive must have regard to the competency standard when considering the application. The competencies to be prescribed in the standard are nationally agreed and set out under State or Commonwealth laws, for example the Chemical Usage (Agricultural and Veterinary) Control Act, or are industry endorsed, and may be revised and renamed as industry practices change. The competencies will be selected from the National Register of Vocational Education and Training maintained by the Australian Skills Quality Authority, (<https://training.gov.au/Home/Tga>) appropriate university courses or a course designed for a specific activity if there is no current course, for example baiting of wild dogs.

Inclusion of these competencies in a standard allows flexibility to maintain the currency of criteria used to assess if a person is fit and proper for the application. Requiring the chief executive to consider these competencies provides an appropriate level of scrutiny and transparency. If prescribed directly in the regulation, the competencies would be rigid and cumbersome to administer.

### Substance management plans

Chapter 4, Part 2 (Substance management plans) provides for entities to make a substance management plan for a regulated place. A substance management plan is a document setting out how known and foreseeable risks associated with dealing with a regulated substance at a regulated place are to be managed.

Substance management plans are not subject to oversight by the Legislative Assembly as they will be made by particular entities required to make a plan and are not subject to review by the chief executive or tabling in the Legislative Assembly. However, an inspector will be able to review an entity's substance management plan during inspections or compliance activities.

A substance management plan is tailored for the entity that is making the plan, after a comprehensive examination of the entity's particular risks around regulated dealings with regulated substances. This is the preferred mechanism for controlling risks, rather than through prescriptive legislation, because the industries and entities to which the Medicines and Poisons legislative framework applies vary greatly and have different risk profiles depending on the industry, scale of operations and the particular circumstances of the facility or business. Prescriptive legislation would also force entities to achieve target safe outcomes in ways that may not suit their business practices, or in ways that may be more costly. The legislation may not keep up with technological advances, for example in relation to secure storage or cold chain handling. It also could not account for every individual risk faced by entities, including more

unusual risks arising out of circumstances specific to some entities. This could lead to an entity technically complying with the letter of the law, but have risk exposure for their dealings with regulated substances.

The Bill requires a substance management plan to address all known and foreseeable risks for each of the types of dealings the entity performs with a regulated substance. To comply, an entity will be required to make a substance management plan that satisfies the requirements of the Substance Management Plan Standard, which means a plan will need to demonstrate how the entity will achieve the outcomes stipulated in the Substance Management Plan Standard. For example, in relation to ‘possess’, the Substance Management Plan Standard is expected to require a substance management plan to address the risk of diversion, theft or illicit use. The standard will specify the minimum outcomes that must be achieved to manage these risks which may include matters such as:

- suitable storage measures to ensure regulated substances are secure, with due regard to their scheduling in the Poisons Standard, the substances’ illicit value, and meeting recommended storage conditions;
- adequate record-keeping for regulated substances to allow a clear audit trail from purchase order through to receipt of stock, records of when stock is moved, used, or disposed of, and reconciliation of stock on hand;
- adequate governance measures around who may and may not receive, access, use and dispose of medicines and how these measures are monitored and reviewed;
- adequate controls to restrict access only to authorised persons; and
- policies for keeping records about stock in a way that the records cannot be tampered with.

This is only a sample of the outcomes that may be required to be met by a plan to satisfy the Substance Management Plan Standard for a single identified risk for a single ‘dealing’. This demonstrates why each plan is unique and should provide flexibility to an entity required to make the plan to address relevant risks. The Substance Management Plan Standard is to be made under the Medicines Regulation and will be tabled in the Legislative Assembly at the time of making the regulations.

Individual substance management plans will not be approved by Queensland Health or tabled in the Legislative Assembly, as this would impact negatively on businesses, delay an entity’s ability to begin an activity, and would place a large regulatory burden on Queensland Health. Queensland Health considers this would result in over-regulation of entities that would not result in sufficient benefit to warrant the regulatory burden and cost for government. By requiring all plans to meet risk management outcomes established by the standard, substance management plans will be sufficiently regulated. Compliance monitoring and investigation activities will take place and will include review of substance management plans.

#### ***Amendment of an Act only by another Act (Henry VIII clauses)***

Section 4(4)(c) of the Legislative Standards Act states that whether legislation has sufficient regard to the institution of Parliament depends on whether the legislation authorises the amendment of an Act only by another Act.

Clause 240 (Regulation-making power) of the Bill provides a head of power for regulations to be made under the Act. Clause 240(3) provides that a regulation may impose a maximum penalty of not more than 100 penalty units. This provision ensures that where appropriate, obligations permitted to be prescribed by regulation can carry the weight of a penalty for non-

compliance, and the penalty will reflect the seriousness of the offence. Although permitting a regulation to impose a maximum penalty of 100 penalty units could be considered enabling the inclusion of significant penalties, the health and safety benefits outweigh any potential breach of this fundamental legislative principle. It is appropriate for legislation with a purpose of minimising public health and safety risks for the use of substances, carries maximum penalties to reflect the seriousness of offences and, importantly, to act as a deterrent. A similar provision can be found in section 461 of the Public Health Act.

In addition to the general regulation-making head of power in clause 240, a number of clauses provide that a specific matter may be prescribed under regulation.

These provisions are considered to have sufficient regard to the institution of Parliament because:

- the matters to be prescribed are consistent with the policy objectives and purpose of the authorising law;
- the matters to be prescribed are technical and clinical in nature;
- this approach will allow the Government to respond promptly and flexibly if changes are needed to the framework in future, ensuring the scheme can be managed appropriately. Some flexibility for Queensland Health to be able to respond rapidly and decisively to matters that pose a risk to public health and safety, such as addressing an outbreak of a highly pathogenic disease, is considered appropriate; and
- any changes to regulations will be tabled in the Legislative Assembly and subject to parliamentary scrutiny and disallowance.

Specific regulation-making powers contained in the Bill are considered in more detail below.

#### Exemptions for low-risk activities

Clause 7 (Exemption for low-risk activities) provides that a regulation may prescribe that a type of activity with a substance is exempt from the operation of the Act.

The inclusion of such a power is justified because the ability to allow new activities with substances that are deemed a negligible risk will enable Queensland to be progressive in its approach to managing activities with substances and to respond appropriately, while ensuring the safety of all Queenslanders. A similar provision is currently contained in section 10 of the Pest Management Act. It is appropriate for these matters to be set out in regulations, due to their detailed and technical nature.

Appropriate safeguards are included in the provision. The Minister may only recommend that a type of activity with a substance be exempt from the operation of the Act if satisfied that the activity could reasonably be expected to pose no, or negligible, health risk to any person. For example, if an unscheduled insecticide is used for pest control and does not have any human health effects, this activity may be exempted due to the negligible risk to public health.

This approach will allow industry to use these substances and reduce the regulatory burden, while not impacting public health and upholding the main purposes of the Act.

### Prescribing of substances

Clauses 11, 12 and 13 provide that in addition to substances listed in the schedules of the Poisons Standard, a regulation may prescribe another substance as a medicine, poisons or prohibited substance.

All states and territories adopt the schedules of the Poisons Standard through their respective medicines and poisons legislation, which ensures that there is a high degree of national uniformity with respect to the regulatory controls placed on medicines and poisons. However, most jurisdictions reserve the right to modify the adoption of the Poison Standard by regulation, if necessary, in order to deal with, for example, an emerging risk that is unique to that particular jurisdiction. The ability to prescribe an additional substance as a medicine, poison or prohibited substance other than those prescribed by Commonwealth law recognises that Queensland can ensure substances can be prescribed if necessary. The making of any such regulation would be subject to Parliamentary scrutiny and disallowance.

This provision will enable proactive management of public health risks related to new and emerging substances, including novel ways to use an existing substance, prior to them being considered for scheduling. Given that the Advisory Committee on Medicines and Poisons Scheduling only meet to discuss scheduling three times a year, and that scheduling decisions may take up to 12 months to take effect, allowing substances to be prescribed by regulation will allow these new and emerging substances to be regulated in a timely manner.

Clause 14 provides that in addition to substances approved for use by the APVMA, a regulation may prescribe another substance as a fumigant or pesticide.

All states and territories adopt the AgVet Code, which ensures that there is a high degree of national uniformity with respect to the regulatory controls placed on pesticides and fumigants. However, most jurisdictions reserve the right to modify the adoption of the AgVet Code by regulation, if necessary, in order to deal with emerging pesticides or fumigants, that have not been registered by the APVMA. The ability to prescribe an additional substance as a pesticide or fumigant other than those prescribed by Commonwealth law recognises that Queensland can ensure substances can be prescribed if necessary. The making of any such regulation would be subject to Parliamentary scrutiny and disallowance.

As above with regard to prescribing a substance as a medicine, poison or prohibited substance, this provision will enable proactive management of public health risks related to new and emerging substances, prior to them being considered by the APVMA and allow these substances to be regulated in a timely manner.

### Pest management activities

Clause 19 (Meaning of *pest management activity*, *fumigation activity* and *pest control activity*) defines pest management activities by reference to the terms ‘pest management activity’, ‘fumigation activity’ and ‘pest control activity’. Clause 19(2) defines fumigation activity as the preparation or use of a substance to: kill a pest; sterilise grain or seed to prevent germination; or treat soil in which pests might be living. The clause also provides that a regulation may prescribe carrying out another activity as a fumigation activity.

This provision may be seen to breach the principle that an Act should only be amended by another Act. However, the ability to appropriately and effectively respond to a new pest management substance or an emerging use or hazard associated with a pest management activity by prescribing activities by regulation is necessary to ensure the safety of the user, the environment and wider community. For example, technological advances could lead to the ability to fumigate laboratory biological specimens, prior to disposal, to sterilise them, which would require regulation under this Act to maintain safety of the practice.

By providing for a regulation to prescribe what constitutes a fumigation activity, the clause allows Queensland Health to respond appropriately to risks, changes in technology, ensures the integrity of the industry and provides confidence to the community and qualified persons dealing with pest management activities and substances.

### High-risk medicines

Clause 40 (Offences for self-prescribing or self-administering high-risk medicines) defines *high-risk medicine* as a medicine prescribed by regulation to be a high-risk medicine. Under this clause, an authorised prescriber for a high-risk medicine must not self-prescribe the high-risk medicine unless they have a reasonable excuse. Subsection (2) provides that a person who is authorised to deal with a high-risk medicine must not self-administer a dose of the medicine unless someone who is authorised to prescribe the medicine has prescribed the medicine for the person's treatment, someone else who is authorised to give a treatment dose of the medicine has given the medicine to the person for their treatment or the person has a reasonable excuse.

It is considered necessary to prescribe high-risk medicines in regulation because the evolutionary nature of drug development means that new high-risk substances regularly enter the market. In addition, the process of drug use evaluation frequently identifies new risks with existing medicines that necessitate tighter controls being placed on these medicines.

### Monitored medicines database

To support the monitored medicines database, a number of clauses provide for matters to be prescribed by regulation.

Clause 41 (Restrictions for monitored medicines) sets out requirements for prescribers and dispensers to check the monitored medicines database when undertaking a *proposed action* (that is, prescribing, supplying, dispensing or giving a treatment dose of a monitored medicine). Subsection (4) provides the requirement to check the database does not apply if the proposed action happens in a situation prescribed by regulation to be exempt.

It is considered justified to prescribe such situations by regulation as the options for managing pain and treating drug dependency may change as new treatment modalities and medicines become available. Additionally, the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee's Inquiry into aged care, end-of-life and palliative care and voluntary assisted dying that is currently underway may see changes to the way Queensland Health monitors and responds to the prescribing of medicines in these patient groups. Overseas experience with similar prescription monitoring programs has shown that the impacts at five years and ten years post-implementation are different, meaning that the risk profiles for the different settings in which prescription monitoring is occurring may change over time. The settings and circumstances will be assessed in terms of the risk of harm present

by an expert advisory group who, through their knowledge and experience of the sector, have insight into situations that pose a lower or higher risk for misuse of medicines. The patient groups that may be considered to be prescribed by regulation for exemption from the requirement to check the monitored medicines database include hospital in-patients whose treatment with monitored medicines will occur in a closed environment, and patients being treated for a terminal illness who may be prescribed large quantities of medicines for palliative care purposes.

Clause 224 (Chief executive to keep database) sets out the purposes of keeping the monitored medicines database, including any other purpose prescribed by regulation. The ability to prescribe other purposes by regulation is necessary to enable Queensland Health to respond flexibly to emerging public health and safety risks.

Clause 225 (Information recorded on database) provides that a regulation may prescribe the information that must be recorded by the chief executive on the database. The information may include personal information; information obtained under the Health Act before the commencement of the clause, despite the purpose for which the information was obtained or created; and information obtained under a law of another jurisdiction for a purpose mentioned in clause 224. It is necessary to prescribe the information that must be recorded on the database by regulation, taking account of the fact that the Queensland database will be part of a federated system, the NDE, and as such, will need a degree of flexibility around some requirements, including the information to be stored, so as to align with other jurisdictions and Commonwealth requirements for all jurisdictions. Planning around the details of the design of the NDE are underway with other states, territories and the Commonwealth. Flexibility will also be needed because of the nature of clinical practice—it is not stagnant, and flexibility will assist the legislation to keep pace with changes in evidence and best practice. The Australian Digital Health Agency has a number of initiatives that may impact on the data required, for example e-prescription. Consequently, the information requested for the database may change over time. To ensure a timely and adequate response to public safety concerns, information requested for the database may need to change, also in a timely manner. For example, a new medicine may emerge which poses a significant risk to public health and safety which would warrant it being specified as a ‘monitored medicine’, which may require additional information to be included in the database.

Clause 226 (Giving information) provides that an information provider must give the chief executive the information mentioned in clause 225 at the time, and in the way, prescribed by regulation, unless they have a reasonable excuse. A maximum penalty of 100 penalty units applies if an information provider fails to comply. This provision is necessary to support the operation of the database by ensuring that particular information is recorded in it. As noted above, it also takes account of the fact that the Queensland database will be part of the NDE, and as such, will need a degree of flexibility around some requirements, including the timing and method of providing information. Prescribing these details by regulation means that where information for recording on the monitored medicines database must be given to the chief executive, Queensland Health will be able to put safeguards in place for how this information is given and to protect it and also ensures that the way stakeholders are asked to supply data is efficient and contemporary.

Clause 227 (Use of information) provides that the chief executive may prescribe an entity by regulation to be a user of the database, and may disclose information in the database to a user by giving them the information or giving the user electronic access to the database. Users to be

prescribed by regulation will include prescribers and dispensers who are treating individual patients, database administrators for the purpose of system improvement and maintenance, and the Health Ombudsman to support its functions. Prescribing users by regulation allows the database to be managed flexibly to respond to changing public health needs. A regulation may prescribe a purpose for which a user may access and use information from the database. The purposes for which particular users will be granted access to the database or given information from the database will include providing electronic access to prescribers and dispensers who are treating individual patients, access to database administrators for the purpose of system improvement and maintenance, and access to the Health Ombudsman to support its functions. It is appropriate to prescribe the purposes by regulation as the purposes are expected to change over time when, for example, the operation of the NDE is finalised, the functionality of the system reflects technology changes and the capability of users matures such as prescribers and dispensers who access the database in providing care for patients. Appropriate safeguards are included. The chief executive may impose a condition on a user for accessing or using information from the database if the condition is consistent with a purpose mentioned in clause 224 or prescribed by regulation for the user under this clause.

Clause 281 (Procedure until monitored medicines database operational) sets out transitional arrangements to deal with the application of the monitored medicines database provisions until the monitored medicines database is operational. The transitional provision applies during the transition period, that is, between commencement of the transitional provision and a day prescribed by regulation as the day the database becomes fully operational. The day the database becomes operational will be prescribed by regulation to ensure that appropriate IT requirements and communications with stakeholders can be undertaken prior to the database going live and the requirements under the scheme commencing.

#### Agents and carers

Clause 51 (Agents and carers) provides that a person does not commit an offence against the Act if they supply a medicine by giving to it a patient, if the medicine has been lawfully supplied for the therapeutic treatment of the patient; for lawfully helping a patient, administer a medicine in accordance with the approved label of the medicine; or administer a medicine to an animal in accordance with the approved label of the medicine. This provision ensures that carers, for example, a child's parent, can administer a medicine without breaching an offence under the Act.

This exemption from the offence provision does not apply to the extent that a person is authorised to supply or administer the medicine, for example, an approved person who is subject to requirements under the Medicines Regulation.

Subsection (3) provides that the exemption also does not apply to a person prescribed by regulation to be a person to whom the subsection does not apply. This will ensure that emerging industries can be regulated appropriately by regulation, where it is not appropriate for the exemption to apply.

#### Approved persons

Clause 54 (Authorisation of prescribed classes of persons) provides that a regulation may prescribe a class of persons to be authorised to carry out a regulated activity with a regulated substance. This concept is central to the medicines and poisons framework, with a range of

approved persons to be authorised under the scheme to carry out a regulated activity with a regulated substance because of their occupation, profession or the position they hold. Approved persons, for example pharmacists, nurses or primary producers using certain pesticides or fumigants on their own property, will not be required to apply for a licence or general approval under the Bill to carry out specific regulated activities.

It is appropriate for approved persons to be prescribed by regulation as this is a matter of detail that is subject to change as models of care evolve. The application of the Bill is also very broad, applying to all types of health practitioners with as-of-right authorities, as well as other persons with a legitimate need to access and use medicines, poisons and prohibited substances for their business or other purposes, such as those licensed for pest management, persons working across animal management such as veterinary surgeons and non-health related individuals with a need to possess or control regulated substances for a specific purpose, such as transport carriers or detention centre management.

The list of approved persons to be included in regulations is extensive and the limitations to be placed on what is to be authorised activities with regulated substances is technical in nature and must be tailored to each type of approved person. The lists of approved persons require detailed definitions and for some categories of health professional, multiple conditions for different activities need to be prescribed separately. This amount and level of detail is better suited to inclusion in subordinate legislation rather than the Act. Substance authorities, such as licences for manufacturing or wholesaling, are included in the Bill, because the Bill can set restrictions for what a particular licence permits the licence holder to do, and conditions for these authorities can be included if this is necessary. This ability to impose conditions is not available for approved persons, particularly those with an as-of-right authority, so it is appropriate to include this detail in the regulations.

### Authorities

Clause 60 (Authorisation for persons subject to work health and safety laws) provides that a person is taken to be authorised to buy, possess or apply an S7 poison, other than a work health and safety excluded poison, in the authorised way, if they do so in compliance with work health and safety law, and if they:

- buy, possess or apply the S7 poison at a place that is subject to a work health and safety law,
- it is not done at a person's residence or accessible by the general public, and
- the person buys, possesses or applies the S7 poison in the course of performing their duties.

Persons who buy, possess or apply S7 poisons in industries such as engineering, construction, agriculture or other trade-related activities which have a legitimate use of these poisons will not be subject to the provisions of the Bill. The Bill requires that the person buy, possess and apply the poison in the course of their duties at the workplace and comply with work health and safety laws. For example, a welder could purchase or use or dispose of a pickling paste containing hydrofluoric acid without requiring a substance authority under the Bill.

The provision does not apply if the buying, possession or application at the place relates to a type of industry prescribed by regulation. This is to protect public health by preventing persons with no legitimate workplace use or competency from accessing dangerous poisons in a workplace. For example, childcare centre workers do not require dangerous poisons in the management of a childcare business, and home-based accountants have no need to access

dangerous poisons, such as hydrofluoric acid, in their workplace. This provision allows additional industries that may be identified in the future to be added to the list of prescribed industries in a timely manner. If a person working in a prescribed industry has a legitimate reason for using a dangerous poison, they can apply for a general approval. In their application, they will be required to include justification of their need to access the poison for workplace use.

Clause 68 (What is a *general approval*) provides that a general approval authorises the holder to carry out the regulated activity with the regulated substance stated in the approval. Subsection (2) provides that a regulation may prescribe different classes of general approval for carrying out different types of activities. It is appropriate to prescribe classes of general approvals by regulation due to the range of diverse activities that will need to be captured, and the need to respond flexibly if further activities need to be added in future. For example, a general approval may authorise a person or an entity to:

- possess a regulated substance for an animal for humane treatment and/or administer a regulated substance to an animal for humane treatment;
- possess, supply or administer a regulated substance as part of a specialised health program such as a commercial immunisation program or palliative care;
- possess and/or supply a regulated substance for the purpose of healthcare in an isolated or remote area (for example, first aid at a mine or an island resort);
- possess, supply or apply a poison (other than a S5 or S6) for teaching or research purposes;
- possess and apply a restricted S7 poison to kill invasive vertebrate animals at a landholder's property; or
- manufacture prohibited substances at a university for research purposes.

Clause 70 (Conditions) provides that a regulation may prescribe standard conditions that apply to a type of substance authority, for example, how to test batches of regulated substances during manufacturing or how to dispose of waste for a regulated substance. It further provides that the regulation may prescribe the standard conditions by reference to a code, guideline, protocol or standard, including a departmental standard. It is considered appropriate to prescribe standard conditions by regulation noting the range of substance authorities that standard conditions will need to be stipulated for, the technical nature of such conditions, and the need to respond flexibly if changes are required in future. The technical nature of the standard conditions to be set out may be lengthy and detailed and is better suited to inclusion in the regulation. For example, if a code, guideline, protocol or standard is updated or renamed, by referring to these in a regulation, the standard conditions to reflect these changes may be updated in a timely manner.

Clause 75 (Requirements for making initial application) sets out the requirements for making an application for a substance authority and provides that a regulation may prescribe the fee payable for the application. Clause 78 (Requirements for making amendment application) sets out the requirements for making an application for an amendment of a substance authority and provides that a regulation may prescribe the fee payable. Clause 82 (Requirements for making renewal application) sets out the requirements for making an application for a renewal of a substance authority and provides that a regulation may prescribe the fee payable. As with other fees, prescribing these fees by regulation is appropriate so that they can be updated annually in accordance with annual indexation.

Clause 76 (Deciding initial application) provides that the chief executive must decide whether or not to grant an application for a substance authority. The chief executive may decide to

impose additional conditions or vary a standard condition if they reasonably believe it is necessary. This provision enables the chief executive to vary a standard condition under the regulations. This is an existing power under the Health (Drugs and Poisons) Regulation and is necessary as the standard conditions under the regulations may not always be appropriate. For example, additional or varied conditions may also be required on a case-by-case basis where a general approval is granted for a unique application such as a research proposal, to protect public health due to the diversity and unpredictable application of poisons for research, or an anaesthetic technician who applies for a general approval to administer anaesthesia under the instruction of an anaesthetist in an emergency.

### Managing regulated activities

Clause 91 (Requirements may be prescribed) provides that a regulation may prescribe requirements for a person, or a class of persons, authorised under clause 54(4), 57 or 62 in relation to carrying out a type of regulated activity with a regulated substance.

As noted above, clause 54 provides that approved persons may be prescribed by regulation to be authorised to carry out a regulated activity with a regulated substance. Clause 57 provides that a person is authorised to carry out a regulated activity with a regulated substance if the person is authorised under an emergency order. Clause 62 provides that particular persons are authorised to carry out a regulated activity with a regulated substance under a substance authority.

It is necessary to be able to prescribe requirements for approved persons authorised under the above clauses. Given the range of approved persons and regulated activities required to be regulated under the scheme, detailed requirements must be prescribed in the regulations for each class of approved person. For example, only a specialist medical practitioner may be authorised to prescribe a specific restricted medicine. These are matters of detail that would not be appropriate to include in the Bill, as flexibility is required to ensure Queensland Health can respond promptly if changes are needed to the framework in future. Also, clinical knowledge of medicines is required to best determine the appropriate scope of practice and safeguards that should be provided for approved persons dealing with a regulated substance.

Without limiting the ability for a regulation to prescribe requirements, subsection (2) provides that a requirement may state the way a regulated activity must be carried out; require a person to comply with an EPA or departmental standard; require a person to comply with another code, guideline, protocol or standard; or require a person to notify the chief executive if particular things happen in relation to a regulated activity or regulated substance.

For example, a requirement may be needed to:

- restrict the types of pesticides that can be used by a person constructing fences on a rural farm and placing a pesticide in the base of the fence post hole, and to impose relevant competencies for the person. These requirements may be necessary to ensure the person handles the pesticide appropriately, preventing pesticides entering the food supply and harming public health; or
- set the limited conditions under which dentists are able administer or prescribe Schedule 8 (S8) medicines to a patient. The conditions include restrictions on a dentist prescribing S8 medicines to the extent that they may not give a repeat prescription for the medicine or prescribing more than three days supply of the medicine, and setting out the particular S8 medicines a dentist may administer or prescribe.

A requirement prescribed under this clause that applies to an approved person is subject to clause 55 (Changes to approved person's authorisation) and 56 (Relationship between different authorisations).

### Substance management plans

To support the development of substance management plans by certain substance authority holders, the Bill provides for particular matters to be prescribed by regulation:

- Clause 92 (Definitions for part) provides that a regulation may prescribe a place to be a *regulated place* and a person to be the *responsible person* for a regulated place; and
- Clause 93 (Requirements for substance management plan) provides that matters to be addressed in substance management plans may be prescribed by regulation, and that the plan should be reviewed at the time prescribed by regulation.

The list of regulated places and responsible persons for those places are most appropriately listed in the regulation as they may be subject to change from time to time. The legislation also needs to keep pace with definitional changes for places or persons in other legislation so that the risk management measures in the substance management plan are maintained and adhered to for the safe use of regulated substances in particular places. For example, early childhood facilities will be required to have a substance management plan, and workers at the facilities will be required to comply with the plan. However, early childhood facilities will be identified by cross-referencing the legislation under which they are established and funded. As these types of references change from time to time, it is appropriate that they are included in a regulation, rather than the Bill, so that they can be updated rapidly. Similar considerations apply to identifying the responsible person for the plan, who is a key figure in the risk management framework. Often, a responsible person will be defined by reference to other legislation, such as for a principal at a school. Any changes in the other legislation must be quickly reflected in the Medicines and Poisons legislation to ensure continuity and consistency in the application of the provisions.

The matters that must be addressed in a substance management plan, with reference to the potential risks, are numerous and detailed. This level of detail is not appropriate for inclusion in the Bill. The details of what must be included in a plan is proposed to be set out in a Substance Management Plan Standard. It is proposed that the standard will address each type of regulated dealing with a regulated substance and identify known or foreseeable risks associated with each dealing. The standard will also provide details of the expected minimum outcomes to be achieved in managing and mitigating these risks. The inclusion of these matters in a standard will mean that they are easier to translate into a Substance Management Plan, as the matters will have a more practical focus. The standard is intended to be an accessible and useable document for stakeholders, and this is best achieved by inclusion as a standard to the regulation.

### Inspectors' powers

The Bill provides for inspectors' functions and powers to ensure compliance with the scheme. A number of matters relating to inspectors are prescribed by regulation:

- Clause 131 (Appointment and qualifications) provides a regulation may prescribe persons that may be appointed as inspectors;

- Clause 132 (Appointment conditions and limit on powers) provides an inspector holds office on conditions, which may be stated in a regulation. A regulation may also limit inspectors' powers; and
- Clause 140 (General power to enter places) sets out the general powers of an inspector to enter a place. Subsection (1)(e) provides that an inspector may enter a place if it is an authorised place that is required to be open for inspection as a condition of the authorisation of the place. *Authorised place* is defined to mean a place where a regulated activity with a regulated substance is authorised to be carried out under an approved person's authorisation or a substance authority.

It is considered justified for these matters to be prescribed by regulation to ensure that Queensland Health can manage its inspectors appropriately to ensure compliance with the scheme. Inspectors appointed for special purposes due to emerging issues may need to be prescribed under a regulation, as to prescribe by amendment to the Act, when made, would cause delay in appointments, particularly where the appointment is of specialists and technical experts. A delay may increase or prolong the public's potential exposure to the harm to be prevented. Conditions under which an inspector holds office may need to be amended to reflect operational requirements. The regulation may, for example, refine appointment conditions to ensure that inspectors undergo appropriate training. The appropriate training may need to change to adapt to changing conditions or circumstances, therefore it is considered appropriate for this detail to be in subordinate legislation. For example, inspectors monitoring compliance with the requirements for the monitored medicines database may require specific qualifications so that they have the requisite knowledge to assess and audit compliance of a technical information system.

#### State analysts

The Bill provides for the appointment of State analysts for the purpose of conducting analysis to support the scheme. Certain matters relating to the appointment of state analysts are prescribed by regulation:

- Clause 189 (Appointment and qualifications of State analyst) provides a regulation may prescribe persons that may be appointed as State analysts; and
- Clause 190 (Appointment conditions of State analyst) provides that a State analyst holds office on conditions, which may be stated in a regulation.

It is considered justified for these matters to be prescribed by regulation to ensure that Queensland Health can manage its State analysts appropriately. For example, the conditions on which a State analyst holds office need to be amended to reflect operational requirements.

#### Extended practice authorities

Clause 232 (Making extended practice authorities) provides that the chief executive may make a document, known as an EPA, stating the places or circumstances in which an approved person may deal with a regulated substance; imposing conditions on dealing with a regulated substance; or requiring an approved person to hold particular qualifications or training to deal with a regulated substance.

In order to ensure the purposes of the Bill are met through people carrying out activities with medicines having the necessary competencies and that health and safety risks being appropriately managed, subsection (3) provides that a regulation may prescribe criteria about

the matters the chief executive must consider before making an EPA. This will include matters such as the types of medicines to be dealt with, the service need to be met by the authority and how the risks associated with the medicines will be managed.

The EPA will not take effect until it is approved by regulation, and it is intended that the name and date of the relevant EPA will be prescribed by regulation. Each time an EPA is updated, including any changes to the conditions, a regulation amendment will prescribe the new name and date. Queensland Health has made a commitment to table any extrinsic material referenced in legislation in the Legislative Assembly, so the updated EPA will be tabled, providing the Legislative Assembly with an opportunity to consider the EPA and any conditions imposed under it.

### Transitional provisions

Clause 243 (Meaning of *equivalent*) provides that an approved person's authorisation or a substance authority under the Medicines and Poisons scheme is equivalent to a former authorisation if the new authorisation authorises substantially the same activity with a substance as the former authorisation authorised, even if the activity is described differently, the conditions of the new authorisation and the former authorisation are not identical or the new authorisation authorised a regulated activity that includes, and is more than, the activity authorised under the former authorisation.

Clause 243 provides that a regulation may prescribe a new authorisation to be equivalent to a former authorisation. This is necessary to provide approved persons and substance authority holders with clarity about their authorisations.

### Transitional Regulation-making power

Clause 282 (Transitional regulation-making power) provides that a regulation may make provision of a saving or transitional nature about a matter for which it is necessary to make provision to allow or facilitate the transition from the Health Act or Pest Management Act to this Act, and for which the Act does not make provision or sufficient provision. The transitional regulation may have retrospective operation to the day the Act commences.

Although the Bill provides for a range of transitional issues, it is possible that unanticipated matters may arise given the complexity of transitioning to the new Bill. The inclusion of such a regulation-making power is justified because it is critical to ensure that any arrangements under the existing scheme that need to be transitioned to the new scheme are identified, to ensure individuals' rights are not adversely affected. For example, the requirements for storage, labelling and record-keeping are outlined in the regulation and an existing exemption from one of these requirements, such as an exemption granted under the Health (Drugs and Poisons) Regulation, may need to be carried over to the new scheme. The regulation-making power will ensure that any transitional issues that have not been identified during drafting of the Bill can be quickly addressed. It is common practice to include a transitional regulation-making power in complex legislative schemes.

Clause 282 also provides that this clause, and any transitional regulation made under it, expire two years after the clause commences. Transitional regulation-making powers and transitional regulations often expire after one year. However, for this Bill, two years is considered necessary to accommodate the phased implementation of the monitored medicines program of work. It

may take more than 12 months before the monitored medicines database becomes operational. Operationalising the database is also affected by the timing of national real-time prescription data sharing, following agreement at the COAG Health Council meeting on 13 April 2018 to a new, federated model. Australian jurisdictions have committed to progress the development and adaptation of their own regulatory systems to connect to, and interface with, national systems to achieve a national solution. The federated model involves the establishment of a National Data Exchange (NDE), which will use prescribing and dispensing information and other information from jurisdictional regulatory systems to provide information to support clinical decision-making. It is proposed under the federated model that each jurisdiction integrates with the NDE, to form a national real-time reporting solution. Transitional provisions may be needed that factor in the timeframes required for integrating the database into the NDE.

Some other provisions in the Bill may not take effect until 12 months after the commencement of the Act. For example, entities that hold a current licence will have 12 months from commencement to develop a substance management plan. If any implementation issues are identified that require changes to the scheme, these may need to be made during a period of up to two years after the commencement of the Act, to provide sufficient time for affected stakeholders to implement any transitional arrangements.

### Definitions

Schedule 1 provides for the definitions of *diversion-risk medicine*, *monitored medicine* and *pest* to be prescribed in regulation. Clause 70(1)(a) provides for a *standard condition* to be prescribed by regulation to apply to a substance authority.

It is considered necessary to define *monitored medicines* and *diversion-risk medicines* in regulation because the evolutionary nature of drug development means that new substances with a potential for diversion for illicit use are regularly developed or identified. In addition, the process of drug use evaluation frequently identifies new risks with existing medicines. For example, quetiapine, an anti-psychotic medicine, has recently been identified as a drug of potential misuse or abuse, a characteristic that was not known at the time this medicine was originally marketed.

It is necessary to define *pest* by reference to the regulation to provide flexibility to add additional classes of pests that become a problem to health, agriculture and industry in a timely manner.

The reasons for prescribing standard conditions by regulation has been outlined and justified above.

## **Consultation**

### **Office of Best Practice Regulation**

During development of the Bills and Regulations, the Office of Best Practice Regulation (OBPR) was consulted.

In March 2019, OBPR assessed the Medicines and Poisons framework and advised that no further regulatory impact assessment was required under the Regulatory Impact Statement system as any impacts have been adequately assessed. OBPR specifically assessed the real-

time reporting database of monitored medicines and considered that while there may be some impacts on stakeholders, on balance the proposal is unlikely to lead to significant adverse impacts and should reduce overall regulatory requirements for prescribers and dispensers.

### **External stakeholder consultation**

Preliminary consultation on the new framework took place in 2014 and 2015. Stakeholders from a broad range of industries regulated under the existing legislation were formally invited to participate in face-to-face discussion groups and information sessions about the proposed approach.

Between September and October 2018, the draft Bill and accompanying Regulations were released on the GetInvolved website for targeted stakeholder feedback, along with a detailed consultation paper and tailored fact sheets. The link to the GetInvolved website was provided to over 400 stakeholders, including relevant peak bodies. Several workshops were held for stakeholders and peak bodies. Stakeholders were invited to either submit their feedback online through the GetInvolved feedback form or via written submission.

A total of 109 submissions were received in response to the targeted external consultation process.

Key stakeholders who submitted feedback included the Australian Medical Association Queensland (AMAQ), Australian Dental Association Queensland, Queensland Nurses and Midwives' Union (QNMU), the Pharmacy Guild of Australia (Queensland Branch), the Pharmaceutical Society of Australia (Queensland Branch), Leading Aged Service Australia – Queensland (LASA-Q), Australian Veterinary Association – Queensland Division, University of Queensland, Stock Feed Manufacturers' Council of Australia, Australian Environmental Pest Managers Association, Local Government Association of Queensland, local governments, land holders in rural and regional Queensland, AgForce Queensland and poison manufacturers, wholesalers and retailers.

Stakeholders were generally supportive of the new framework. Many strongly supported the new real-time prescription monitoring system, approved persons provisions and the approach to licences and general approvals. The feedback received was used to refine the framework, and ensure it meets modern industry practices.

#### *Pharmacy sector*

The pharmacy sector, including The Pharmacy Guild of Australia (Queensland Branch) and The Pharmaceutical Society of Australia (Queensland Branch), generally supported the new legislation including the introduction of a real-time prescription monitoring system and substance management plans. Several stakeholders expressed an interest in being involved in the real-time prescription monitoring system project and will be important participants in the development of this body of work. The sector was supportive of changes that will allow pharmacists to better manage their stock and to safely dispose of medicine waste, however recommended that guidance materials be provided to facilitate implementation of these changes. Queensland Health will develop implementation materials, such as fact sheets, and training for authorised officers to facilitate the changes.

*Australian Medical Association Queensland*

AMAQ was generally supportive of the new legislation, in particular real-time prescription monitoring. AMAQ expressed some reservations about midwives and nurse practitioners being authorised to prescribe S8 medicines and automatic recognition of scheduled medicines endorsements established by National Boards for optometrists and podiatrists. These scopes of practice have been endorsed by the appropriate National Boards, established under the Health Practitioner Regulation National Law, who set out the qualifications and other requirements that must be met. The amendments relating to suitably qualified midwives and nurse practitioners prescribing S8 medicines have since been incorporated into the Health (Drugs and Poisons) Regulation. The Medicines and Poisons framework will simply translate what is already in the Health (Drugs and Poisons) Regulation, with no additional policy changes.

*Substance management plans*

Many stakeholders supported the substance management plan policy, with the approach considered similar to other quality or risk management plans already in place. Some stakeholders sought further clarification about implementation of this policy, such as what information should be included in the plan. The *Substance Management Plan Standard* will provide an overarching set of standards around risk management applicable across industries, however, some stakeholders requested that the draft Standard include more detail. Queensland Health proposes to roll out a comprehensive communications strategy during implementation, including templates and sample substance management plans for different categories of entities, and ongoing information will be available to stakeholders. Stakeholders will also be advised that existing policies, procedures and accreditation documentation may form part, or all of their plan, which will minimise any resource impacts.

One stakeholder raised concerns in relation to substance management plans including whether they would adequately address risks around medication management in RACFs. Substance management plans will serve as a risk mitigation tool, but there are also other controls in the legislation to address these risks. Substance management plan requirements will be consistent with the requirements under the Commonwealth's *Guiding principles for medication management in residential aged care facilities*.

Stakeholders also queried how substance management plans will be monitored by Public Health Units. Monitoring of substance management plans will be included in training for inspectors.

*Aged care workers*

QNMU raised concerns about the provisions in the draft Medicines and Poisons Bill and Medicines Regulation that would allow aged care workers to assist residential aged care facility residents with their medicines, citing safety concerns. QNMU is of the view that only registered nurses and supervised enrolled nurses should be able to assist residential aged care facility residents with their medicines. As a result, the agents and carers provision in the Medicines and Poisons Bill (clause 51) which allows a carer to lawfully help a patient by administering a medicine, will not apply to a person prescribed by regulation. It is intended to prescribe aged care workers by regulation, with the detail of their requirements under the draft Medicines Regulation to be determined prior to making of the Regulation. Further refinement to the regulation of aged care workers under the Medicines and Poisons scheme may be needed

following the Royal Commission into Aged Care Quality and Safety and the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee's Inquiry into aged care, end-of-life and palliative care, and voluntary and assisted dying.

#### *Poisons and pest management industry feedback*

The pest management industry was supportive of the new legislation, however requested that there be a separate regulation for poisons and pest management to avoid confusion with requirements for medicines.

Most feedback received from poisons and pest management stakeholders sought clarification on the legislation, and was resolved with changes to the draft Poisons Regulation and further consultation.

Universities and local governments were supportive of the new entity level approvals, noting that the new regime would reduce both administrative burden and wait times for new employees to commence their duties.

#### *Agricultural sector feedback*

AgForce Queensland sought clarification about the implications of the new scheme on primary producers. Under the Pest Management Act, pest management activities in primary production were exempt from the Act, however, the requirements of the Health (Drugs and Poisons) Regulation in relation to high risk poison such as strychnine and fluoro acetic acid use for wild animal control applied. Under the new scheme, primary producers and their employees are still exempt from the need to have a pest management licence when undertaking pest management activities on their own properties. However, fee for service pest management providers are required to hold a pest management licence if undertaking this work in primary production. The requirements for primary producers using high risk poisons to hold an approval continue under the new scheme. Further clarification was sought in relation to the various types of fee for service pest management activities in primary production such as cattle dipping in public dips and post-harvest treatment of produce. These service providers would not be required to have a licence provided they hold nationally agreed competencies. Both the key bodies, the Australian Environmental Pest Managers Association and AgForce Queensland indicated their support for this approach.

The Veterinary and Livestock industry were consulted extensively about new provisions for treating herds of animals with antibiotics. The industry was supportive of the new provisions that reduce red tape on primary producers while still ensuring veterinary surgeons adhere to appropriate models of antibiotic stewardship.

#### *Fee structure*

The proposed Medicines and Poisons framework contains no new or increased fees. The existing fee structure has been translated into the new framework and no new or additional fees will be payable, for example fees for primary producers who hold a licence or approval will not change. No issues were raised during consultation on the proposed fee structure.

## Consistency with legislation of other jurisdictions

The Medicines and Poisons Bill adopts the schedules of the Poisons Standard in the same way as all other Australian states and territories. All jurisdictions restrict access to, and use of, these scheduled substances to those who have a legitimate need and only to persons authorised to do certain activities with scheduled substances. Queensland's Medicines and Poisons legislation adopts similar mechanisms as other jurisdictions to authorise certain persons to deal with medicines and poisons, for example through recognising a person's registration as a health practitioner, or granting licences and permits.

To better address inconsistencies remaining between jurisdictions, particularly in relation to specific authorities to deal with medicines and rules for performing certain functions such as writing prescriptions and securely storing medicines, Queensland's Medicines and Poisons Bill adopts outcomes-based controls. In this way, the new scheme will remove some interjurisdictional inconsistencies, particularly in relation to storage, transport, and disposal of medicines, which will improve flexibility for businesses and reducing regulatory burdens for those operating across state and territory borders.

### *Real-time prescription monitoring*

In April 2018, there was national agreement through the COAG Health Council to implement real-time prescription monitoring, and Victoria and the Australian Capital Territory have subsequently commenced legislation enabling this. The Medicines and Poisons Bill provides a head of power for the establishment of a real-time prescription monitoring scheme to essentially align with those jurisdictions and to meet Queensland's obligations under the national agreement.

### *Medicinal cannabis*

The provisions of the *Health and Other Legislation Amendment Act 2019* that did not commence on assent will be commenced by proclamation on 1 July 2019 and will repeal the *Public Health (Medicinal Cannabis) Act 2016* and amend the Health Act to significantly streamline the regulatory framework for prescribing medicinal cannabis in Queensland by allowing it to be regulated and treated the same as other S4 or S8 medicines.

The Medicines and Poisons legislation continues to treat medicinal cannabis the same as other S4 or S8 medicines, consistent with how medicinal cannabis is regulated in many other jurisdictions in Australia.

### *Terminology*

The Bill adopts the same terminology as used in the Poisons Standard to closely align with the Poisons Standard, and therefore with other states and territories. This will assist users of the legislation who operate across borders or under Commonwealth legislation.

### *Pest management*

All states and territories have legislation requiring the licensing of pest management technicians and the activities they can undertake. Similarly, control of wild dogs and other

invasive pests using high-risk poisons, such as strychnine and fluoro acetic acid, are regulated using similar mechanisms as proposed under the Bill.

# Notes on provisions

## Chapter 1 Preliminary

### Part 1 Introduction

#### Short title

*Clause 1* provides that, when enacted, the short title of the Act will be the *Medicines and Poisons Act 2019*.

#### Commencement

*Clause 2* provides for the commencement of the Act on a day to be fixed by proclamation.

### Part 2 Purposes of Act

#### Main purposes

*Clause 3* states the purposes of the Act are to:

- ensure particular substances are made, sold, used and disposed of in an appropriate, effective and safe way;
- ensure any health risks arising from the use of the substances are managed appropriately;
- ensure persons who are authorised to carry out activities using the substances have the necessary competencies to carry out the activities safely.

#### How main purposes are to be achieved

*Clause 4* states that the main purposes of the Act will be achieved by:

- identifying particular activities and substances to be controlled;
- authorising classes of persons to use these substances in controlled ways for particular purposes;
- providing a scheme to authorise additional activities with the substances under approvals or licences;
- requiring persons authorised to use the substances to have the necessary competencies and be accountable for their safe and effective use;
- requiring that particular things be done to ensure that the safety, quality and appropriate use and disposal of the substances at all stages, from manufacture to supply to the consumer and final disposal as waste; and
- providing for compliance with this Act to be monitored and enforced.

## **Part 3                      Application and operation of Act**

### **Act binds all persons**

*Clause 5* provides that the Act will bind all persons including the State and, as far as the legislative power of the Parliament permits, the Commonwealth and other states. Nothing in the Act makes the State, the Commonwealth or another State liable to be prosecuted for an offence against the Act.

### **Relationship with other Acts**

*Clause 6* provides that this Act does not limit or otherwise affect the application of the following Acts:

- *Agricultural and Veterinary Chemicals (Queensland) Act 1994*, which applies the Agvet Code and Agvet Regulations made under the Agricultural and Veterinary Chemicals Code Act as laws of Queensland;
- *Agricultural Chemicals Distribution Control Act 1966*;
- *Chemical Usage (Agricultural and Veterinary) Control Act 1988*;
- *Drugs Misuse Act 1986*;
- *Public Health Act 2005*;
- *Radiation Safety Act 1999*; and
- *Therapeutic Goods Act 2019*.

### **Exemption for low-risk activities**

*Clause 7* provides an activity, of a type prescribed by regulation, with a substance is exempt from the operation of this Act. The Minister must be satisfied the activity with the substance could reasonably be expected to pose no, or a negligible, health risk to any person, before recommending to the Governor in Council the making of a regulation prescribing a type of activity.

## **Part 4                      Interpretation**

### **Division 1                Definitions generally**

#### **Definitions**

*Clause 8* provides that particular words used in the Act are defined in the dictionary in schedule 1.

#### **Relationship with Poisons Standard**

*Clause 9* provides that, to the extent the context permits, words and expressions which are defined in the Poisons Standard and used in this Act have the same meaning in this Act as they have in the Poisons Standard.

The Poisons Standard, which is also referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons*, means the current Poisons Standard under section 52A(1) of the

Therapeutic Goods Act. The Poisons Standard is a Commonwealth regulatory document that classifies medicines or poisons into schedules depending on the level of control over the availability of the medicine or poison that is required to protect public health and safety. The Poisons Standard contains decisions made by a joint Commonwealth and State committee which classifies substances into the appropriate schedules. The Poisons Standard also includes model provisions about containers and labels, a list of products recommended to be exempt from these provisions, and recommendations about other controls on drugs and poisons. The Australian Health Ministers' Advisory Council is responsible for scheduling policy and the Secretary of the Commonwealth Department of Health is the decision maker on scheduling of medicines and chemicals, and other changes to the Poisons Standard.

An interpretation provision in the Poisons Standard applies for interpreting the words and expressions of this Act. However, this does not apply to the definition of *poison*. A schedule of the Poisons Standard applies to a substance if the substance is listed in the schedule and the substance is not excluded from the schedule. Furthermore, if the Poisons Standard mentions a restriction for the substance, the restriction applies in relation to the substance.

As detailed in Table 1, the legislation will use the terms “medicine”, “poison” and “prohibited substance” to reflect the classification of the Poisons Standard.

**Table 1: Regulated substances**

New Terminology	Poisons Standard Schedule
Medicine (An S2, S3, S4 or S8 regulated substance for therapeutic use)	<ul style="list-style-type: none"> <li>• pharmacy medicine (S2)</li> <li>• pharmacist only medicine (S3)</li> <li>• prescription only medicine or prescription animal remedy (S4)</li> <li>• controlled medicine (S8)</li> </ul>
Poison (A poison is a regulated substance that is not a medicine, fumigant or pesticide)	<ul style="list-style-type: none"> <li>• any S2, 3, 4 or 8 medicine for non-therapeutic use</li> <li>• low harm poison (S5)</li> <li>• moderate harm poison (S6)</li> <li>• dangerous poison (S7)</li> </ul>
Prohibited substance	<ul style="list-style-type: none"> <li>• S9 substances that should be available only for medical or scientific research, or for analytical, teaching or training purposes</li> <li>• S10 substances or preparations, the sale, supply or use of which should be prohibited for the purposes listed because of their known dangerous properties</li> </ul>

## Division 2 Substances

### Meaning of *substance*

*Clause 10* provides that a substance includes an ingredient, compound, preparation or extract of a substance.

For this Act, a substance may be described by reference to any of the following matters:

- the Poisons Standard;
- a code, guideline, protocol or other standard;
- the way in which the substance is, or is intended to be, used;
- the purpose for which the substance is, or is intended to be, used;
- the quantity of the substance;
- the packaging or labelling of the substance;
- the physical or chemical state or form of the substance.

### **Meaning of *medicine***

*Clause 11* provides a definition for a *medicine* as a substance to which the Poisons Standard, schedule 2, schedule 3, schedule 4 or schedule 8 applies.

However, a substance is not a medicine to the extent it is treated as a poison under clause 12(2).

A regulation may prescribe another substance to be a medicine and provide for the substance to be treated as if it were an S2, S3, S4 or S8 medicine.

### **Meaning of *poison***

*Clause 12* provides a definition for a *poison* as a substance, other than a fumigant or pesticide, to which the Poisons Standard, schedule 5, schedule 6 or schedule 7 applies.

A medicine is treated as a poison under this Act if the medicine is not used, or is not intended to be used for a therapeutic use, as defined in part 1 of the Poisons Standard. For example, where a medicine is used in non-clinical research or as an analytical reagent, it is treated as a poison. Also, a medicine is treated as a poison if the medicine is not disposed of, or is not intended to be disposed of, after the therapeutic use of the medicine.

This does not apply to waste from a medicine disposed of because it is not required for the therapeutic use. Unused, unwanted medicine that has been placed in a medicines' return bin (part of the Return Unwanted Medicines (RUM) Project funded by the Commonwealth Government) is intended to be disposed of and is left as waste at a place, a community pharmacy, (in accordance with the definition of *dispose* in clause 28).

A regulation may prescribe another substance to be a poison and provide for the substance to be treated as if it were an S5, S6 or S7 poison.

### **Meaning of *prohibited substance***

*Clause 13* defines a *prohibited substance* as a substance to which the Poisons Standard, schedule 9 or schedule 10 applies (an S9 or S10 *prohibited substance*).

A regulation may prescribe another substance to be a poison and provide for the substance to be treated as if it were an S9 or S10 prohibited substance.

### **Meaning of *fumigant* and *pesticide***

*Clause 14* defines a *fumigant* as a substance that is approved for use, to carry out an activity of a type mentioned in clause 19(2)(a) to (d) by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Clause 14 defines a *pesticide* as a substance approved for use, to carry out an activity of a type mentioned in clause 19(3)(a) to (c) by the APVMA.

The APVMA is an independent statutory authority established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Cth) to assess, register and review agricultural and veterinary (Agvet) chemicals, including pesticides, fumigants and veterinary medicines, for use in Australia. This assessment takes into account product efficacy, concentration, application, target species and host animals or plants, assuming that the product is applied with good agricultural practice by competent users. As part of this process, a chemical label is approved which details specific use instructions. The APVMA also runs a permit system allowing access to chemicals for uses which are not registered on-label, for example the use of strychnine for wild dog control. The APVMA maintains a Public Chemical Registration Information System and an Agricultural and Veterinary Permits system so that the public can access information regarding registered Agvet products, approved labels and permits issued for non-registered products or uses.

A regulation may prescribe another substance to be a fumigant or pesticide.

In this clause, *APVMA approved*, in relation to a use for a substance, means the substance is approved, registered or permitted for the use by the Australian Pesticides and Veterinary Medicines Authority in the exercise of a function or power under the Agvet Code of Queensland, section 21.

### **Meaning of *S7 substance***

*Clause 15* defines a *S7 substance* as an *S7* poison or a fumigant or pesticide containing a substance to which the Poisons Standard, schedule 7 applies. For example, an *S7* fumigant is not captured as a poison, but is considered a fumigant. An *S7* pesticide is not captured as a poison, but is considered a pesticide.

### **Meaning of *hazardous poison***

*Clause 16* defines a *hazardous poison* as an *S7* substance, or a medicine treated as a poison under clause 12(2).

### **Meaning of *regulated substance***

*Clause 17* defines a *regulated substance* as a medicine, poison, prohibited substance, fumigant or pesticide.

If the expression *S2*, *S3*, *S4*, *S5*, *S6*, *S7*, *S9* or *S10* is followed by the word ‘regulated substance’, it means a substance listed in a schedule of the Poisons Standard that has the same number as the expression or a substance prescribed by regulation to be a regulated substance for a prescribed schedule that has the same number as the expression. If the expression *S2* through

to S10 is followed by the phrase ‘medicine’, ‘poison’ or ‘prohibited substance’, the regulated substance is subject to the meaning of the phrase under this Act.

### **Division 3                      Activities**

#### **Meaning of *deals* with a regulated substance**

*Clause 18* provides that a person *deals* with a regulated substance if they do any of the following activities:

- manufactures the substance;
- buys the substance;
- possesses the substance;
- supplies the substance;
- if the substance is a medicine, administers the medicine, prescribes or makes a standing order for the medicine;
- if the substance is a poison, applies the poison;
- disposes of waste from the substance; or
- asks or directs another person to do something mentioned above.

#### **Meaning of *pest management activity*, *fumigation activity* and *pest control activity***

*Clause 19* defines a *pest management activity* as a fumigation activity or a pest control activity.

A *fumigation activity* is the preparation or use of a substance to kill a pest, sterilise grain or seed to prevent germination, treat soil in which pests might be living or carry out another activity prescribed by regulation.

A *pest control activity* is the preparation or use of a substance to kill, stupefy or repel a pest, inhibit its feeding or modify its physiology to alter its natural development or reproductive capacity. A *pest* is defined Schedule 1.

#### **Meaning of *regulated activity***

*Clause 20* provides that a *regulated activity*, is a dealing with a regulated substance or a pest management activity.

#### **Meaning of *manufacture* a regulated substance**

*Clause 21* provides that to *manufacture* a regulated substance means to carry out any activity using any substance for the purpose of making the regulated substance, including any process or step undertaken to produce the regulated substance or to prepare the regulated substance for supply to the public or a person. For example, testing batches of manufactured substances, compounding medicines in preparation for supply and repackaging poisons for supply.

### **Meaning of *buy* a regulated substance**

*Clause 22* provides that to *buy* a regulated substance includes give a purchase order for the substance and otherwise attempt to obtain the substance, whether or not for consideration.

See also clause 29 in relation to the distribution or transfer of regulated substances in workplaces.

### **Meaning of *possess* a regulated substance**

*Clause 23* provides that to *possess* a regulated substance means to have custody or control of the substance.

To remove any doubt, two or more persons can jointly possess a regulated substance at the same time.

### **Meaning of *supply* a regulated substance**

*Clause 24* provides that *supply* a regulated substance for the purposes of the Act means sell or give the substance to a person. However, *supply* a regulated substance does not include administering the substance if it is a medicine, or applying the substance if it is a poison, or disposing of waste from the substance.

See also clause 29 in relation to the distribution of transfer of regulated substances in workplaces.

### **Meaning of supply-related terms**

*Clause 25* provides that *sell* a regulated substance includes an attempt to sell the substance or make the substance available for sale.

*Dispense a medicine* means sell the medicine to a person on prescription.

*Give a treatment dose* of a medicine, means give 1 or more doses of the medicine to a person to be taken by a particular person, or administered to an animal, at a later time. For example, a medical practitioner may provide a patient with a pack of medicine, rather than write a prescription for the medicine.

### **Meaning of *administer* a medicine**

*Clause 26* provides that a person *administers* a medicine where the person introduces a dose of the medicine into the body of a person or animal by any means or gives a dose of the medicine to a person to be taken immediately. Examples include injecting a medicine into the body of a person or animal, putting cream on the skin of a person or animal or drops into their eyes, handing a dose of tablets to a person to swallow immediately or feeding an animal food that has a medicine mixed into it. Subsection (2) provides that *administer* does not include dispensing the medicine.

### **Meaning of *apply* a poison**

*Clause 27* provides that *apply* a poison means add, apply, disperse, inject, spray or spread the poison. Examples of applying a poison include cleaning an aluminium surface with poison, electroplating metal using a solution containing a poison, adding a poison to another substance to create a chemical reaction or using a poison to calibrate or test a scientific or analytical instrument.

### **Meaning of *dispose* of waste**

*Clause 28* provides that *dispose* of waste from a regulated substance means discard, destroy or abandon the substance waste at a place.

The term dispose covers different methods used for disposing unwanted regulated substances. These methods include chemical inactivation, dilution, disposal to landfill and incineration. The definition does not include recycling or recovery of the substance, as these would be considered manufacturing processes as the regulated substance retains its intended function.

### **Distribution or transfer in workplaces**

*Clause 29* applies if an entity is authorised to carry out a regulated activity with a regulated substance at 1 or more places, and the regulated substance is distributed or transferred between workers for the entity at or between the places.

Despite clause 22 and 24, the distribution or transfer of the regulated substance is treated as possessing, rather than buying or supplying the substance.

## **Division 4 Authorisations**

### **How a person is authorised under this Act**

*Clause 30* provides that an approved person, a person acting under an emergency order, the holder of a substance authority, or another person acting under a substance authority, is authorised to carry out a regulated activity with a regulated substance under this Act.

This Act authorises a person mentioned in subsection (1) only to the extent they carry out the regulated activity with the regulated substance in the authorised way.

See chapter 3, part 1, division 1 in relation to the authorisation of approved persons. See chapter 3, part 1, division 2 in relation to the authorisation of persons under emergency orders. See chapter 3, part 2, division 1 in relation to the authorisation of holders of substance authorities and other persons acting under substance authorities.

Subsection (2) provides that the Act authorised a person mentioned in subsection (1) only to the extent the person carries out the regulated activity with the regulated substance in the authorised way.

## **Meaning of *authorised way***

*Clause 31* provides that a person carries out a regulated activity with a regulated substance in the *authorised way* if the person authorised under clause 54(4), 57 or 62 to carry out the regulated activity with the regulated substance, the person complies with the requirements prescribed for the person under clause 91(1) for carrying out the regulated activity with the regulated substance and the person complies with any substance management plan that applies to the person.

This provision enables trained professionals to undertake their professional practice obligations without needing to list every authorised action in the legislation. These professionals are sufficiently experienced and highly trained to know what the authorised way is when referring to particular activities. Additionally, the regulation is relatively prescriptive on what constitutes the authorised way for each type of dealing.

## **Chapter 2            Offences**

### **Part 1                General offences**

#### **Division 1          Regulated substances**

##### **Offence to deal with prohibited substances**

*Clause 32* states it is an offence (with a maximum penalty of 750 penalty units) for a person to deal with a prohibited substance unless they deal with the substance in the authorised way, or have a reasonable excuse. Examples of a reasonable excuse in relation to possessing a prohibited substance include when a health practitioner or employee working in a hospital receives a prohibited substance while treating a patient or a person becomes responsible for the affairs of the holder of a substance authority who is critically ill, dies, is imprisoned or becomes bankrupt. A general approval can authorise a regulated activity with a prohibited substance.

Examples of situations where a general approval would be issued for dealing with a prohibited substance include the use of a prohibited substance for analytical or research purposes or for the sedation of large animals at a zoo.

##### **Offence to manufacture medicines or hazardous poisons**

*Clause 33* states it is an offence (with a maximum penalty of 750 penalty units) to manufacture a medicine or hazardous poison unless the person manufactures the medicine or poison in the authorised way or has a reasonable excuse.

##### **Offence to buy or possess S4 or S8 medicines or hazardous poisons**

*Clause 34* states it is an offence (with a maximum penalty of 200 penalty units) for a person to buy or possess an S4 or S8 medicine or a hazardous poison unless they buy or possess the medicine or poison in the authorised way or has a reasonable excuse. This offence does not apply to a person to whom an S4 or S8 medicine is lawfully supplied for their own therapeutic treatment, the therapeutic treatment of someone else for whom the person is an agent, or the treatment of an animal. An example of reasonable excuse is where a person becomes

responsible for the affairs of the holder of a substance authority who is critically ill, dies, is imprisoned or becomes bankrupt.

Subsection (1) does not apply to a person who is given an S4 or S8 medicine lawfully supplied for the therapeutic treatment of someone else or an animal and temporarily possesses the medicine until it is needed for the treatment. For example, a teacher at a school may temporarily hold prescribed medicine for a student for the student's treatment.

This provision is intended to prevent the use of S7 substances for domestic and home garden uses due to the high public health risks associated with their use and lack of competency of home owners.

## **Offence to supply medicines or hazardous poisons**

*Clause 35* states it is an offence (with a maximum penalty of 500 penalty units) for a person (the *supplier*) to supply a medicine or a hazardous poison to someone else (the *recipient*), unless the supplier lawfully possesses the medicine or poison and the medicine or poison is supplied in the authorised way, or the supplier has a reasonable excuse.

The following matters are immaterial to whether an offence is committed:

- the quantity of the medicine or poison supplied;
- whether or not the supplier and the recipient are at the same place when the medicine or poisons is supplied;
- whether the medicine or poison is supplied by indirect means (for example by internet, telephone or vending machine).

The offence provision is also intended to cover regulated substances supplied over the internet or where a person acts as an agent, but does not physically handle the regulated substance.

## **Division 2 Medicines**

### **Subdivision 1 Administration and supply generally**

#### **Offence to administer medicines**

*Clause 36* states it is an offence (with a maximum penalty of 200 penalty units) to administer a medicine to someone else or an animal unless the person administers the medicine in the authorised way or has a reasonable excuse.

An example of a situation of a reasonable excuse to administer medicine other than in the authorised way would be in a school or early childhood service setting where a person is not an authorised person to administer a medicine. The Medicines Regulation provides for certain persons at schools and early childhood care facilities to be authorised to administer certain emergency medicines (specifically an adrenaline (epinephrine) autoinjector or an inhaled asthma reliever other than an S4 medicine) with the relevant training. As the administration of one of these medicines can be life-saving, it is not appropriate that, for example, a person who is not an authorised person identifies that a child is in urgent need of an adrenaline (epinephrine) autoinjector being administered because of anaphylaxis, waits for an authorised person to be

found. Delay may put the child at increased risk. Instead, because the situation is an emergency, they could administer the adrenaline (epinephrine) autoinjector to the child without committing an offence against clause 36 because they have a reasonable excuse. This example would apply to administration to anyone at a school or early childhood service, by anyone at the place, including staff or visitors.

### **Offence to supply or administer animal medicines to humans**

*Clause 37* states it is an offence (with a maximum penalty of 100 penalty units) to deal with an animal medicine in relation to the following dealings, unless the person has a reasonable excuse:

- supply the medicine to another person for human therapeutic use;
- administer the medicine to another person;
- self-administer the medicine.

It is a reasonable excuse for the person to deal with the animal medicine because no other medicine is available to treat a human ailment, disease or injury, for example, where there is a rare parasitic infection.

An *animal medicine* means a medicine manufactured or supplied for administration to an animal or labelled with an approved label stating the medicine is for administration to an animal.

### **Offence to prescribe or make standing orders**

*Clause 38* states it is an offence (with a maximum penalty of 200 penalty units) for a person to prescribe or make a standing order for a medicine unless the person prescribes or makes the standing order in the authorised way or has a reasonable excuse.

## **Subdivision 2 Particular substances**

### **Unlawfully buying diversion-risk medicines**

*Clause 39* states it is an offence (with a maximum penalty of 100 penalty units) for a person to use a document the person has unlawfully prepared, or knows has been unlawfully prepared, for buying a diversion-risk medicine.

It is also an offence (with a maximum penalty of 100 penalty units) for a person to give someone who is authorised to prescribe or supply the medicine a statement that the person knows is false or misleading in any way or a statement that omits anything without which it is false or misleading for the purpose of buying a diversion-risk medicine.

### **Offences for self-prescribing or self-administering high-risk medicines**

*Clause 40* states it is an offence (with a maximum penalty of 100 penalty units) for a person who is authorised to prescribe a high-risk medicine to self-prescribe the medicine, unless the person has a reasonable excuse.

An example of a reasonable excuse in this context includes a person who is authorised to prescribe a high-risk medicine being injured in an accident and asking someone to urgently administer a high-risk medicine that is an analgesia to the person.

It is also an offence (with a maximum penalty of 100 penalty units) for a person who is authorised to deal with a high-risk medicine to self-administer a dose of the medicine, unless someone else who is authorised to prescribe the medicine has prescribed the medicine for the person's treatment, or someone else who is authorised to give a treatment dose of the medicine has given the medicine to the person for the person's treatment or the person has a reasonable excuse.

A *high-risk medicine* means a medicine prescribed by regulation to be a high-risk medicine.

### **Restrictions for monitored medicines**

*Clause 41* states it is an offence (with a maximum penalty of 20 penalty units) for a prescriber or dispenser of a monitored medicine to fail to check the monitored medicines database to see whether the person has previously been prescribed or supplied any monitored medicine before taking a proposed action. A proposed action is the prescriber for a monitored medicine proposing to prescribe or supply the monitored medicine for a person or a dispenser proposing to dispense, or give a treatment dose of, a monitored medicine to a person.

The above does not apply to the prescriber or dispenser if the action happens in a situation prescribed by regulation to be exempt or the prescriber or dispenser has a reasonable excuse for not complying.

In this clause, *dispenser*, of a monitored medicine, means a person who is authorised to dispense and give a treatment dose of a monitored medicine. *Prescriber*, of a monitored medicine means a person who is authorised to prescribe and supply a monitored medicine.

### **Offence to dispose of waste from S8 medicine**

*Clause 42* states it is an offence (with a maximum penalty of 200 penalty units) to dispose of waste from an S8 medicine unless the person disposes of the waste by giving it to an appropriate person, disposes of the waste in the authorised way, or has a reasonable excuse.

In this clause, an *appropriate person* means a person authorised to dispose of waste from an S8 medicine or possess an S8 medicine until the waste can be disposed of in the authorised way.

Disposal of waste is also regulated under the *Environmental Protection Act 1994* and the *Waste Reduction and Recycling Act 2011*.

## **Division 3            Poisons and pest management**

### **Offence to apply poisons**

*Clause 43* states that is an offence (with a maximum penalty of 200 penalty units) for a person to apply a poison, other than an S5 or S6 poison, unless the person is lawfully supplied the

poison and the person applies the poison in the authorised way, in accordance with the poison's approved label, or has a reasonable excuse.

### **Offence to carry out pest management activities**

*Clause 44* states that it is an offence (with a maximum penalty of 200 penalty units) for a person to carry out a pest management activity, unless the person carries out the activity in the authorised way, has a reasonable excuse.

This offence does not apply to a person who is any of the following:

- a primary producer, or an agent of a primary producer, who carries out a pest control activity using a pesticide on an unprocessed product located on land owned or occupied by the primary producer;
- a primary producer, or agent of a primary producer, who carries out a fumigation activity using a fumigant on land owned or occupied by the primary producer;
- a person responsible for caring for or growing a plant, who carries out a pest control activity using a pesticide on the plant at a place that is primarily used for horticultural, recreational or sporting activities;
- a person who carries out a pest control activity using a household pesticide to control a pest, including a pest on an animal, at residential premises, other than for a pest management business.

The person must use the fumigant or pesticide in accordance with the approved label of the fumigant or pesticide.

In this clause, a *household pesticide* means a pesticide ordinarily used in households and available to buy in a retail store. For example, a bait for killing cockroaches available to buy at a supermarket or flea and tick treatment for dogs available to buy at a pet store.

A *primary producer* means a person producing or storing agricultural or horticultural products.

An *unprocessed product* means an agricultural or horticultural product that is located in the place where it was produced and has not been processed for sale.

### **Offence to offer to carry out pest management activities if unauthorised**

*Clause 45* states that it is an offence (with a maximum penalty of 200 penalty units) for a person to offer to carry out a pest management activity for a pest management business unless the person has a pest management licence or the person employs someone else with a pest management licence to carry out the pest management activity.

This provision relates to businesses, such as carpet cleaners offering to treat carpet for infestations as part of the carpet cleaning process, when they have no pest management authorisation. This provision excludes people using a pesticide to protect themselves when performing an unrelated service. For example, a plumber spraying a pipe with a pesticide before putting their hand in the space.

## **Offence to require or permit unauthorised persons to carry out pest management activities**

*Clause 46* states that it is an offence (with a maximum penalty of 200 penalty units) for a person (a *manager*) who is authorised to carry out a pest management or operates a pest management business to permit or require another person to carry out a pest management activity for the manager if the manager knows the person is not authorised to carry out the activity, unless the manager has a reasonable excuse.

## **Offence to dispose of waste from hazardous poison, pesticide or fumigant**

*Clause 47* states that it is an offence (with a maximum penalty of 200 penalty units) for a person to dispose of waste from a hazardous poison, pesticide or fumigant unless the person disposes of the waste in the authorised way or has a reasonable excuse.

## **Division 4 Miscellaneous**

### **Offence for giving or keeping false, misleading or incomplete information and records**

*Clause 48* states it is an offence (with a maximum penalty of 50 penalty units) for a person to give the chief executive information the person knows is false or misleading in a material particular, make or keep a record the person knows is false or misleading in a material particular; or make or keep a record the person knows is incomplete in a material particular.

This applies to a person who gives oral or written information to the chief executive in order to obtain or keep an authorisation under this Act, or in response to a request for information under this Act or who is required to keep records under the Act.

Subsection (2)(a) does not apply to a person if the person, when giving information in a document, tells the chief executive, to the best of the person's ability, how the document is false or misleading and gives the correct information, if the person has, or can reasonably obtain it.

## **Part 2 Exclusions from offences and defences**

### **Division 1 Excluded persons**

#### **State officers and helpers**

*Clause 49* provides that the following persons (each a *State officer*) do not commit an offence against this Act only because the State officer performs the officer's functions or exercises the officer's powers:

- an inspector or State analyst;
- a health Act official;
- a person employed within a part of the department known as Forensic and Scientific Services;
- a police officer.

A person does not commit an offence against this Act if the person helps a State officer to perform the officer's functions or exercise the officer's powers. A helper is intended to be anyone who assists a State Officer carry out their duties. Examples of a helper may include a Local Government Officer or an expert called on for advice.

### **Persons authorised under other laws**

*Clause 50* recognises authorities under other Acts and Commonwealth law. It provides that a person does not commit an offence if they carry out a regulated activity with a regulated substance if they are authorised to do so under another Act or a law of the Commonwealth. If a person does not comply with the conditions of their authority, they do not commit an offence under this Act, but the Act under which the authority is provided.

If the person's related authority impliedly permits the person to possess a regulated substance without expressly stating that possession is permitted, the related authority is taken to permit possession of the regulated substance to the extent required to act under the related authority.

Examples of related authorities include an approval under the *Chemical Usage (Agricultural and Veterinary) Control Act 1988*, a licence under the *Radiation Safety Act 1999* or an approval, licence or permission under the Therapeutic Goods Act.

A person is also authorised if they have an equivalent authority under another Act. For example, an approval under the *Work Health and Safety Act 2011* to possess a restricted carcinogen that is also a restricted S7 poison, would be considered equivalent to a general approval under this Act for the substance.

### **Agents and carers**

*Clause 51* provides at subsection (1) that a person does not commit an offence against this Act if the person:

- supplies a medicine by giving it to someone else (a *patient*) if the medicine has been lawfully supplied for the therapeutic treatment of the patient;
- for lawfully helping a patient administers a medicine in accordance with the approved label of the medicine; or
- administers a medicine to an animal in accordance the approved label of the medicine.

However, subsection (1) does not apply to the extent the person is authorised, under this Act, to supply or administer the medicine (e.g. an approved person who is subject to the requirements of the Medicines Regulation).

Examples of the application of this offence exclusion related to possession and administration include where a parent administers a medicine to their child, a carer supplies a medicine to a person in their care in accordance with the medicine's label, or a pet owner administers a medicine to their animal in accordance with the medicine's approved label.

Subsection (3) provides that subsection (1) does not apply to a person prescribed by regulation to be a person to whom the subsection does not apply.

## **Clinical Trials**

*Clause 52* applies to a person who is permitted to deal with a regulated substance for a human clinical trial approved by a human research ethics committee. The person does not commit an offence against this Act to the extent the person acts in accordance with any protocol or guidelines approved for the human clinical trial by the human research ethics committee.

*Human research ethics committee* means a committee registered with the National Health and Medical Research Council established under section 5B of the *National Health and Medical Research Council Act 1992* (Cth) and operating in accordance with the human research guidelines issued under section 10 of the *National Health and Medical Research Council Act 1992* (Cth).

## **Division 2            Defence provision**

### **Defence for workers**

*Clause 53* provides that in a proceeding for an offence against a provision of this Act, it is a defence for a worker for an entity to prove that the entity did not provide the worker with suitable equipment, facilities, training or other resources that would have allowed the person to comply with the provision.

See also clause 214 in relation to the liability of executive officers of corporations.

## **Chapter 3            Authorising regulated activities**

### **Part 1                Approved persons and emergency orders**

#### **Division 1            Approved persons**

##### **Authorisation of prescribed classes of persons**

*Clause 54* states that regulation may prescribe a class of persons to be authorised to carry out a regulated activity with a regulated substance. For subsection (1), the regulated activity for which the class of persons is prescribed may be limited by reference to the circumstances in which, or the purposes for which, the regulated activity may be carried out by the class of persons. An *approved person* is a member of a class of persons prescribed under subsection (1) for a regulated activity with a regulated substance for the class of persons.

Subject to clause 30(2), the approved person is authorised to carry out the regulated activity with the regulated substance.

An authorisation under subsection (4) is an *approved person's authorisation*.

This clause is subject to clauses 55 and 56.

## Changes to approved person's authorisation

*Clause 55* provides that if the chief executive takes administrative action in relation to the approved person's authorisation; or the approved person is a health practitioner subject to a condition, notation or undertaking (each a *condition*) on the person's registration under the Health Practitioner Regulation National Law that relates to the approved person's authorisation; or the approved person is a veterinary surgeon subject to a condition on the person's registration under the *Veterinary Surgeons Act 1936*, the approved person's authorisation is changed to the extent necessary to give effect to the administrative action or condition. If the administrative action is suspension, the approved person's authorisation ends for the period of the suspension or otherwise, is changed to the extent necessary to give effect to the administrative action or condition.

For example, an approved person's authorisation authorises the person to deal with an S8 medicine. The chief executive takes administrative action to suspend the approved person's authorisation. The approved person's authorisation does not authorise the person to deal with the S8 medicine. An approved person's authorisation authorises the person to deal with any S8 medicine. The approved person is subject to a condition under the Health Practitioner Regulation National Law stating the person must not deal with a particular S8 medicine. The approved person's authorisation does not authorise the person to deal with the particular S8 medicine.

## Relationship between different authorisations

*Clause 56* provides that if an approved person's authorisation (the *primary authorisation*) relates to carrying out a regulated activity with a regulated substance and the approved person is authorised in another way under another provision of this Act (an *alternative authorisation*) in relation to the regulated activity with the regulated substance.

For example, an approved person's authorisation does not authorise the person to prescribe an S8 medicine and the person holds a prescribing approval authorising the person to prescribe the S8 medicine in particular circumstances. An approved person's authorisation authorises the person to apply an S7 substance, other than a particular poison, and the person holds a general approval authorising the person to apply the particular poison.

To the extent practicable, the primary authorisation and the alternative authorisation are to be read together. However, if the primary authorisation is inconsistent with the alternative authorisation, the primary authorisation does not apply to the approved person to the extent of the inconsistency.

## Division 2                      Emergency orders

### Authorisation under emergency order

*Clause 57* provides, subject to clause 30(2), a person is authorised to carry out a regulated activity with a regulated substance if the person is authorised under an emergency order to carry out the activity with the substance.

See clause 31 for when the person carries out the regulated activity with the regulated substance in the authorised way.

## Chief executive may make emergency order

*Clause 58* provides the chief executive may make an order (an *emergency order*) authorising a person to carry out a regulated activity with a regulated substance, who would not normally be able to undertake the regulated activity. Emergency orders would be used in situations where a prompt response is required and there may be insufficiently qualified persons available to undertake the work. For example, in relation to biosecurity events, disaster situations, declared public health emergencies, emergency situations and other events, at a State or local level, which may impact negatively on public health, including an event that has the potential to cause human disease through exposure to infection. Examples of situation include:

- the chief executive of Queensland Health could authorise the spraying of mosquitoes following a flood event by qualified persons who do not have a current pest management licence due to the scale of the activity;
- the chief executive of the Department of Agriculture and Fisheries (DAF) could issue a Biosecurity Emergency Order due to the presence of Asian honey bees which are declared prohibited matter under the *Biosecurity Act 2014*. To support the activities of DAF, the chief executive of Queensland Health could issue an emergency order allowing suitable DAF employees to use specified pesticides without a pest management licence to respond to the biosecurity event in a timely manner;
- the chief executive of Queensland Health could authorise registered nurses, pharmacists or ambulance officers to supply anti-viral medicines to people during an influenza pandemic; or
- the chief executive of Queensland Health could authorise a pharmacist to supply prescription-only medicines to patients without a doctor's prescription where a flood has resulted in prescriptions being lost or destroyed.

An emergency order must state the event to which the order applies, a description of the area to which the order applies, the day the order starts and ends, the regulated activity with the regulated substance that may be carried out, the class of persons who may carry out the regulated activity and any conditions applying to the regulated activity. An emergency order must end no later than three months after the day it starts.

These conditions may include the circumstances in which a person may carry out the activity (for example, training the person requires to undertake the activity).

## Publication of emergency order

*Clause 59* provides that the chief executive must, immediately after making an emergency order, take reasonable steps to ensure persons likely to be directly affected by the order are made aware of the order. For example, by publishing media releases, advertising in newspapers or by telephoning or writing to affected persons. In addition, the chief executive must publish the emergency order on the department's website as soon as practicable, but no later than two business days, after it is made.

This provision ensures transparency by requiring the chief executive to publish the notice so that the public is advised of the measures being taken.

An emergency order is not invalid only because of a failure of the chief executive to comply with subsection (1).

## **Division 3                      Miscellaneous**

### **Authorisation for persons subject to work health and safety laws**

*Clause 60* applies to a person buying, possessing or applying an S7 poison, other than a WHS excluded poison, at a place if:

- the place is subject to a work health and safety law;
- the buying, possession or application is not done at a part of the place that is a person's residence or accessible by the general public; and
- the person buys, possesses or applies the S7 poison in the course of performing the person's duties at the place.

This clause does not apply if the buying, possession or application at the place relates to a type of industry prescribed by regulation.

The person is taken to buy, possess or apply the S7 poison in the authorised way, if the person buys, possesses or applies the S7 poison in compliance with the work health and safety law.

*Resource authority* is defined in section 10 of the *Mineral and Energy Resources (Common Provisions) Act 2014*.

*WHS excluded poison* means an S7 poison prescribed by regulation to be a WHS excluded poison for this clause.

In this clause, *work health and safety law* means the *Work Health and Safety Act 2011* or a provision of an Act relating to safely carrying out activities permitted under a resource authority.

Persons who possess or apply S7 poisons in industries such as engineering, construction, agriculture or other trade-related activities which have a legitimate use of these poisons will not be subject to the provisions of the Bill. The Bill requires that the person possess and apply the poison in the course of their duties at the workplace and comply with work health and safety laws. For example, a welder could purchase or a use or dispose of a pickling paste containing hydrofluoric acid without requiring a substance authority under the draft Bill.

However, these provisions do not apply to persons working in prescribed industries. Prescribed industries will be specified in the Poisons Regulation and include industries such as child care services and financial services. These provisions do not apply to restricted S7 poisons and prohibited substances. Restricted S7 poisons are prescribed under the Poisons Regulation and include cyanide, liquid nicotine and strychnine.

## Part 2 Authorisation under substance authorities

### Division 1 Preliminary

#### What is a *substance authority*

*Clause 61* states a *substance authority* is:

- a manufacturing licence;
- a wholesale licence;
- a retail licence;
- a pest management licence;
- a prescribing approval; or
- a general approval.

#### Authorisation under substance authority

*Clause 62* provides that, subject to clause 30(2), a person is authorised to carry out a regulated activity with a regulated substance if the person is the holder of a substance authority that authorises the holder to carry out the activity; or is stated, or is a member of a class of persons stated, to be authorised under the authority to carry out the activity. For example, an employee or representative of a substance authority or a student or volunteer for the holder of a substance authority.

### Division 2 Types of substance authorities

#### What is a *manufacturing licence*

*Clause 63* states that a *manufacturing licence* is a licence that authorises a person to carry out the following regulated activities with a regulated substance stated in the licence:

- manufacture of the regulated substance at a place stated in the licence;
- possession of the regulated substance at a place stated in the licence;
- possession of the regulated substance for transportation to a place where a person is authorised, or where it is not unlawful for a person, to possess the substance;
- supply of the regulated substance, primarily by wholesale, to a person who is member of the class of persons stated on the licence to whom the substance may be supplied the substance, or, otherwise, a person who is authorised, or for whom it is not unlawful, to carry out a regulated activity with the substance;
- disposal of waste from the regulated substance.

A manufacturing licence may, if stated in the licence, authorise the buying and possession of another stated regulated substance for manufacturing the regulated substance to be manufactured under the licence (the *final product*) or the manufacture, and disposal of waste from, another stated regulated substance that is a by-product of the manufacture of the final product.

If an entity wishes to manufacture prohibited substances, e.g. for laboratory standards, they will need to apply for a general approval or a licence. The type of authority issued will depend

on the quantity of substance proposed to be manufactured. Commercial quantities will require a manufacturing licence.

### **What is a *wholesale licence***

*Clause 64* states that a *wholesale licence* is a licence that authorises a person to carry out the following regulated activities with a regulated substance stated in the licence:

- buying stock of the regulated substance;
- possession of the regulated substance at a place stated in the licence;
- possession of the regulated substance for transportation to a place where a person is authorised, or where it is not unlawful for a person, to possess the substance
- supply of the regulated substance, primarily by wholesale, to a member of the class of persons, which is stated on the licence, to whom the substance may be supplied, or, otherwise, a person who is authorised, or for whom it is not unlawful, to carry out a regulated activity with the regulated substance;
- disposal of waste from the regulated substance.

### **What is an *S2 retail licence* or an *S7 retail licence***

*Clause 65* states that an *S2 retail licence* is a licence that authorises a person to carry out the following regulated activities with an S2 medicine stated in the licence:

- buying stock of the medicine;
- selling the medicine by retail at a place stated in the licence.

It also states an *S7 retail licence* is a licence that authorises a person to carry out the following regulated activities with an S7 substance stated in the licence:

- buying stock of the medicine;
- possession of the substance at a place stated in the licence;
- possession of the substance for transportation to a place where a person is authorised, or where it is not unlawful for a person, to possess the substance;
- selling the substance by retail to a person who is a member of the class of persons, which is stated on the licence, to whom the substance may be sold, or, otherwise, a person who is authorised, or for whom it is not unlawful, to carry out a regulated activity with the substance;
- disposal of the waste from the substance.

Disposal of substance waste may also be subject to regulation under the *Environmental Protection Act 1994* and the *Waste Reduction and Recycling Act 2011*.

### **What is a *pest management licence***

*Clause 66* provides that a *pest management licence* is a licence that authorises a person to carry out the pest management activities stated in the licence using a fumigant or pesticide stated in the licence. It will also allow a pest management technician to possess and apply pesticides or fumigants and dispose of the substance waste, in a way stated in the licence.

The licence will be endorsed for the types of pest management activity that the person wishes to perform and for which they have the necessary competencies. Pest management technicians will be required to only use APVMA approved pesticides and fumigants. Pest management technicians seeking to supply S7 pesticides or fumigants will also be required to obtain an S7 retail licence.

### **What is a *prescribing approval***

*Clause 67* provides that a *prescribing approval* is an approval that authorises a person to carry out any of the following regulated activities with a medicine stated in the approval:

- prescribing the medicine for a person, or a class of persons, stated in the approval in the stated circumstances;
- buying, possessing, administering, dispensing and giving a treatment dose of the medicine in the stated circumstances.

### **What is a *general approval***

*Clause 68* states that a *general approval* is an approval that authorises a person to carry out a regulated activity with a regulated substance stated in the approval. A regulation may prescribe different classes of general approvals for carrying out different types of regulated activities.

## **Division 3                      Duration and conditions of substance authorities**

### **Duration**

*Clause 69* provides that a substance authority remains in force for the term decided by the chief executive and stated in the authority, unless sooner suspended, cancelled or surrendered.

### **Conditions**

*Clause 70* states that a substance authority is subject to a condition (a *standard condition*) prescribed by regulation to apply to a substance authority, and any additional condition decided by the chief executive under part 3. If the chief executive decides to change a standard condition under part 3, the substance authority is subject to the changed condition instead of the standard condition. For subsection (1), the regulation may prescribe a standard condition for a substance authority by reference to a code, guideline, protocol or standard, including a departmental standard. For example, a regulation may prescribe how and when a substance authority holder must advise the chief executive of changes to their circumstances.

### **Failure to comply with substance authority conditions**

*Clause 71* states it is an offence (with a maximum penalty of 200 penalty units) for a person to whom a substance authority applies to fail to comply with the conditions of the authority, unless they have a reasonable excuse.

## **Division 4                      Changes of circumstances**

### **Transfer unavailable**

*Clause 72* prohibits the transfer of a substance authority from one person or entity to another. If the sole holder of a substance authority dies, the authority is cancelled.

### **Changes affecting substance authority**

*Clause 73* applies if the holder of a substance authority notifies the chief executive of a change in circumstances in relation to the authority.

The chief executive may require the holder to apply to amend the substance authority in a stated way, or apply for a new substance authority, by a stated reasonable day. The chief executive must give the holder an information notice for the decision to make a request under subsection (2).

Where a holder does not comply with the request before the stated day, their substance authority is taken to have been cancelled on the stated day.

If the holder applies for a new substance authority, the substance authority is cancelled on the day the application is decided.

### **Finalising a substance authority**

*Clause 74* applies if a person stops being the holder of a substance authority.

The chief executive may give the person a notice authorising the person to carry out a stated regulated activity with a regulated substance in a stated way for a stated period. For example, a notice states that a person who has surrendered a manufacturing licence for S7 poisons may store the poisons at the place where the poisons were manufactured for 6 months until the poisons can be taken to a disposal facility.

The person is taken to carry out the regulated activity with the regulated substance in the authorised way if the person complies with the notice.

## **Part 3                              Applications for substance authorities**

### **Division 1                      Initial Applications**

#### **Requirements for making initial application**

*Clause 75* requires that an application for a substance authority (an *initial application*) must be made to the chief executive, in the approved form and accompanied by the fee prescribed by a regulation. If the application is for a pest management licence, it must be made by an individual of at least 17 years.

The fee is required to be paid at the time the application is submitted. If the application is denied, withdrawn or approved for a period shorter than what was applied for, a refund of the appropriate amount will be issued.

### **Deciding initial application**

*Clause 76* provides that the chief executive must decide whether or not to grant the initial application. In considering the initial application, the chief executive may have regard to any of the following matters:

- the need for, and the safety and efficacy of, the regulated activity with the regulated substance proposed in the application;
- whether a relevant person is a fit and proper person for the substance authority applied for, including whether they have a criminal history (see clause 216);
- any standard conditions for the substance authority for which the application is made;
- whether the place at which the regulated activity is proposed to be carried out is suitable for the activity;
- if a substance management plan is required under clause 93(1) for the place, whether a plan has been prepared; and
- if the application is for a pest management licence, a health assessment under clause 90.

In considering whether a person is a fit and proper person, the chief executive may have regard to the relevant person's skills, experience, qualifications and knowledge relevant to the regulated activity and regulated substance to which the application relates, whether the relevant person has committed an offence against a corresponding law, whether the relevant person engages or has engaged in conduct that risks, or is likely to risk, a regulated substance being used for a purpose that is unlawful, whether the applicant has the means to carry out the regulated activity to which the application relates, including financial resources and access to suitable staff and materials, and any conditions or other limitations placed on a practitioner's registration, or disciplinary action taken against the practitioner, under practitioner law.

If the initial application relates to matters stated in a competency standard, the chief executive must have regard to the competency standard when considering the application. In this clause, *competency standard*, means a departmental standard stating training and competency requirements for a person carrying out a regulated activity with a regulated substance.

If the chief executive decides to grant the initial application, the chief executive may also decide to take either of the following actions if the chief executive is satisfied the action is reasonably necessary:

- impose additional conditions on the substance authority; or
- change a standard condition.

### **Notice about decision**

*Clause 77* provides that if the chief executive decides to grant the initial application without imposing additional conditions or changing any standard conditions, the chief executive must give the applicant a notice stating that the substance authority is granted, the day the decision takes effect and that the standard conditions apply to the substance authority.

If the chief executive decides to grant the initial application subject to additional conditions or changes to any standard conditions, or decides to refuse to grant the application, the chief executive must give the applicant an information notice for the decision.

## **Division 2            Amendments of substance authorities**

### **Requirements for making amendment application**

*Clause 78* provides the holder of a substance authority may apply (an *amendment application*) to the chief executive to amend the authority. The amendment application must be made to the chief executive in the approved form and be accompanied by the fee prescribed by regulation.

### **Deciding amendment application**

*Clause 79* provides the chief executive must decide whether or not to grant the amendment application.

In considering the amendment application, the chief executive may have regard to the conditions of the substance authority and any changes to the matters considered by the chief executive when the substance authority was granted.

### **Notice about decision**

*Clause 80* provides if the chief executive decides to grant the amendment application, the chief executive must give the applicant a notice stating the amendment for the substance authority and the day the decision takes effect.

If the chief executive decides to refuse to grant the amendment application, the chief executive must give the applicant an information notice for the decision.

### **Minor amendment by chief executive**

*Clause 81* states that the chief executive may decide to amend a substance authority, without an application by the holder of the authority, if the amendment is only for a formal or clerical reason, or for another reason which does not adversely affect the interests of the holder.

As soon as practicable after deciding to make the amendment, the chief executive must give the holder a notice stating the amendment and the reason for the amendment.

## **Division 3            Renewal applications**

### **Requirements for making renewal application**

*Clause 82* states that the holder of a substance authority may apply (a *renewal application*) to the chief executive to renew the authority unless the authority states it must not be renewed. The renewal application must be made to the chief executive, be in the approved form and be accompanied by the fee prescribed by regulation and must be made within the period starting 90 days before the term of the substance authority ends.

However, the chief executive may accept the application within 30 days after the term of the authority ends if satisfied it is reasonable to do so in the circumstances. If the chief executive accepts the renewal application, the substance authority is taken to have authorised the carrying out of the regulated activity with the regulated substance stated in the authority for the period between the day the authority ended, and the day the chief executive accepted the application.

### **Deciding renewal application**

*Clause 83* provides that the chief executive must decide whether or not to grant the renewal application. In considering the renewal application, the chief executive may have regard to the conditions of the authority and any changes to the matters considered by the chief executive when the substance authority was granted.

If the chief executive decides to grant the renewal application, the chief executive may also decide to take impose additional conditions on the substance authority or change a condition of the substance authority, including a standard condition, if the chief executive is satisfied the action is reasonably necessary.

### **Notice about decision**

*Clause 84* provides that if the chief executive decides to grant the renewal application without imposing additional conditions or changing any conditions, the chief executive must give the applicant a notice stating that the substance authority is renewed, the day the decision takes effect and the conditions that apply to the substance authority.

If the chief executive decides to grant the renewal application subject to additional conditions or changes to any conditions, or decides to refuse to grant the application, the chief executive must give the applicant an information notice for the decision.

### **Substance authority in force while renewal application considered**

*Clause 85* provides a substance authority subject to a renewal application continues in force from the day the renewal application continues in force from the day the renewal application is accepted by the chief executive until the application is decided or taken to have been withdrawn under division 4. A renewal application does not continue in force if the substance authority is earlier suspended or cancelled under chapter 4, part 3.

However, if the application is refused, or taken to be refused, the substance authority continues in force until an information notice for the refusal is given to the applicant.

## **Division 4            Considering applications**

### **Subdivision 1        Preliminary**

#### **Definitions for division**

*Clause 86* defines the terms *application*, *final consideration day* and *further information notice* for the purposes of this division.

An *application* means an initial, amendment or renewal application. A *final consideration day* for an application is the day that is 90 days after:

- if the chief executive gives the applicant a notice under clause 87(1), the day the chief executive receives the further information stated in the notice; or
- if the chief executive gives the applicant more than one notice under clause 87(1), the day the chief executive receives the further information stated in the last notice;
- otherwise – the day the chief executive receives the application.

## **Subdivision 2 Further information requests and period for deciding applications**

### **Further information request**

*Clause 87* provides that the chief executive may give an applicant a notice within 90 days after the chief executive receives the applicant's application stating further information the chief executive considers is reasonably required from the applicant to decide the application.

The notice must state a reasonable period, of at least 30 days after the day the notice is given, for compliance with the notice. The notice may require the further information to be verified by statutory declaration.

Where there is non-compliance with the information notice, the application is deemed to have been withdrawn.

### **Agreement to extend period for decision**

*Clause 88* permits the chief executive and the applicant to agree on a later day by which the applicant's application is to be decided at any time before the final consideration day. The chief executive must give the applicant notice of the agreed upon day. Additional time may be required where the application is complex and the assessment may extend beyond the 90 days.

### **Period for deciding application**

*Clause 89* provides that the chief executive must decide an application on or before the agreed day, if the day by which the application must be decided has been extended by agreement under clause 88, or otherwise, on or before the final consideration day for the application.

If the chief executive has asked, under clause 216, for a criminal history report about a relevant person in relation to the application, the day by which the application must be decided is extended by the number of days it takes for the criminal history report to be given to the chief executive after the chief executive asks for the report.

The chief executive is taken to have refused to grant the application if the chief executive fails to decide the application by the day required under this clause.

The applicant is entitled to be given an information notice for the deemed refusal.

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## Subdivision 3 Health assessments

### Health assessment for pest management licences

*Clause 90* applies in relation to an application for a pest management licence.

The chief executive may ask the applicant to undergo an assessment (a *health assessment*) by a medical practitioner of the applicant's physical and mental health. This provision will be used in a limited number of cases where either the individual declares a medical condition that may affect their work or the chief executive is otherwise made aware of a medical condition that may affect or be affected by the person undertaking pest management activities.

The chief executive must give the applicant a notice stating the reason for requesting the health assessment and the reasonable day by which the assessment is to be done. The notice must also either provide the name of the particular medical practitioner who is to conduct the assessment, or give the qualifications of a medical practitioner who may conduct the assessment.

The assessment conducted by the medical practitioner must include a written report stating the practitioner's findings about the applicant's mental and physical health in relation to carrying out the type of regulated activity to which the application relates.

An applicant who fails to give the written report to the chief executive by the day stated in the notice under subsection (3)(c), without a reasonable excuse, is taken to have withdrawn their application.

## Chapter 4 Managing regulated activities

### Part 1 Requirements for carrying out regulated activities in the authorised way

#### Requirements may be prescribed

*Clause 91* provides a regulation may prescribe requirements for a person, or a class of persons, authorised under clause 54(4), 57 or 62 in relation to carrying out a type of regulated activity with a regulated substance.

Under clause 31, a person mentioned in subsection (1) must comply with the requirements prescribed for the person to carry out a regulated activity with a regulated substance in the authorised way.

Without limiting subsection (1), a requirement may do 1 or more of the following things:

- state the way a regulated activity must be carried out;
- require a person to comply with an extended practice authority or departmental standard;
- require a person to comply with another code, guideline, protocol or standard;
- require a person to notify the chief executive if particular things happen in relation to a regulated activity or regulated substance.

A requirement prescribed under subsection (1) that applies to an approved person is subject to clauses 55 and 56.

## Part 2                      Substance management plans

### Definitions for part

*Clause 92* defines the terms *regulated place*, *responsible person* and *substance management plan* for the purposes of this part.

A *regulated place* means a place prescribed by regulation to be a regulated place where a dealing happens, or is proposed to happen, with a regulated substance.

A *substance management plan*, for a regulated place, means a document setting out how known and foreseeable risks associated with any dealing with a regulated substance are to be managed at the regulated place. Examples of risks associated with dealings with regulated substances include compromised quality of a regulated substance during production, unauthorised access to a regulated substance or inappropriate use of a regulated substance.

A *responsible person*, for a regulated place, means a person prescribed by regulation to be the responsible person for the regulated place.

### Requirements for substance management plan

*Clause 93* states it is an offence (with a maximum penalty of 250 penalty units) for the responsible person for a regulated place to deal with a regulated substance at the place that complies with subsection (2) before making a substance management plan, unless the person has a reasonable excuse. The Regulations will list who the responsible person is for each type of regulated place that must make a substance management plan.

This means that, where an entity has been issued with a new substance authority, they may not commence operating under the authority until such time as the substance management plan is in place. For example, where an entity is granted a manufacturing licence, that entity may not commence any activity under that licence until the responsible person has made the substance management plan for that place. Because the definition of manufacturing includes carrying out any activity using any substance for the purpose of making the regulated substance, a substance management plan must be made prior to the purchase of raw ingredients, whether the raw ingredients are scheduled substances or not.

There are transitional arrangements included in the Bill for regulated places that are currently in existence at the time of commencement of the Act or within the first 12 months of commencement. Please see clause 280 for information on substance management plans with regards to transitional arrangements.

It is also an offence (with a maximum penalty of 250 penalty units) for the substance management plan for the regulated place to fail to address the matters prescribed by regulation and state the day the plan starts, the location of the place, the dealings and regulated substances to which the plan applies, and the persons (*staff*) at the place to whom the plan applies. The substance management plan must also be written in a way that is likely to be easily understood by staff.

The responsible person must ensure the substance management plan is made available to staff when it is made and is reviewed at the time prescribed by regulation. Non-compliance with these requirements carries a maximum penalty of 250 penalty units.

In a proceeding for an offence against subsection (3), it is a defence for the responsible person to prove the person took reasonable steps to comply with the subsection.

*Staff*, for the purposes of this clause, refers to contractors, agents, volunteers and employees.

## **Compliance with substance management plan**

*Clause 94* states that it is an offence (with a maximum penalty of 200 penalty units) for a person stated in a substance management plan under clause 93(2)(a)(iv) to fail to comply with the plan, unless the person has a reasonable excuse.

## **Part 3                      Administrative action**

### **Division 1                Preliminary**

#### **Definitions for part**

*Clause 95* defines terms for the purposes of this part.

*Administrative action*, in relation to an authority, means action changing a condition of an authority, suspending an authority for a stated period or indefinitely or cancelling a substance authority.

*Agreed administrative action* is defined in clause 103(3).

An *authority* means a substance authority or an approved person's authorisation.

*Condition*, of an approved person's authorisation, means the circumstances in which, or purposes for which, the approved person is authorised under clause 54(4), or a requirement prescribed under clause 91(1) for the approved person in relation to carrying out a regulated activity with a regulated substance.

*Holder*, of an authority, means for a substance authority, the entity granted the substance authority or for an approved person's authorisation, the approved person.

*Review day*, for administrative action, means the earliest day on which the chief executive is required under this part to consider ending or changing the administrative action.

*Show cause notice* is defined in clause 97(2).

*Show cause period*, for a show cause notice, is defined in clause 97(2)(d).

## **Division 2            Taking administrative action generally**

### **Grounds for taking action**

*Clause 96* provides the chief executive may take administrative action in relation to an authority if the chief executive believes:

- a relevant person for the authority has contravened a requirement under this Act or a corresponding law;
- the administrative action is reasonably necessary to prevent or minimise a health risk;
- a relevant person for the authority is not a fit and proper person, including whether they have a criminal history (see clause 216); or
- a relevant person for the authority has made a materially false or misleading representation to obtain the authority.

However, the chief executive may take administrative action under this clause only if the chief executive has considered giving a compliance notice to the person about the matter to which the proposed administrative action relates.

### **Show cause notice before taking action**

*Clause 97* applies if the chief executive is proposing to take administrative action in relation to an authority under clause 96.

The chief executive must first give the holder of the authority a notice (a *show cause notice*) stating the following:

- that the chief executive proposes to take the administrative action;
- the proposed administrative action, including whether it applies to all regulated activities with regulated substances to which the authority relates or a particular regulated activity or regulated substance;
- the reasons for the proposed administrative action;
- that the holder may within a stated period of at least 21 days (the *show cause period*), give the chief executive a written response to the show cause notice.

### **Chief executive must consider response**

*Clause 98* provides that if the holder of the authority, within the show cause period, gives the chief executive a written response to the show cause notice, the chief executive must consider the written response before deciding whether or not to take the proposed administrative action stated in the show cause notice.

### **Decision not to take administrative action**

*Clause 99* provides that if the chief executive decides not to take the proposed administrative action stated in the show cause notice, the chief executive must give the holder notice of the decision.

## **Decision to take administrative action**

*Clause 100* applies if the show cause period has ended and the chief executive has considered any written response from the holder of the authority, and the chief executive believes there is a ground for taking administrative action.

The chief executive may decide to take the administrative action stated in the show cause notice or to take other administrative action that is less onerous. If the chief executive decides to take administrative action to suspend the authority indefinitely or change the conditions of the authority, the chief executive must also decide the review day for the administrative action.

The chief executive must give the holder an information notice for a decision under subsection (2) or (3).

The administrative action takes effect on the day stated in the information notice.

The day stated in the information notice under subsection (5) must not be earlier than the day the notice is given to the holder.

## **Division 3                    Immediate or agreed administrative action**

### **Application of division**

*Clause 101* provides that this division applies in relation to taking administrative action despite another division of this part.

Each clause of this division applies even if the chief executive has started, but not completed, the process for making a decision under another clause of this division.

### **Immediate administrative action**

*Clause 102* provides that the chief executive may decide to take administrative action in relation to an authority on a ground mentioned in clause 96(1) without giving the holder of the authority a show cause notice.

Subsection (1) only applies if the chief executive considers it reasonably necessary to take the administrative action immediately because there is an urgent need to prevent a serious health risk to any person, including to the holder.

The chief executive must also decide the review day for the administrative action if a decision to take administrative action to suspend an authority indefinitely or to change the conditions of an authority is taken.

The chief executive must give the holder an information notice for a decision under subsections (1) or (3).

The administrative action takes effect on the day stated in the information notice.

The day stated in the information notice under subsection (5) must not be earlier than the day the notice is given to the holder.

### **Agreed administrative action**

*Clause 103* provides that the chief executive may take administrative action in relation to an authority, other than cancellation of the authority, if a relevant person for the authority to whom the action applies agrees to the action being taken.

However, if the authority is a substance authority, the chief executive may take the administrative action only if the holder of the authority also agrees to the action.

Action taken under subsection (1) is agreed administrative action. The chief executive and the relevant person must agree to a review day for the administrative action.

The chief executive must give the holder a notice stating the terms of the agreed administrative action and the review day that has been agreed by the relevant person for the administrative action.

The administrative action takes effect on the day stated in the notice. The day stated in the notice under subsection (6) must not be earlier than the day the notice is given to the holder.

## **Division 4            Reviewing administrative action**

### **Application of division**

*Clause 104* provides that this division does not apply in relation to administrative action that is the cancellation of a substance authority.

### **Request by holder to review administrative action**

*Clause 105* provides the holder of an authority in relation to which administrative action has been taken may ask the chief executive, in writing, to review the administrative action and give the chief executive information supporting the holder's request under paragraph (a). The holder may make a request under subsection (1) only on or after the review day for the administrative action.

### **Decision after reviewing administrative action on request**

*Clause 106* provides the chief executive must consider a request made under clause 105 and decide whether to end the administrative action, continue the administrative action (*further administrative action*), or take other administrative action in relation to the authority that is less onerous (also *further administrative action*).

However, if the administrative action being considered is agreed administrative action, the chief executive may take further administrative action (*further agreed action*) only if the relevant person to whom the further administrative action applies agrees to the action and the holder of the substance authority agrees to the further administrative action.

If the chief executive decides to take further administrative action that is the suspension of the authority indefinitely or changing the conditions of the authority, the chief executive must also decide the review day for the further administrative action.

If the chief executive decides to end the administrative action, or decides to take further agreed action, the chief executive must give the holder notice of the decision.

If subsection (4) does not apply, the chief executive must give the holder an information notice for the decision.

### **Review of administrative action by chief executive**

*Clause 107* provides that the chief executive may decide to review administrative action taken in relation to an authority (the *original action*) whether or not a request for the review of the original action has been made by the holder of the authority and whether or not the decision is made before the review day for the original action.

However, the review must be on a ground mentioned in clause 96(1). If the chief executive proposes to change or continue the original action, the chief executive must give the holder of the authority a show cause notice.

Clauses 97 to 100 apply in relation to the show cause notice as if the original action had not been taken and the proposed change or continuation of the original action were the proposed administrative action to be taken under the clauses.

If the chief executive decides to end the administrative action, the chief executive must give the holder notice of the decision.

## **Part 4 Compliance notices**

### **Giving a compliance notice**

*Clause 108* provides that the chief executive or an inspector may give a person a notice (a *compliance notice*) requiring the person to rectify the matter if they believe the following:

- a person has contravened a provision of this Act in circumstances that make it likely the contravention will continue or be repeated;
- a matter relating to the contravention is reasonably capable of being rectified; and
- it is appropriate to give the person an opportunity to rectify the matter.

### **Content of compliance notice**

*Clause 109* provides that a compliance notice must state the following matters:

- the chief executive or inspector believes the person has contravened a provision of the Act in circumstances that make it likely the contravention will continue or be repeated;
- the provision the chief executive or inspector believes has been contravened;
- briefly, how it is believed the provision has been contravened;
- the matter the chief executive or inspector believes is reasonably capable of being rectified;

- the reasonable steps the person must take to rectify the matter;
- that the person must take the steps within a stated period that is reasonable, having regard to any health risks posed by the contravention; and
- that it is an offence to fail to comply with the compliance notice without a reasonable excuse.

### **Failure to comply with compliance notice**

*Clause 110* states it is an offence (with a maximum penalty of 200 penalty units) for a person given a compliance notice to not comply with the notice, unless they have a reasonable excuse.

## **Chapter 5            Monitoring and enforcement**

### **Part 1                Special powers**

#### **Division 1           Emerging risk declarations**

##### **What is an *emerging risk declaration***

*Clause 111* defines an *emerging risk declaration* as a declaration made by the chief executive declaring one or more of the following in relation to a substance that is not a regulated substance:

- the substance must not be made sold or used in the State;
- the substance may be used only in a particular device or in a particular way;
- a particular device must not be used with the substance;
- the substance must be disposed of in a particular way.

This provision will assist where a new substance or product comes onto the market that may contain a substance likely to cause a significant health risk and has not been assessed by the scheduling committee.

##### **Making emerging risk declaration**

*Clause 112* permits the chief executive to make an emerging risk declaration in relation to a substance that is not a regulated substance if the chief executive believes the substance is being made, sold or used in the State, including by using a device, and there is an urgent need to regulate, or further regulate, the substance under this Act because of a health risk.

However, the chief executive may not make an emerging risk declaration in relation to a medical device under the Therapeutic Goods Act.

The emerging risk declaration may state particular conditions that apply to carrying out an activity with the substance, including conditions about the use of particular devices. However, the chief executive may only impose conditions if satisfied the conditions are reasonably necessary to prevent or minimise a health risk.

The intent of this clause is to allow the chief executive to be responsive to changing circumstances and new information where there is an indication that an unregulated substance creates an unacceptable health risk.

This division is included because the rights, obligations, powers and offences in the Act are all prefaced upon dealing with substances scheduled under a substance category in the national Poisons Standard. The scheduling of a substance into a substance category is undertaken at the national level through the Advisory Committee on Chemicals Scheduling (ACCS) and the Advisory Committee on Medicines Scheduling is a complex and lengthy process. Only pure medicines or poisons are scheduled. Other national agencies such as the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the APVMA that undertake chemicals assessment only assess single, active substances according to their proposed use.

NICNAS does not register industrial chemicals or chemical products and cannot prohibit the introduction of a chemical after assessment. The agency has limited powers to regulate the use of chemicals and regulation is achieved by ‘cooperative compliance’, which relies on importers or manufacturers to notify the relevant authority of the intent to manufacture or import the substance. As a result, there is potential for substances to emerge on the market without assessment or registration.

Responsibility for managing risks associated with chemicals that are not scheduled or registered for particular uses falls to the states and territories. Examples of circumstances where the national frameworks may fail to manage substance risks include:

- the substance may be a thing or a compound (e.g. tattoo ink, facial wipe). The scheduling framework does not capture mixes, blends, compounds or other similar things;
- the harm may occur as an unintentional consequence of a physiological reaction with an unscheduled substance or product not required to be regulated. For example, where a substance (the original substance) not covered by other existing legislation is consumed or used, and a physiological reaction occurring upon consumption or use produces a substance (a metabolite or by-product) that causes harm or illness.

In this latter case, scheduling the original substance may have implications for the regulatory scheme as a whole, as the restrictions applied to a certain situation may not be appropriate for a broad approach.

Where these extraordinary situations may cause acute or chronic harm to health, there is an expectation by the public and other government agencies that Queensland Health has the ability to take action expeditiously.

### **Matters to be included in emerging risk declaration**

*Clause 113* states that the emerging risk declaration must state a description of the substance to which the declaration applies, and if the declaration relates to a device, it must include a description of the device and either a description of the particular way that device may or may not be used in relation to the substance, or a statement that the device must not be used with the substance. The declaration must also state any conditions declared to apply to carrying out an activity with the substance. It may also state a day on which it takes effect and a day on which it ends.

A substance is defined broadly in clause 10, and includes an ingredient, compound, preparation or extract of a substance.

### **Publication of emerging risk declaration**

*Clause 114* requires the chief executive to publish the emerging risk declaration on the department's website. The chief executive must also take reasonable steps to ensure that persons likely to be affected by the declaration are made aware of its making, for example, by publishing media releases, advertising in newspapers or by contacting affected persons. Persons likely to be affected by the declaration may include the manufacturer, sellers, industry groups, businesses or other government agencies whose portfolio responsibilities are affected by the making of the declaration.

However, an emerging risk declaration is not invalid only because of a failure by the chief executive to comply with subsection (1).

### **Effect and duration of emerging risk declaration**

*Clause 115* states that the emerging risk declaration takes effect when it is published on the department's website or a later day stated in the declaration. Unless it is sooner revoked, the emerging risk declaration for substance continues in effect until the earliest of the following days:

- the stated end day;
- the day the substance stated in the declaration becomes a regulated substance;
- the day the device stated is registered as a medical device under the Therapeutic Goods Act;
- the day that is three months after the day the declaration takes effect.

If a provision of this Act or a decision made under this Act is inconsistent with the emerging risk declaration, the declaration prevails to the extent of the inconsistency.

### **Failure to comply with emerging risk declaration**

*Clause 116* states it is an offence (with a maximum penalty of 500 penalty units) for a person to fail to comply with the emerging risk declaration unless the person has a reasonable excuse.

### **Renewal of emerging risk declaration**

*Clause 117* provides that before the emerging risk declaration ends, the chief executive may renew the declaration by publishing a notice on the Queensland Health website. A renewal may only be made if the chief executive believes that more time is required to allow the substance stated in the declaration to be prescribed under clause 11, 12 or 13 as a medicine, poison or prohibited substance, or the substance to be considered under the Therapeutic Goods Act for listing in the Poisons Standard, or the device to be registered as a medical device under the Therapeutic Goods Act.

The substance, or use of the substance with a device should, in the meantime, continue to be regulated under this Act to prevent or minimise a health risk.

In renewing the emerging risk declaration, the chief executive may decide to change any matter stated in the declaration if the chief executive considers the change reasonably necessary.

The notice for the renewal of the declaration must state the emerging risk declaration to which the renewal applies, the day (no later than 3 months after the day on which the renewal is published) that the declaration ends and any changes to a matter stated in the declaration, including a brief statement of the change and the reasons for the changes. The renewal takes effect on the day when the emerging risk declaration would have ended, had it not been renewed.

The chief executive must take reasonable steps to ensure persons likely to be directly affected by the renewal of the declaration are aware of the renewal, for example, by media releases, advertising in newspapers or by contacting persons affected. The renewal of the emerging risk declaration is not invalid only because of a failure of the chief executive to comply with subsection (6).

## **Division 2                      Recall orders and public warnings**

### **Subdivision 1              Recall orders**

#### **Application of subdivision**

*Clause 118* states that this subdivision does not apply in relation to a regulated substance if the substance is also regulated under another Act or a Commonwealth law, and a power under the other Act or law has been exercised for the recall of the substance, whether or not the substance has been recalled. For example, a delegate of the Secretary of the Commonwealth Department of Health has powers under the Therapeutic Goods Act to mandate a sponsor to recall a medicine to protect public health.

#### **Chief executive may make recall order**

*Clause 119* applies if the chief executive considers a product containing a regulated substance poses a health risk.

The chief executive may make a written order (*a recall order*) that is directed to a stated person (*the responsible person*) who the chief executive believes is responsible for the manufacture, possession or supply of the regulated substance and requires the responsible person to recall the product from manufacture, possession or supply.

Without limiting subsection (2), the chief executive may make a recall order for a product if the chief executive considers the order reasonably necessary to prevent or minimise a health risk because:

- the product labelling is inaccurate;
- the product packaging is not sufficiently secure, having regard to the nature of the product;
- the product, when used in accordance with the label for the use of the product, is not safe or effective; or
- the product is contaminated or not consistent with the usual specifications for the product.

## **Notice required for making recall order**

*Clause 120* requires that, before making a recall order, the chief executive must give the responsible person for the proposed recall order a notice stating the following matters:

- the chief executive intends to make a recall order;
- the terms of the proposed order;
- the reasons for making the proposed order;
- that the person may give the chief executive written submissions, within 7 days after the day the notice is given, about why the chief executive should not make the proposed recall order.

The responsible person may, within the period stated in the notice under subsection (1)(d), give the chief executive written submissions about why the proposed order should not be made.

## **Urgent recall order**

*Clause 121* provides if the chief executive considers a recall order must be made urgently to prevent a serious health risk to a person, the chief executive may make the order without complying with clause 120. However, as soon as practicable, and no later than 48 hours, after the recall order is made, the chief executive must give the responsible person for the order a notice stating the following matters:

- the terms of the order;
- the reasons for making the order
- that the person may give the chief executive written submissions, within 7 days after the day the notice is given, about why the chief executive should revoke the order.

The responsible person may, within the period stated in the notice under subsection (2)(c), give the chief executive written submissions about why the recall order should be revoked.

## **Decision about recall order**

*Clause 122* states that, after considering any written submissions made under clause 120(2) by the responsible person for a proposed recall order, the chief executive must decide whether to make the recall order. After considering any written submissions made under clause 121(3) by the responsible person for a recall order, the chief executive must decide whether to revoke the order. If the chief executive decides to make, or not revoke, a recall order, the chief executive must give the responsible person for the recall order an information notice for the decision.

## **Notifying public about recall order**

*Clause 123* requires the chief executive to publish, on the department's website, information that is sufficient to alert the public about the potential health risk identified in a recall order. The chief executive may publish the information in any other way the chief executive considers reasonably necessary to alert the public, for example publishing media releases or advertising in newspapers or other publications.

## Content of recall order

*Clause 124* requires a recall order to state details of the product that is recalled under the order, the responsible person for the order, the reasons for the recall of the product, what the responsible person must do to recall the product and the reasonable period for which the order is in effect. Without limiting subsection (1)(d), the recall order may state the responsible person must do any of the following:

- stop the manufacture or supply of the product;
- take reasonable steps to recover the product from another person;
- isolate or dispose of the product;
- repackage or relabel the product; or
- publish warnings about the product.

## Failure to comply with recall order

*Clause 125* states it is an offence (with a maximum penalty of 500 penalty units) for a responsible person for a recall order to fail to comply with the order, unless they have a reasonable excuse

## Effect of recall order

*Clause 126* states that subject to clause 128, the chief executive is not liable for any cost incurred in complying with a recall order. The recall order remains in force for the period stated in the order, unless it is sooner revoked by the chief executive.

## Subdivision 2 Public warnings

### Statement of warning

*Clause 127* permits the Minister or chief executive or chief health officer (each a *senior administrator*) to make a public statement identifying, and giving warnings or information about, any of the following matters:

- contraventions of this Act that have resulted in notification action being taken (being a compliance notice, recall order or show cause notice under chapter 4, part 3), and the persons who committed the contraventions;
- practices regulated under a relevant law that, in the reasonable opinion of the senior administrator, are unlawful;
- offences committed against a relevant law (being this Act, the *Agricultural and Veterinary Chemicals (Queensland) Act 1994*, the *Agricultural Chemicals Distribution Control Act 1966* or the *Chemical Usage (Agricultural and Veterinary) Control Act 1988*) and the persons who committed the offences.

The statement may identify particular contraventions, practices, offences and persons. However, the senior administrator must not make a statement unless satisfied it is in the public interest to do so, and a public statement or warning has not been made, and is not about to be made, under another Act or process that is more appropriate in the circumstances.

Without limiting what is in the public interest for subsection (3)(a), the making of the public statement is in the public interest if the senior administrator is reasonably satisfied the statement is reasonably necessary to prevent or minimise a health risk in relation to a regulated substance.

No liability is incurred by the State for the making of, or for anything done for the purpose of making, a public statement under this clause in good faith.

In this clause, *chief health officer* means the chief health officer under the *Hospital and Health Boards Act 2011*, section 52.

*Notification action* means the giving a compliance notice, making a recall order, taking immediate administrative action under clause 101 or giving a show cause notice under chapter 4, part 2.

*Relevant law* means this Act, the *Agricultural and Veterinary Chemicals (Queensland) Act 1994*, the *Agricultural Chemicals Distribution Control Act 1966*, the *Chemical Usage (Agricultural and Veterinary) Control Act 1988*.

## **Division 3                    Compensation**

### **Compensation for emerging risk declaration or recall order**

*Clause 128* provides a person directly affected by an emerging risk declaration or the responsible person for a recall order may apply to the chief executive for compensation.

The chief executive must pay just and reasonable compensation to the applicant if the applicant suffered loss because of the making of the emerging risk declaration or recall order and there were insufficient grounds for the making of the declaration or order.

If the chief executive decides to refuse the application, or to pay an amount of compensation less than the amount sought by the applicant, the chief executive must give the applicant a QCAT information notice for the decision.

## **Part 2                            General provisions about inspectors**

### **Division 1                    Appointment**

#### **Inspectors under part**

*Clause 129* states that this part provides for the appointment of inspectors and gives inspectors particular powers.

#### **Functions of inspectors**

*Clause 130* provides that an inspector has the following functions:

- to investigate, monitor and enforce compliance with this Act,
- to investigate or monitor whether an occasion has arisen for the exercise of powers under this Act,

- to facilitate the exercise of powers under this Act.

### **Appointment and qualifications**

*Clause 131* empowers the chief executive to appoint, by instrument in writing, a health service employee, a public service employee or other persons prescribed by regulation as an inspector.

The chief executive may appoint a person as an inspector only if satisfied the person is appropriately qualified.

### **Appointment conditions and limit on powers**

*Clause 132* states that an inspector holds office on any conditions stated in the inspector's instrument of appointment, a signed notice given to the inspector or a regulation. The instrument of appointment, a signed notice given to the inspector or a regulation may limit the inspector's powers. In this clause, a *signed notice* means a notice signed by the chief executive.

### **When office ends**

*Clause 133* provides that an inspector's appointment ends when the term of office specified in the conditions under which the person holds office (a *condition of office*) ends, another condition under which the person holds office ends or the person's resignation under clause 134 takes effect. Subsection (1) does not limit the ways the office of a person as an inspector ends.

### **Resignation**

*Clause 134* states an inspector may resign by signed notice given to the chief executive.

## **Division 2            Identity cards**

### **Issue of identity card**

*Clause 135* requires the chief executive to issue an identity card to each inspector. The identity card must contain a recent photo of the inspector and a copy of the inspector's signature, and must identify the person as an inspector under the Act. The card must have an expiry date. A person may be issued a single identity card for this Act and other purposes.

### **Production or display of identity card**

*Clause 136* requires an inspector to produce their identity card for the person's inspection before exercising a power in relation to a person, or to have the identity card displayed so as to be clearly visible to the person when exercising the power. However, if it is not practicable in the circumstances to produce or display the card, the inspector must produce the identity card for the person's inspection at the first reasonable opportunity.

However, an inspector does not exercise a power in relation to a person simply by entering a place as mentioned in clause 140(1) (b) or (d).

## **Return of identity card**

*Clause 137* states that it is an offence (with a maximum penalty of 20 penalty units) for an inspector to fail to return their identity card to the chief executive within 21 days of ceasing to be an inspector, unless the person has a reasonable excuse.

## **Division 3                    Miscellaneous provisions**

### **References to exercise of powers**

*Clause 138* states that if a provision of this chapter refers to the exercise of a power by an inspector and there is no reference to a specific power, the reference is to the exercise of all or any inspectors' powers under this Act or a warrant, to the extent that the powers are relevant.

### **Reference to document includes reference to reproductions from electronic document**

*Clause 139* states that a reference in this chapter to a document includes a reference to an image or writing produced from an electronic document or an image or writing not yet produced, but reasonably capable of being produced, from an electronic document, with or without the aid of another article or device.

## **Part 3                        Entry of places by inspectors**

### **Division 1                Power to enter**

#### **General power to enter places**

*Clause 140* permits an inspector to enter a place if the occupier at the place consents under division 2 to the entry and clause 144 has been complied with for the occupier.

An inspector may also enter a place if the place:

- is a public place and entry is made when the place is open to the public;
- entry is authorised under a warrant and if there is an occupier of the place, clause 152 has been complied with for the occupier;
- it is a professional practice place of a person authorised under this Act and the entry is made when the place is open for carrying on business or otherwise open for entry;
- it is an authorised place that is required to be open for inspection as a condition of the authorisation of the place;
- the entry is authorised under clause 141 and clause 146 has been complied with.

Subsection (2) provides that subsection (1)(d), (e) and (f) does not authorise entry to a part of a place where a person resides. Where entry is made by consent, the power of entry is subject to any conditions of the consent. The power ceases if consent is withdrawn.

Consent may be given for re-entry and is subject to the terms of consent.

If a warrant provides power to enter or re-enter a place, then the entry or re-entry is subject to the terms of the warrant.

An *authorised place* means a place where a regulated activity with a regulated substance is authorised to be carried out under an approved person's authorisation or a substance authority.

A *professional practice place* of a person authorised under this Act means a place where the person lawfully practises a profession, or performs functions, for which the person is authorised. In addition, if the person holds a pest management licence, a professional practice place includes a place where building work under the *Queensland Building and Construction Commission Act 1991* is being, or is about to be, carried out.

## **Power to enter place to check compliance with compliance notice or recall order**

*Clause 141* empowers an inspector to enter a place, at a reasonable time, to check compliance with the compliance notice or recall order. A compliance notice must have been given to a person or a recall order must have been given to a responsible person and the person must practise a profession or perform a function at a place that is subject of a matter mentioned in a notice or order. This power is subject to the restrictions on entry under clause 140(2).

## **Division 2                      Entry by consent**

### **Application of division**

*Clause 142* states that this division applies if inspector intends to ask an occupier of a place to consent to the inspector or another inspector entering the place.

### **Incidental entry to ask for access**

*Clause 143* provides that for the purpose of asking the occupier for their consent, an inspector may, without the occupier's consent or a warrant, enter land around premises at the place to the extent that is reasonable to contact the occupier, or enter part of the place which the inspector reasonably considers members of the public ordinarily are allowed to enter when they wish to contact an occupier of the place.

### **Matters inspector must tell occupier**

*Clause 144* requires the inspector, before asking for consent to enter, to explain to the occupier the purpose of the entry, including the powers intended to be exercised, and to tell the occupier they are not required to consent and that consent may be given subject to conditions and may be withdrawn at any time.

### **Consent acknowledgement**

*Clause 145* states that if consent is given, the inspector may ask the occupier to sign an acknowledgement of the occupier's consent. The acknowledgement must state the purpose of the entry, including powers intended to be exercised. The acknowledgement must also state that the occupier has been given an explanation about the purpose of the entry, including the powers intended to be exercised, and that they are not required to consent and that the consent may be subject to conditions and may be withdrawn at any time. The acknowledgement must

also state that the occupier gives the inspector or another inspector consent to enter the place and exercise powers, the time and day consent was given and any conditions of consent.

If the occupier signs the acknowledgement, the inspector must, as soon as practicable and no later than one business day, give a copy to the occupier. If the occupier's consent to entry is an issue in a proceeding and the signed acknowledgement is not produced in evidence, the person relying on the lawfulness of the entry must prove the occupier gave consent to enter.

## **Division 3            Entry for checking compliance**

### **Entry of place under s 141**

*Clause 146* provides that an inspector must, before entering a place under clause 141, make a reasonable attempt to locate an occupier of the place and obtain the occupier's consent to the entry (see division 2 in relation to entry consent).

If the inspector is unable to locate an occupier after making a reasonable attempt to do so, or if the occupier refuses to consent to the entry, the inspector may enter the place.

If after being unable to locate an occupier, the inspector subsequently finds an occupier present at the place, or if an occupier refused consent to the entry, the inspector must make reasonable attempts to produce their identity card for the occupier's inspection and inform the occupier of the reason for entering the place and that the inspector is authorised under this Act to enter the place without permission of the occupier (see, however, the restrictions on entry under clause 140(2)).

If the inspector enters the place after being unable to locate an occupier, the inspector must leave a notice in a conspicuous position and in a reasonably secure way stating the date and time of the entry and information addressing the matters mentioned in subsection (3)(b).

In determining reasonableness when attempting to locate the occupier the inspector should give due regard to the definition of *occupier*, the amount of time taken to attempt to locate the occupier and other relevant criteria such as the size or location of the premises.

For reasonable security of a notice the inspector should consider accessibility to the notice by persons other than the stated person on the notice and the likelihood that the notice could be otherwise misplaced or lost.

## **Division 4            Entry under warrant**

### **Subdivision 1        Obtaining warrant**

#### **Application for warrant**

*Clause 147* allows an inspector to apply to a magistrate for a warrant for a place. The inspector must prepare a written application that states the grounds on which the warrant is sought. The written application must be sworn.

If all the information required by the magistrate about the application is not provided in the way the magistrate requires, the magistrate may refuse to consider the application. For example, the magistrate may require additional information supporting the written application to be given by statutory declaration.

### **Issue of warrant**

*Clause 148* provides for a magistrate to issue a warrant for a place only if satisfied there are reasonable grounds for suspecting that there is at the place, or will be at the place within the next 7 days, a particular thing or activity that may provide evidence of an offence against the Act.

The warrant must state the following:

- the place to which the warrant applies;
- that an inspector may with necessary and reasonable help and force enter the place and any other place necessary for entry to the place and exercise their powers;
- particulars of the offence that the magistrate considers appropriate;
- the name of the person suspected of having committed the offence unless the name is not known or the magistrate considers it inappropriate to state the name;
- the evidence that may be seized under the warrant;
- the hours of the day or night when the place may be entered;
- the magistrate's name;
- the day and time of the warrant's issue; and
- the warrant's end day, which must be within 14 days of the warrant's issue.

### **Electronic application**

*Clause 149* provides for an application for a warrant under clause 147 to be made by phone, fax, email, radio, videoconferencing or any other form of electronic communication if the inspector reasonably considers it necessary because of urgent circumstances or because of other special circumstances, for example, remoteness of location. The written application under clause 147(2) must be prepared before the electronic application is made, however the electronic application may be made before the written application is sworn.

### **Additional procedure if electronic application**

*Clause 150* provides that for an electronic application made under clause 149, the magistrate may issue the warrant (the *original warrant*) only if satisfied the application under clause 149 was necessary and appropriately made. The magistrate may refuse to consider the application as if it had been made under clause 149, that is until the magistrate has been given all the information required about the application in the way the magistrate requires. For example, the magistrate may require additional information supporting the written application to be given by a statutory declaration.

After the magistrate issues the original warrant, they must either give the inspector a copy of the warrant if reasonably practicable (for example, sending a copy by fax or email), or otherwise the magistrate must tell the inspector the information mentioned in clause 148(2). The inspector must then complete a form of warrant containing these details. Either the copy

of the warrant or the form of warrant (the *duplicate warrant*), whichever is produced, is a duplicate warrant and has the same effect as the original warrant.

At the first reasonable opportunity, the inspector must send the magistrate the written application complying with clause 147(2) and (3) and, if a form of warrant was produced, the completed form of warrant.

If an issue arises in a proceeding about whether an exercise of power was authorised by a warrant issued under this clause and the original warrant is not produced in evidence, the onus of proof is on the person relying on the lawfulness of the exercise of the power to prove a warrant authorised the exercise of the power.

This clause does not limit clause 147.

### **Defect in relation to a warrant**

*Clause 151* provides that a warrant, including a duplicate warrant, is not invalidated by a defect in the warrant or compliance with this subdivision unless the defect affects the substance of the warrant in a material particular.

## **Subdivision 2      Entry procedure**

### **Entry procedure**

*Clause 152* applies if an inspector is intending to enter a place under a warrant issued under this division.

Subsection (2) provides that the inspector must make a reasonable attempt to identify the inspector to a person who is an occupier of the place and is present by producing their identity card, give the person a copy of the warrant (or duplicate warrant), inform the person that the warrant permits the inspector's entry to the place and give the person an opportunity to allow the inspector immediate entry without using force.

However, the inspector does not need to comply with subsection (2) if they believe on reasonable grounds that immediate entry to the place without compliance is required to ensure the execution of the warrant is not frustrated.

## **Part 4                      Other inspectors' powers and related matters**

### **Division 1                  Stopping or moving vehicles**

#### **Application of division**

*Clause 153* states that this division applies if an inspector reasonably suspects or is aware that a thing in or on a vehicle may provide evidence of the commission of an offence against the Act.

## **Power to stop or move**

*Clause 154* provides for an inspector to signal or otherwise direct a person in control of a moving vehicle to stop the vehicle and bring it to, and keep it at a convenient place within a reasonable distance to allow the inspector to exercise their powers. The inspector may also direct a person in control of a stationary vehicle not to move the vehicle until the inspector has exercised their powers, or to move the vehicle to a stated reasonable place to allow for the inspector to exercise their powers.

When giving a direction under this clause, the inspector must give a warning that it is an offence not to comply with the direction.

## **Identification requirements if vehicle moving**

*Clause 155* requires an inspector who proposes to give a direction under clause 154(1) to a person in a moving vehicle to clearly identify the inspector is exercising powers. For example, by use of a loudhailer or a sign. When the vehicle stops, the inspector must immediately produce the inspector's identity card for inspection by the person in control of the vehicle. Subsection (3) applies despite clause 136.

## **Failure to comply with direction**

*Clause 156* provides it is an offence (with a maximum penalty of 50 penalty units) for a person in control of a vehicle to fail to comply with a direction under clause 154 to stop or move a vehicle, unless the person has a reasonable excuse.

Reasonable excuses include that the vehicle was moving and the inspector did not comply with clause 155 and clearly identify themselves as an inspector exercising their powers, or that immediate compliance would have endangered another person or caused loss or damage to property and the person complies as soon as it is practicable to do so.

The offence does not apply to the situation where a direction is given under clause 154(2), a stationary vehicle and the person is not given an offence warning for the direction.

## **Division 2            General powers of inspectors after entering places**

### **Application of division**

*Clause 157* states that the powers under this division may be exercised if an inspector enters a place under clause 140(1)(a), (c), (d) or (e). Where the inspector enters under clause 140(1)(a) or (c), the powers under this division are subject to any conditions of consent to entry or the terms of the warrant.

### **General powers**

*Clause 158* allows for the inspector to carry out any of the following (each a *general power*):

- search any part of the place;

- inspect, examine or film any part of the place or anything at the place;
- take things or a sample of or from a thing at the place for examination;
- place identifying marks in or on things at the place;
- take an extract or copy of a document at the place or take the document to another place to copy;
- produce an image or writing at the place from an electronic document;
- take a thing containing an electronic document (e.g. a computer or USB drive) to another place to produce an image or writing;
- take to, into or onto the place and make use of any person, equipment and materials reasonably required to enable the inspector to exercise their powers (e.g. by taking recording equipment onto the place, or taking a person who has a specific expertise but is not an inspector to assist with identifying relevant evidence);
- remain at the place for the time necessary to achieve the purpose of the entry.

The inspector may take a necessary step to allow the exercise of a general power.

If the inspector takes a document or a device or article reasonably capable of producing a document from an electronic document (e.g. a computer or USB drive) from the place, the inspector must copy or produce the document and return the original document or device to the place as soon as possible.

This clause provides definitions for the terms *examine*, *film* and *inspect* for the purposes of this clause.

*Examine* includes analyse, test, account, measure, weigh, grade, gauge and identify.

*Film* includes photograph, videotape and record an image in another way.

*Inspect*, a thing, includes open the thing and examine its contents.

### **Power to require reasonable help**

*Clause 159* empowers the inspector to require the occupier of the place or another person at the place to provide reasonable help to exercise a general power (a *help requirement*). For example, the inspector may ask the other person to produce a document or give information. The inspector must warn the person it is an offence not to comply with a help requirement unless the person has a reasonable excuse.

### **Offence to contravene help requirement**

*Clause 160* provides it is an offence (with a maximum penalty of 50 penalty units) for a person to fail to comply with a help requirement unless the person has a reasonable excuse.

It is a reasonable excuse that complying with the requirement might incriminate the person or expose them to a penalty. However, this excuse is not available if a document or information the subject of a help requirement is required to be held or kept by the person under the Act.

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## **Division 3            Seizure by inspectors and forfeiture**

### **Subdivision 1        Power to seize**

#### **Seizing evidence at a place that may be entered without consent or warrant**

*Clause 161* empowers an inspector, who enters a place under this Act without the consent of the occupier of the place and without a warrant, to seize a thing at the place if the inspector reasonably suspects the thing is evidence of an offence against this Act.

#### **Seizing evidence at a place that may be entered only with consent or warrant**

*Clause 162* provides that an inspector, who with the occupier's consent or under a warrant, enters a place they may only enter with consent or under a warrant, may seize a thing at the place which they reasonably suspect is evidence of an offence against the Act only where the seizure is consistent with the purpose of entry as explained to the occupier when asking for consent or the evidence is that for which a warrant has been issued.

However, the inspector may also seize anything else at the place if they reasonably suspect the thing is evidence of an offence against this Act and its seizure is necessary to prevent it from being hidden, lost or destroyed, or if they reasonably suspect the thing has just been used in the commission of an offence against the Act.

#### **Seizure of property subject to security**

*Clause 163* states that an inspector may carry out a seizure for a thing and exercise powers relating to the thing despite a lien or other security over the thing being claimed by another person. However, the seizure does not affect the other person's claim to the lien or other security against a person, but this claim does not extend to the inspector or a person acting under the direction or authority of the inspector.

For example, an inspector may seize a piece of manufacturing plant as evidence, despite the fact that the plant is leased from a third party. Subsection (2) provides that the seizure will not affect the security interest held by that third party over the piece of manufacturing plant. The security interest claim will not extend to the inspector, or a person acting under the direction or authority of the inspector. The security interest claim will remain against the person who is the party to the security interest.

### **Subdivision 2        Powers to support seizure**

#### **Power to secure seized thing**

*Clause 164* provides that, having seized a thing under this division, an inspector may either leave it at the place of seizure and take reasonable action to restrict access to it or move it from that place. Where a seized thing is left at the place, examples of reasonable actions to restrict access to the thing include sealing the thing or the entrance to the place and marking the thing or place to show access is restricted or making equipment inoperable. The inspector may also require a person reasonably believed to be in control of the place or thing to either move the

thing from the place of seizure or do something to secure the seized thing that is the same as something the inspector may do to the seized thing or place as described in subsection (2).

### **Offence to contravene other seizure requirement**

*Clause 165* makes it an offence (with a maximum penalty of 50 penalty units) for a person not to comply with a requirement made of the person under clause 164(2)(c) unless they have a reasonable excuse. Because there are a number of ways an inspector may require a person to move a seized thing or take reasonable action to restrict access to a seized thing or place, a reasonable excuse under this clause will depend on whether the seized thing is to be moved, or be left at the place where it has been seized, and will relate to the requirement that has been made.

### **Offence to interfere**

*Clause 166* provides it is an offence (with a maximum penalty of 100 penalty units) to tamper with a seized thing to which access has been restricted or with anything used to restrict access to the thing under clause 164 unless approval has been given by the inspector or there is a reasonable excuse. For example, it is an offence to reconnect power supply to a seized thing which has been rendered inoperable.

Similarly, it is also an offence (with a maximum penalty of 100 penalty units) to enter a place to which access has been restricted, or to tamper with anything used to restrict access to the place under clause 164, unless approval has been given by an inspector or there is a reasonable excuse. For example, it is an offence to remove a mark that the inspector has made to show that access to the place is restricted, or to break a padlock that the inspector has secured to prevent access to the place, without approval or a reasonable excuse.

## **Subdivision 3      Safeguards for seized things**

### **Receipt and information notice for seized thing**

*Clause 167* prescribes the process that an inspector must follow after seizing a thing under this division, other than where the inspector reasonably believes the thing has been abandoned, there is no-one apparently in possession of it, or where compliance with this process would be unreasonable because of the condition, nature and value of the thing.

As soon as practicable after seizing the thing, the inspector must give its owner or the person in control of it a receipt for the thing which generally describes the thing and its condition and an information notice about the decision to seize it. These may be given in the same document and relate to more than one seized thing.

If neither the owner nor the person from whom the thing is seized is present at the time of its seizure, the receipt and information notice may be left in a conspicuous position and in a reasonably secure way at the place of seizure.

This clause also allows the inspector to delay giving the receipt and information notice if they reasonably suspect giving them would frustrate or hinder their investigation. However, the inspector may only delay giving the receipt and information notice while they continue to have the reasonable suspicion and while they remain in the vicinity of the place where the thing was

seized to keep it under observation. For example, an inspector could not seize a thing, leave the place and return at a later time to provide the receipt and information notice.

### **Access to seized thing**

*Clause 168* states that, until a seized thing is either forfeited or returned, the inspector who seized it must allow its owner to inspect the thing at any reasonable time and from time to time. A reasonable time would be during normal business hours. If the seized thing is a document, the owner of the document must be allowed to copy it, free of charge. However, an inspection or copying of the document can be refused if it is impracticable or unreasonable to do so.

### **Return of seized thing**

*Clause 169* requires the chief executive to return a seized thing that is not forfeited or transferred under subdivision 4 or 5 and which is not the subject of a disposal order under clause 174 to its owner as soon as the chief executive stops being satisfied there are reasonable grounds for retaining it.

If a thing is not returned to the owner within three months of being seized, the owner may apply to the chief executive for its return. The chief executive must make a decision about the application within 30 days and either return the thing or retain the thing if there are reasonable grounds. If the chief executive decides to retain the thing, they must give the owner a notice of the decision, including the grounds for retaining the thing.

Reasonable grounds for retaining a thing include, but are not limited to, that it is being or is likely to be examined, that it is needed for a current or future proceeding for an offence or for an appeal from a decision in a proceeding, or that it is not lawful for the owner to possess the thing.

Nothing in this clause affects a lien or other security over the seized thing.

## **Subdivision 4      Forfeiture**

### **Forfeiture by chief executive decision**

*Clause 170* permits the chief executive to decide a seized thing is forfeited to the State if an inspector:

- cannot find its owner after making reasonable inquiries;
- cannot return it to the owner after making reasonable efforts; or
- reasonably believes it is necessary to keep the thing to prevent it from being used to commit the offence for which it was seized.

The inspector is not required to make inquiries if it would be unreasonable to make inquiries to find an owner or make efforts if it would be unreasonable to make efforts to return the thing to an owner, for example, if the owner has migrated to another country.

Regard must be had to the thing's condition, nature and value in deciding whether it is reasonable to make inquiries or efforts and what inquiries or efforts, including the period over which they are made, are reasonable.

### **Information notice about forfeiture decision**

*Clause 171* applies if the chief executive decides under clause 170(1) to forfeit a thing. The chief executive must as soon as practicable give person who owned the thing immediately before the forfeiture (*former owner*) an information notice about a decision.

Where the owner cannot be found or the thing is not reasonably returnable to them under clause 170(1)(a) or (b), the information notice may be given by leaving it in a conspicuous position and a reasonably secure way at the place where the thing was seized. The information notice must advise the owner of the thing that an application for a stay of the decision may be made if they appeal against the decision.

The requirement to provide an information notice does not apply where the owner cannot be located or the thing is not reasonably returnable to them and the thing was seized at a public place or a place where the notice is unlikely to be read by the owner.

## **Subdivision 5            Dealing with property forfeited or transferred to State**

### **When thing becomes property of the State**

*Clause 172* provides that a thing becomes the property of the State if it is forfeited to the State under clause 170(1) or the owner and the State agree in writing to transfer the ownership of the thing to the State.

### **How property may be dealt with**

*Clause 173* provides that, where a thing becomes the property of the State under clause 172, the chief executive may deal with the thing as they consider appropriate (e.g. by destroying it or giving it away). The chief executive must not deal with the thing in a way that could prejudice the outcome of an appeal against the forfeiture. If the thing is sold, the proceeds of the sale must be returned to the former owner of the thing after the costs of the sale are deducted if it is reasonable to do so.

This provision is subject to any disposal order that may have been made by the court under clause 174 for the thing.

## **Division 4            Disposal orders**

### **Disposal order**

*Clause 174* applies if a person is convicted of an offence under the Act. It empowers a court, on its own initiative or on application by the prosecution, to make a *disposal order*. The disposal order authorises the disposal of anything owned by the person that was either the subject of, or used to commit, the offence. A disposal order may also be made in relation to

another thing the court considers likely to be used by the person or another person in committing a further offence against the Act.

In making this decision, the court may require notice to be given to anyone the court considers appropriate, including persons who may have property in the thing, and must hear any submissions that any person claiming to have property in the thing may wish to make.

A disposal order may be made whether or not the thing has been seized under the Act, and if it was seized, whether or not it has been returned to the former owner. The court may also make any order to enforce the disposal order that it considers appropriate.

This clause does not limit the court's powers under another law.

## **Division 5            Other information-obtaining powers of inspectors**

### **Power to require name and address**

*Clause 175* provides for an inspector, under certain circumstances, to require a person to give their name and residential address (known under the Act as a *personal details requirement*). The circumstances under which a personal details requirement may be made are that the inspector:

- finds a person committing an offence against the Act;
- finds a person in circumstances that lead them to reasonably suspects the person has just committed an offence against the Act; or
- has information that leads the inspector to reasonably suspect a person has just committed an offence against this Act.

The inspector may also require evidence to be given that verifies the correctness of the name and address provided by the person, if it is reasonable to expect the person to be in possession of this evidence or otherwise able to give the evidence.

A person to whom a personal details requirement is made must also be advised it is an offence not to comply with the requirement.

### **Offence to contravene personal details requirement**

*Clause 176* provides it is an offence (with a maximum penalty of 50 penalty units) for a person not to comply with a personal details requirement unless the person has a reasonable excuse. However, a person may not be convicted of an offence under this provision unless they are also found guilty of the offence in relation to which the personal details requirement was made.

### **Power to require production of document**

*Clause 177* permits an inspector to require a person to make the following available for inspection at a nominated reasonable time and place (a *document production requirement*):

- a document given to the person under the Act (e.g. a substance authority);

- a document required to be kept by the person under the Act (e.g. a substance management plan, or records of sale for particular substances);
- a clear written reproduction of a document or information required to be kept under the Act which is stored or recorded by means of a device (e.g. an electronic prescription or purchase order).

The inspector may copy the document and require the person responsible for keeping the document to certify that the copy is a true copy of the document (known under the Act as a *document certification requirement*). The copy may be for the whole document or an entry in the document.

The inspector must return the document to the person as soon as practicable after copying it. If a document certification requirement is made of a person, the inspector may keep the document until the person complies with the requirement.

### **Offence to contravene document production requirement**

*Clause 178* provides it is an offence (with a maximum penalty of 50 penalty units) for a person to fail to comply with a document production requirement unless the person has a reasonable excuse. However, it is not a reasonable excuse to fail to comply on the basis that complying might tend to incriminate the person or expose the person to a penalty.

The inspector must inform the person that they must comply with the requirement even though complying might tend to incriminate them or expose them to a penalty and that there is a limited immunity for individuals under clause 188 against the future use of the information or document given in compliance with the requirement. A person may not be convicted of an offence under this provision if the inspector has failed to inform them of these matters.

A court which convicts a person under this provision may, as well as imposing a penalty, order the person to comply with the document production requirement.

### **Offence to contravene document certification requirement**

*Clause 179* provides it is an offence (with a maximum penalty of 50 penalty units) for a person to fail to comply with a document certification requirement unless the person has a reasonable excuse. However, it is not a reasonable excuse to fail to comply on the basis that complying might tend to incriminate the person or expose the person to a penalty.

The inspector must inform the person, in a way that is reasonable in the circumstances, that they must comply with the requirement even though complying might tend to incriminate them or expose them to a penalty and that there is a limited immunity under clause 188 against the future use of the information or document given in compliance with the requirement. A person cannot be convicted of an offence against this provision if the inspector has failed to inform them of these matters.

### **Power to require information**

*Clause 180* provides that an inspector who reasonably believes an offence against the Act has been committed and a person may be able to give information about the offence may give a notice to the person requiring them to give information related to the offence by a stated

reasonable time. If the information required is an electronic document, the person must provide a clear image or written version of the electronic document.

### **Offence to contravene information requirement**

*Clause 181* provides it is an offence (with a maximum penalty of 50 penalty units) for a person to fail to comply with a requirement made under clause 180(2) unless the person has a reasonable excuse. It is a reasonable excuse for an individual not to give the information if giving the information might tend to incriminate or expose the individual to a penalty.

## **Part 5                      Miscellaneous provisions relating to inspectors**

### **Division 1                Damage**

#### **Duty to avoid inconvenience and minimise damage**

*Clause 182* states that an inspector must, in exercising a power, take all reasonable steps to cause as little inconvenience and do as little damage as possible.

#### **Notice of damage**

*Clause 183* requires, where an inspector or their assistant damages a thing in the exercise or purported exercise of a power, for the inspector to give a notice of the damage to a person who appears to be an owner or person in control of the damaged thing. If it is not practical to give the notice to a person, the inspector must leave the notice in a reasonably secure way and conspicuous position at the place where the damage happened.

The obligation to give notice of damage does not arise where the inspector reasonably considers the damage trivial or reasonably believes there is no one apparently in possession of the thing or it has been abandoned.

If the inspector reasonably suspects that to comply with requirement to give the notice it may frustrate or hinder the performance of the inspector's function, the giving of the notice may be delayed. However, the inspector may only delay giving notice while they continue to have the reasonable suspicion and while they remain in the vicinity of the place.

If the damage is believed to have been caused by a latent defect in the thing or by other circumstances beyond the control of the inspector or their assistant, that belief may be stated in the notice.

The notice must state the particulars of the damage and that the person who suffered the damage may claim compensation. Provisions relating to compensation are detailed in clause 184.

### **Division 2                Compensation**

#### **Compensation for exercise of powers generally**

*Clause 184* provides that a person may claim compensation from the State if that person incurs loss because of the exercise or purported exercise of a power by or for an inspector. The loss

may include a loss arising from compliance with a requirement made under the seizure, forfeiture, or information-obtaining provisions of part 4, division 3 or 5.

Compensation may be claimed and ordered in a proceeding brought in a court with jurisdiction for the recovery of the amount claimed, or in a proceeding for an alleged offence against the Act where the investigation of the offence gave rise to the claim.

If the court is satisfied it is just to make the order in the circumstances of the particular case, the court may order the payment of compensation.

Clause 182 does not provide for a statutory right of compensation other than as provided by this clause.

*Loss* includes costs and damage.

## **Division 3            Other offences relating to inspectors**

### **Giving inspector false or misleading information**

*Clause 185* provides it is an offence (with a maximum penalty of 50 penalty units) to knowingly give an inspector false or materially misleading information. This offence applies to information given in relation to the administration of the Act, whether or not the information was given in response to exercise of a specific power under the Act. However, an offence does not occur if the information is in a document given by the person and the person tells the inspector, to the best of the person's ability, how the document is false or misleading and, if they have or can reasonably obtain the correct information, gives the correct information.

### **Obstructing inspector**

*Clause 186* states it is an offence (with a maximum penalty of 100 penalty units) to obstruct an inspector exercising a power unless the person has a reasonable excuse. It is also an offence to obstruct a person who is assisting an inspector to exercise a power.

Where a person has obstructed an inspector or their assistant, the inspector must warn the person that it is an offence to cause an obstruction unless there is a reasonable excuse and that they consider the person's conduct an obstruction.

*Obstruct* for the purposes of this clause, includes where a person assaults, hinders, resists, attempts to obstruct and threatens to obstruct the inspector or their assistant.

### **Impersonating inspector**

*Clause 187* states it is an offence (with a maximum penalty of 100 penalty units) to impersonate an inspector.

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## **Division 4                    Other provisions**

### **Evidential immunity for individuals complying with particular requirements**

*Clause 188* states that, where a person complies with a requirement to provide information or a document to an inspector under clause 159 or 177, evidence of the information or document and other evidence directly or indirectly derived from the information or document is not admissible against the individual to the extent the evidence tends to incriminate the individual or expose them to a penalty.

However, this immunity does not apply to a proceeding about the false or misleading nature of the information or anything in the document or in which the false or misleading nature of the information or document is relevant evidence. The immunity also does not apply to a proceeding in relation to administrative action taken against the individual or a proceeding in relation to a compliance notice applying to the individual.

## **Part 6                            State analysts and analysis of things**

### **Appointment and qualifications of State analyst**

*Clause 189* empowers the chief executive to appoint a health service employee, a public service employee or other persons prescribed by regulation as a State analyst.

The chief executive may appoint a person as a State analyst only if satisfied the person is appropriately qualified.

### **Appointment conditions of State analyst**

*Clause 190* states that a State analyst holds office on any conditions stated in the State analyst's instrument of appointment, a signed notice given to the State analyst or a regulation. The instrument of appointment, a signed notice given to the State analyst or a regulation may limit the State analyst's powers. In this clause, a *signed notice* means a notice signed by the chief executive.

### **When office of State analyst ends**

*Clause 191* provides that a State analyst's appointment ends when the term of office specified in the conditions under which the person holds office (a condition of office) ends, another condition under which the person holds office ends or the person's resignation under clause 192 takes effect. Subsection (1) does not limit the ways the office of a person as a State analyst ends.

### **Resignation of State analyst**

*Clause 192* states that a State analyst may resign by signed notice given to the chief executive.

## **Chief executive may approve laboratory**

*Clause 193* provides that the chief executive may approve a laboratory to analyse things taken under this Act if the chief executive is satisfied the laboratory has the resources and expertise to conduct the analysis.

## **Analysis**

*Clause 194* states that if an inspector takes a thing for analysis under this Act, the inspector must give the thing to a State analyst for analysis as soon as practicable. If a State analyst receives a thing for analysis, the State analyst must, as soon as practicable after receiving the thing, analyse the thing or give the thing for analysis to a laboratory that has been approved by the chief executive under clause 193.

If a thing is analysed by the State analyst, the State analyst must complete a certificate of analysis for the thing and give the certificate to the inspector who took the thing for analysis. If a thing is analysed at a laboratory that has been approved by the chief executive under clause 193, the State analyst must obtain a certificate of analysis for the thing from the person at the laboratory who analysed the thing and give the certificate to the inspector who took the thing for analysis.

## **Certificate of analysis to indicate method used**

*Clause 195* provides that a certificate of analysis completed under clause 194 must include information about the method used to conduct the analysis.

## **Chapter 6                      Reviews and legal proceedings**

### **Part 1                              Review of decisions**

#### **Division 1                      Preliminary**

#### **Definitions for part**

*Clause 196* defines the following terms for this part of the Act:

- an *affected person*, in relation to a decision, is a person who has been given or is entitled to be given an information notice for the original decision, or a person who applied for the internal review;
- an *internal review*, of an original decision, is defined in clause 198(1);
- an *internal review decision* is a decision made or taken to be made under clause 200 on an application for internal review of an original decision; and
- an *original decision* is a decision for which an information notice must be given under this Act, other than a decision to seize or forfeit a thing under chapter 5, part 4.

## Division 2 Internal review

### Review process must start with internal review

*Clause 197* provides an affected person may not apply to QCAT for review of an original decision, unless the affected person has applied for an internal review of the decision and a decision has been, or is taken to be, made about the internal review,. However, this clause does not apply to a decision about compensation made under clause 128.

### Who may apply for internal review

*Clause 198* states that an affected person for an original decision may apply to the chief executive for a review of the decision under this division (*internal review*).

A person who is entitled to be given an information notice for an original decision but has not yet received one may ask the chief executive for that notice. However, the chief executive's failure to give such notice does not limit or otherwise affect the person's right to apply for a review of the decision.

### Requirements for application

*Clause 199* requires an internal review application to be in the approved form and supported by enough information to enable the chief executive to decide the application. The application must be made within 14 days after the applicant is given the information notice. However, the chief executive may at any time extend the time for making the internal review application.

If the person has not been given an information notice, the application must be made within 28 days after the day the person becomes aware of the decision.

The application does not affect the operation of the decision or prevent the decision being implemented.

### Internal review

*Clause 200* requires that, within 28 days after receiving an internal review application, the chief executive must conduct an internal review of the original decision. The chief executive must review the original decision, and decide whether to confirm the original decision, amend this decision or substitute another decision. The chief executive must give the affected person a QCAT information notice for the decision.

The chief executive and the affected person may, before the 28 days is over, agree to a longer period for the chief executive to comply with subsection (1).

Unless the original decision was made by the chief executive personally, the application must be dealt with by a person who did not make the original decision and who is in a more senior office than the person who made the original decision. The power under section 27A of the *Acts Interpretation Act 1954* to delegate functions does not alter this provision.

If the chief executive does not give the affected person a QCAT information notice within 28 days, or the agreed longer period, the chief executive is taken to confirm the decision.

## **Division 3                      Stays**

### **QCAT may stay operation of original decision**

*Clause 201* states an affected person for an original decision may immediately apply to QCAT for a stay of the operation of the decision. The application may be made at any time within the application period for an internal review of the original decision.

QCAT may make an order staying the operation of the original decision only if it considers the order is desirable having regard to the interests of any person whose interests may be affected, any submission made by the entity that made the original decision and the public interest.

QCAT does not have to give a person whose interests may be affected an opportunity to make submissions if it is satisfied it is not practicable because of the urgency of the case or for another reason.

A stay by QCAT under this clause may be given on conditions QCAT considers appropriate, and operates for the period fixed by QCAT and may be amended or revoked by QCAT.

The period of a stay by QCAT must not extend past the period within which an application for internal review may be made under division 2 or the period within which an application for review of the internal review decision may be made under the QCAT Act. The QCAT Act, section 22(3) enables QCAT to stay the operation of the internal review decision, either on application by a person or on its own initiative.

## **Division 4                      External review**

### **Applying for external review**

*Clause 202* provides that a person given or entitled to be given a QCAT information notice may apply to QCAT for a review of an internal review decision or a decision about compensation under clause 128. The application must be in the manner prescribed in the QCAT Act. Section 22(3) of that Act allows QCAT to stay the operation of an internal review decision, either on application or its own initiative.

## **Division 5                      Appeals**

### **Appealing seizure or forfeiture decision**

*Clause 203* provides that a person who must be given an information notice for the chief executive's decision (a *property decision*) to seize or forfeit a thing may appeal the decision to a Magistrates Court (the *court*).

The appeal is started by filing a notice of appeal with the registrar of the court. The notice of appeal must state fully the grounds of the appeal. The notice of appeal must be filed within 28 days after the person receives the information notice for the decision, or becomes aware of the decision. However, on application and at any time, the court may extend the time for filing this notice.

A copy of the notice of appeal and any application to extend the time for filing a notice of appeal must be served on the chief executive.

The appeal does not affect the operation of the property decision or prevent the property decision being implemented.

### **Staying operation of decision**

*Clause 204* provides that a person to whom clause 203(1) applies may apply to the court for a stay of the operation of the property decision. The court may, by order, grant a stay of the property decision to ensure the effectiveness of the appeal.

The stay may be given on conditions the court considers appropriate. The stay operates for the period decided by the court, however this period must not extend past the time when the court decides the appeal.

### **Powers of court on appeal**

*Clause 205* provides that, in deciding an appeal against the property decision, the court has the same powers as the chief executive in making the decision, is not bound by the rules of evidence and must comply with natural justice.

An appeal is by way of rehearing. The court may confirm the property decision or set aside the property decision and either substitute another decision or return the matter to the chief executive with directions the court considers appropriate.

### **Effect of court's decision on appeal**

*Clause 206* states that, if the court substitutes another decision for the property decision, the substituted decision is taken to be the decision of the chief executive, and the chief executive may give effect to the substituted decision as if it were their original decision and no application for review or appeal had been made.

If the court sets aside the property decision and returns the matter to the chief executive with directions, and the chief executive makes a new decision in accordance with the directions, the new decision may not be reviewed or appealed against under this part.

## **Part 2                      Legal proceedings**

### **Division 1                Evidence**

#### **Application of division**

*Clause 207* states that the division applies to legal proceedings under the Act.

#### **Evidentiary aids generally**

*Clause 208* states the things that may be used as evidentiary aids in a matter.

A certificate purporting to be signed by the chief executive stating any of the following matters is evidence of the matter:

- a stated document is one of the following things made, granted given, issued or kept under this Act:
  - an appointment or decision;
  - a direction, notice or requirement;
  - a record in a database or register;
  - a departmental standard;
  - an emergency order;
  - an extended practice authority;
  - a substance authority;
- a stated document is a code, guideline, protocol or other standard mentioned in this Act;
- a stated document is a document given to the chief executive under this Act;
- a stated document is a copy of, or an extract from a part of, a thing mentioned in paragraph (a), (b) or (c);
- on a stated day, or for a stated period, a stated person was or was not authorised under this Act;
- on a stated day, or for a stated period, a substance authority was or was not in force or was or was not subject to a stated condition;
- on a stated day, or for a stated period, an appointment as an inspector or State analyst was or was not in force for a stated person;
- on a stated day:
  - a stated person was given a stated notice or direction;
  - a stated requirement was made of a stated person; or
  - a stated amount is payable by a stated person and has not been paid.

In a complaint starting a proceeding, a statement that the matter came to the knowledge of the complainant on a stated day is evidence of when the matter came to the complainant's knowledge.

In relation to a thing seized or taken by an inspector, a certificate purporting to be that of a State analyst stating any of the following matters is evidence of the matters:

- the analyst's qualifications;
- the analyst took or received the thing from a stated person;
- the thing was analysed at a stated place on a stated day or during a stated period;
- the methodology used to analyse the thing;
- the results of the analysis.

In a proceeding in which the chief executive applies under clause 213 to recover costs, a certificate by the chief executive stating that stated costs were incurred and the way in which, and purpose for which, they were incurred is evidence of the matters stated.

### **Evidence of regulated substance**

*Clause 209* states that, in a legal proceeding in which it is necessary to prove that a particular substance is a regulated substance, evidence that the particular substance is commonly supplied

under the same name or description as the particular substance is evidence that the particular substance is the same type of regulated substance.

Also, evidence that the particular substance or container for the particular substance, is labelled or marked in the way prescribed under this Act for a type of regulated substance is evidence that the particular substance is the same type of regulated substance.

### **Health assessment not admissible**

*Clause 210* provides that a report about a person's health assessment done by a medical practitioner under clause 90 is inadmissible as evidence in a legal proceeding, other than a review relating to the report, unless the person consents to the report being admitted, produced or given as evidence. A person cannot be compelled to produce the report or give evidence about the report or its contents in a proceeding, other than a review proceeding relating to the report.

In this clause, *review proceeding* means a proceeding for an internal or external review under part 1.

## **Division 2                      Proceedings**

### **Offences against this Act**

*Clause 211* states that an offence against the Act is to be heard and decided summarily.

A proceeding for the offence must start within 1 year after the offence was allegedly committed, or 6 months of the offence coming to the complainant's knowledge (but within 2 years after the offence was allegedly committed), whichever period is the later.

### **Proceeding not to commence if compliance notice in effect**

*Clause 212* provides that a person who has been given a compliance notice in relation to a provision that it is an offence to contravene cannot be prosecuted for the offence unless they fail to comply with the notice and does not have a reasonable excuse for failing to comply.

### **Recovery of particular costs of investigation**

*Clause 213* states that, if the following conditions apply, a court which considers it just in the particular circumstances may order a person to pay the chief executive an amount equal to costs incurred by the chief executive:

- a court convicts a person of an offence against the Act;
- the chief executive applies to the court for an order against the person for the payment of the costs the State for the investigation of the offence; and
- the court finds the costs were not, and could not reasonably have been, expected to be incurred for the investigation of the offence and were reasonably incurred.

The court may order the person to pay the State an amount equal to the costs if it is satisfied it would be just to make the order in the circumstances of the particular case.

In deciding whether to make the order, the court must have regard to the extent to which the person's conduct during the investigation contributed to the costs being incurred and whether the offence was committed, wholly and partly, for a commercial purpose and any other relevant matter.

This clause does not limit the court's powers under the *Penalties and Sentences Act 1992* or another law.

An application to a court for costs, and any order made by the court on the application, is a judgment in the court's civil jurisdiction. As such, an issue arising in the application must be decided on the balance of probabilities.

### **Executive officer may be taken to have committed offence**

*Clause 214* states that if a corporation commits a serious offence (being an offence against a provision of chapter 2, part 1, division 1 or clauses 42, 43, 44, 46, 47, 48, 71, 93(1) and (3), 94, 110, 116, and 125), each executive officer of the corporation is taken to have also committed the offence if they authorised or permitted the corporation's conduct constituting the offence, or they were knowingly concerned, either directly or indirectly, in the corporation's conduct.

Proceedings may be conducted against the executive officer, and they may be convicted of the offence, whether or not the corporation has also been proceeded against or convicted in relation to that offence. However, this does not affect the liability of the corporation for the offence, or the liability of any person for the offence under chapter 2 of the Criminal Code, whether or not the person is an executive officer of the corporation.

## **Chapter 7            General**

### **Part 1                Criminal History**

#### **Exceptions to criminal history disclosure requirements**

*Clause 215* provides that the *Criminal Law (Rehabilitation of Offenders) Act 1986* does not apply to a request, disclosure or notification made in relation to an individual's criminal history under this subdivision. This allows the chief executive to take an applicant's expired criminal convictions into account when considering applications for substance authorities, despite expiration of the rehabilitation period for those convictions. This means an applicant's full history may be taken into account when determining whether that person should be able to possess, manufacture, supply or use a medicine or poison.

The ability to consider a person's full criminal history is consistent with the objectives of the Act to protect public health and safety by preventing the misuse or diversion of regulated substances. Pest management technicians undertake work in domestic premises and consideration of the person's previous criminal history is necessary for public health and safety.

## **Criminal history report**

*Clause 216* provides that the chief executive may ask the police commissioner for a written report about the criminal history of the relevant person that includes a brief description of the circumstances of a conviction or allegation mentioned in the criminal history. However, the chief executive may make the request only if the chief executive is considering if the relevant person is a fit and proper person for a substance authority and the relevant person has given the chief executive written consent for the request.

The commissioner of police must comply with the request, but only in relation to information either in the police commissioner's possession or to which the commissioner has access.

## **Changes in criminal history must be disclosed**

*Clause 217* applies if the chief executive has made a criminal history request about a person, the person is later convicted of an indictable offence, and at the time of the conviction, the person is an approved person or is a relevant person for a substance authority.

It is an offence (with a maximum penalty of 100 units) for the person to fail to give notice within 14 days after the conviction to the chief executive, unless the person has a reasonable excuse.

The notice must include the existence of the conviction, details adequate to identify the offence of which the person was convicted, when the offence was committed, and the sentence imposed on the person.

## **Destruction of criminal history information**

*Clause 218* states that the chief executive must ensure any document containing criminal history information is destroyed as soon as practicable after it is no longer needed for the purpose for which it was given. For further information about the confidentiality of criminal history information see part 2.

# **Part 2                      Confidentiality**

## **Definitions for part**

*Clause 219* defines the following words for the purposes of this part:

- *administrator* means a person who is, or was, the chief executive or a person who is or was involved in the administration or enforcement of this Act (e.g. a health service employee or public service employee);
- *confidential information* means information that is personal information or information that would be likely to damage the commercial activities of a person to whom the information relates, that has become known to an administrator in the course of performing the administrator's functions under this Act. It does not include criminal history information or information that is lawfully available to the public.

## Confidentiality of information

*Clause 220* provides it is an offence (with a maximum penalty of 50 penalty units) for an administrator, either directly or indirectly, to disclose confidential information or criminal history information.

However, it is not an offence if the confidential information is disclosed:

- under this Act;
- if disclosure is required or permitted by law;
- with the consent of the person to whom the information relates; or
- in a form that does not identify the person to whom the information relates.

The more general confidentiality provisions under section 142 of the *Hospital and Health Boards Act 2011* do not apply to an administrator in relation to confidential information to which this Act applies.

## Disclosure of information to entities performing relevant functions

*Clause 221* states an administrator can only disclose confidential information to any of the following entities if satisfied the information will be collected, stored and used by the entity in a way that protects the privacy of the persons to whom the information relates from unjustified intrusion and is reasonably necessary for the entity to exercise its functions:

- a health ombudsman official;
- a coroner investigating the death of a person under the *Coroners Act 2003*;
- the chief executive of the department in which the *Food Act 2006* or the *Food Production (Safety) Act 2000* is administered;
- a law enforcement agency for the purpose of detecting, investigating, preventing or prosecuting an offence involving a regulated substance;
- the Australian Health Practitioner Regulation Agency, or a National Health Practitioner Board, established under the Health Practitioner Regulation National Law;
- the APVMA for performing its functions under the *Commonwealth Agricultural and Veterinary Chemicals Act 1994* (Cth) or *Agricultural and Veterinary Chemicals Code Act 1994* (Cth);
- the Secretary under the *Therapeutic Goods Act* for performing the Secretary's functions under that Act or the *Therapeutic Goods Act 2019*;
- a corresponding law entity;
- an entity of the Commonwealth or another State entity for performing its functions relating to:
  - a practitioner law;
  - the management of health and safety risks in public places and workplaces;
  - the importation or exportation of goods or substances into or from Australia;
- a foreign regulatory authority performing its functions relating to the importation or exportation of regulated substances into or from Australia.

In this clause, *corresponding law entity* means an entity of the Commonwealth or another State that administers, or performs functions in relation to, a corresponding law. *Practitioner law* in relation to a health practitioner means the Health Practitioner Regulation National Law.

*Practitioner law* in relation to a veterinary surgeon means the Veterinary Surgeons Act or a law of another State that provides for, or provided for, the same or similar matters as that Act.

### **Disclosure for therapeutic treatment of person**

*Clause 222* permits an administrator to disclose confidential information to a health practitioner providing therapeutic treatment to the person to whom the information relates if the disclosure is reasonably necessary for the therapeutic treatment.

### **Requests by chief executive for information**

*Clause 223* provides that the chief executive may, by a notice, ask the head of a public sector unit to give the chief executive information, including confidential information, that is reasonably necessary for the chief executive to carry out their functions under the Act and urgently prevent a health risk in relation to a substance, within a stated reasonable time. The *head* of a public sector unit means the chief executive of the unit.

The head of the public sector unit must comply with the notice unless the head considers the disclosure of the information would prejudice the investigation of a contravention, or possible contravention, of a law, or would prejudice the effectiveness of a lawful method or procedure for preventing, detecting, investigating or otherwise dealing with a contravention or possible contravention of a law, or would endanger a person's life or physical safety.

Also, the head of the public sector entity must ensure the information given in compliance with the notice only relates to the chief executive's function under this Act and that the privacy of a person to whom the information relates is protected from unjustified intrusion, to the extent possible.

## **Part 3                      Databases and registers**

### **Division 1                Monitored medicines database**

#### **Chief executive to keep database**

*Clause 224* provides that the chief executive must keep an electronic database (the *monitored medicines database*) to record information about the prescription and supply of monitored medicines. The purposes of keeping the monitored medicines database are:

- to promote safe practices for the therapeutic use of monitored medicines and reduce community harm caused by monitored medicines;
- to ensure particular health practitioners are complying with this Act, a corresponding law, or the requirements of a National Health Practitioner Board established under the Health Practitioner Regulation National Law;
- to assist a health ombudsman official investigate health service complaints under the Health Ombudsman Act;
- to enable particular health practitioners to access the database to record and review information for the therapeutic treatment of persons;
- to facilitate evaluation and research into monitored medicines;
- to facilitate national consistency in the therapeutic use of monitored medicines; and

- any other purpose prescribed by regulation.

### **Information recorded in database**

*Clause 225* provides that a regulation may prescribe the information that must be recorded by the chief executive in the monitored medicines database. The information prescribed may include personal information; information obtained under the repealed *Health Act 1937* before the commencement of this clause, despite the purpose for which the information was obtained or created; and information obtained under a law of another jurisdiction for a purpose mentioned in clause 224.

### **Giving Information**

*Clause 226* provides that it is an offence (with a maximum penalty of 100 penalty units) for an information provider to fail to give the chief executive the information mentioned in clause 225 at the time, and in the way, prescribed by regulation, unless the information provider has a reasonable excuse. In this clause, *information provider* means an entity prescribed by regulation to an information provider for this clause.

This clause will not require entities to share information unless it is otherwise lawful. The scope of use will depend on the law under which the information is given. The entity may or may not have restrictions on giving personal information. For example, information may only be able to be given to the chief executive for performing the chief executive's functions.

### **Use of information**

*Clause 227* provides the chief executive may disclose information in the monitored medicines database to a user by giving the information to the user, or giving the user electronic access to the database. The chief executive may disclose the information to the user only for a purpose prescribed by regulation for the user. The chief executive may also impose a condition on a user for accessing or using information from the monitored medicines database if the condition is consistent with a purpose mentioned in clause 224 or prescribed for the user under subsection (2). In this clause, *user* means an entity prescribed by regulation to be a user for this clause.

## **Division 2            Registers**

### **Chief executive to keep registers**

*Clause 228* provides the chief executive must keep a register about each of the following matters:

- administrative action taken under chapter 4, part 3 (the *administrative action register*);
- substance authorities (the *substance authority register*).

### **Content of administrative action register**

*Clause 229* provides that the administrative action register must contain the name and a brief description of the administrative action taken in relation to the person.

## Content of substance authorities register

Clause 230 provides that the substance authority register for substance authorities must contain the following information about each substance authority:

- the identification number allocated to the authority;
- the name of the holder or, if the holder trades as a business, the entity's business or trading name and the name of the person responsible for overseeing or supervising the regulated activity authorised under the authority;
- the type of the authority or regulated activity authorised under the authority;
- the term of the authority and the day the authority ends;
- the postcode of the place where the regulated activity under the authority will be carried out.

The purpose of clause 230 is to allow information that would otherwise be confidential information to be provided regarding whether a person has a substance authority. For example, if a member of the public wanted to verify that a pest management technician was licensed, it would not be possible to otherwise provide this information.

## Publishing registers

Clause 231 provides that the chief executive may publish the administrative action register and the substance authority register, on the department's website (each a *public register*).

The register provisions will enable a person to readily determine whether a substance authority holder is authorised to perform a particular regulated activity with a regulated substance such as issuing a purchase order for the substance or destroying medicines.

For example, a seller will be able to determine whether a substance authority holder is authorised to purchase the medicines they are seeking to purchase and, if there are limitations on their licence, what substances these limitations might prevent them from lawfully purchasing.

The register provision, in relation to substance authorities that are prescribing approvals, would allow Queensland Health to confirm, for a dispensing pharmacist, that a medical practitioner is authorised to write a prescription for a restricted medicine because the medical practitioner has a current prescribing approval authorising the medical practitioner to deal with the restricted medicine.

However, the chief executive must not include confidential information on a public register unless the chief executive is satisfied that the inclusion of the confidential information is reasonably necessary to avoid a health risk, and the inclusion of the confidential information will not place a person at risk of harm.

Also, the chief executive must remove information about administrative action from the public register if the administrative action no longer has effect.

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## **Part 4                      Extended practice authorities and departmental standards**

### **Division 1                  Extended practice authorities**

#### **Making extended practice authorities**

*Clause 232* provides that the chief executive may make a document (an *extended practice authority*) stating the places or circumstances in which an approved person may deal with the regulated substance, impose conditions on dealing with the regulated substance or require an approved person to hold particular qualifications or training necessary to deal with a regulated substance. The chief executive may make an extended practice authority by adopting all or a part of another entity's code, guideline, protocol or standard.

A regulation may prescribe matters the chief executive must consider before making an extended practice authority under subsection (2).

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.

An extended practice authority takes effect when it is approved by regulation.

An extended practice authority provides an extension to what an approved person is able to do under this Act. An extended practice authority may authorise a suitably qualified approved person to administer or supply medicines in specific clinical circumstances such as identifying and treating sexually transmitted diseases. The authorisation of the approved person depends on clinical circumstances and the current treatment for a health condition, both of which change over time. Extended practice authorities require clinical advice on current best practice and consideration of clinical resources to determine the nature of the treatment that may be delivered safely in the circumstances. They require a rigorous clinical and editorial process that reviews current clinical guidelines and clinical literature and responds to health service needs.

### **Division 2 Departmental standards**

#### **Making departmental standards**

*Clause 233* permits the chief executive to make a standard (a *departmental standard*) about carrying out a regulated activity with a regulated substance and other matters relating to the purposes and administration of this Act.

Matters which may be dealt with under a departmental standard include, but are not limited to, the following:

- procedures for carrying out regulated activities (for example, a standard stating how to prepare and lay baits for the control of wild dogs or a standard about prescribing or supplying monitored medicines);
- 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 substances are safe and suitable for the intended use of the products;
- requirements for tracing the movement of regulated substances from manufacture to final disposal, including requirements about documentation and electronic transactions.

The chief executive may also make a departmental standard by adopting another entity's code, guideline, protocol or standard, in whole or in part. A departmental standard has effect in relation to a person if a provision of a regulation states it applies to the person.

### **Consultation about departmental standards**

*Clause 234* provides that before making a departmental standard, the chief executive must take reasonable steps to consult with entities that are proposed to be subject to the standard, or have expertise about the matters proposed to be dealt with by the standard. However, a failure to comply with this requirement does not affect a departmental standard's validity.

### **Use of departmental standards in proceedings**

*Clause 235* applies in proceedings for an offence against a provision of this Act if the provision states a departmental standard provides for a way that is not the only way of complying with the provision.

The departmental standard is admissible in the proceedings as evidence of whether or not the provision has been complied with.

The court may have regard to the departmental standard in deciding whether or not the provision has been complied with.

Subsections (2) and (3) do not prevent a person from introducing evidence of compliance with the provision in a way that is different from the departmental standard but otherwise satisfies the requirements of the provision.

## **Division 3                      Publishing**

### **Availability of extended practice authorities and standards**

*Clause 236* states that the chief executive must publish each extended practice authority and departmental standard free of charge on the Queensland Health website.

## **Part 5                              Miscellaneous**

### **Civil remedies not affected**

*Clause 237* states that nothing in this Act affects or limits a civil remedy a person may have against an approved person, the holder of a substance authority or another person in relation to a matter dealt with under this Act.

## Delegation by chief executive

Clause 238 allows the chief executive to delegate their functions and powers under this Act, other than under clause 127, to an appropriately qualified person who is a public service employee or health service employee. Clause 127 allows the chief executive to make a public statement about particular matters.

## Approved forms

Clause 239 allows the chief executive to approve forms for use under this Act.

## Regulation-making power

Clause 240 provides a regulation-making power for the Governor in Council.

A regulation may be made about the following matters:

- the packaging, labelling, containing and storing of regulated substances;
- security practices for the supply of regulated substances;
- record-keeping and accounting for regulated substances;
- risk management and notification requirements for regulated activities with regulated substances;
- the establishment and use of electronic systems, computers and other devices in relation to regulated activities with regulated substances;
- the advertising of regulated substances;
- fees for applications and other matters under this Act, including criminal history checks and analysis of things by State analysts.

A regulation may impose a penalty of up to 100 penalty units for a contravention of that regulation.

## Chapter 8 Repeal, savings and transitional provisions

### Part 1 Repeals

#### Repeal of Acts

Clause 241 repeals the *Health Act 1937* and the *Pest Management Act 2001*.

### Part 2 Savings and transitional provisions

#### Division 1 Preliminary

#### Definitions for part

Clause 242 defines the following terms for the purposes of part 2:

- *former authorisation* means a HDPR approval, HDPR authority or pest licence;
- *HDPR* means the repealed *Health (Drugs and Poisons) Regulation 1996*;

- *HDPR approval* means an endorsement, other than an authority, under the HDPR;
- *HDPR authority* means an authority under the HDPR;
- *HDPR standing order* means *written instruction*, as defined in paragraph (b), HDPR, appendix 9;
- *Health Act* means the repealed *Health Act 1937*;
- *medicated animal feed* means a product containing an S4 medicine that is used to feed, or is mixed with food to feed, a food-producing animal within the meaning of schedule 3, part 2 of the *Biosecurity Regulation 2016*;
- *new authorisation* means an approved person's authorisation or a substance authority;
- *pest licence* means a licence under the Pest Management Act;
- *Pest Management Act* means the repealed *Pest Management Act 2001*.

### **Meaning of *equivalent***

*Clause 243* provides that, for this part, a new authorisation is *equivalent* to a former authorisation if the new authorisation authorises substantially the same activity with a substance as the former authorisation authorised, even if:

- the activity is described differently;
- the conditions of the new authorisation and the former authorisation are not identical; or
- the new authorisation authorises a regulated activity that includes, and is more than, the activity authorised under the former authorisation.

Without limiting subsection (1), a regulation may prescribe a new authorisation to be equivalent to a former authorisation.

### **Equivalent administrative action**

*Clause 244* applies if a provision of this part provides that a suspension or cancellation of a former authorisation is taken to be administrative action. The administrative action has the same effect to the same extent as the suspension or cancellation of the former authorisation.

If a new authorisation is equivalent to a cancelled HDPR authority, the administrative action is taken to be indefinite suspension of new authorisation.

If the suspension or cancellation of the former authorisation is taken to be administrative action, it must be included in the administrative action register.

## **Division 2            Continued former authorisations**

### **Subdivision 1        Preliminary**

#### **Ending of former authorisations not provided for**

*Clause 245* provides that a former authorisation not provided for under this part ends on the commencement.

### **Subdivision 2        HDPR approvals and pest licences**

#### **Holders who become approved persons upon commencement**

*Clause 246* applies to a person if immediately before the commencement, the person held an HDPR approval or pest licence and, on the commencement, a new authorisation that is an approved person's authorisation applies to the person and the new authorisation authorises a regulated activity that is more limited than the activity authorised under the person's HDPR approval or pest licence.

The person's HDPR approval or pest licence continues in effect until the day that is three months after the commencement. However, if, within 3 months after the commencement, the person applies for a substance authority equivalent to the approval or licence, the person's HDPR approval or pest licence continues until the day the application for the substance authority is decided.

For subsection (2), in relation to an HDPR approval, the HDPR continues to apply in relation to the approval as if this Act had not commenced. In relation to a pest licence, the Pest Management Act continues to apply in relation to the licence as if this Act had not commenced.

### **Holders who do not become approved persons on commencement**

*Clause 247* applies to a person who held an HDPR approval or pest licence immediately before the commencement, and on the commencement, does not hold a new authorisation that is an approved person's authorisation, and is required under this Act to hold the new authorisation to carry out the activity that was authorised under the approval or licence.

The person's HDPR approval or pest licence continues in effect until a substance authority equivalent to the HDPR approval or pest licence is granted to the person, or the term of the HDPR approval or the pest licence ends under the HDPR or Pest Management Act as the case may be, or the HDPR approval or pest licence is cancelled or surrendered under the HDPR or Pest Management Act as the case may be, whichever comes first.

However, if before the term of the HDPR approval or pest licence ends under the HDPR or Pest Management Act, the person applies for a substance authority equivalent to the approval or licence and the chief executive has not decided whether to grant the substance authority on the day the term of the approval or licence would otherwise end, then the HDPR approval or pest licence continues in effect until the day the chief executive decides the application. This is despite subsection 2.

If the existing approval is an HDPR approval, the HDPR continues to apply in relation to the approval as if this Act had not commenced. If the existing approval is an existing pest approval, the Pest Management Act continues to apply in relation to the approval as if this Act had not commenced.

### **Approval holders who no longer need authorisation**

*Clause 248* applies if immediately before the commencement, a person held an HDPR approval or pest licence to carry out an activity with a substance and on the commencement, the person

is not required under this Act to hold a new authorisation to carry out the activity with the substance. The HDPR approval or pest licence ends on the commencement.

### **Manufacturing licences for medicated animal feed**

*Clause 249* applies to an HDPR approval that immediately before the commencement, was a restricted drug manufacturer licence authorising the manufacture of medicated animal feed. On commencement, the HDPR approval is taken to be a manufacturing licence authorising the manufacture of the medicated animal feed with each substance that was approved under the HDPR approval, under the supervision of the person responsible for supervising the manufacture under the HDPR approval, at the place that was approved for manufacturing the feed under the HDPR approval, and for the term of the HDPR approval.

To remove any doubt, it is declared that no conditions of the HDPR approval, other than those mentioned in subsection (2) apply to the manufacturing licence.

This clause applies despite clauses 246 to 248.

### **Approvals for drug dependent persons**

*Clause 250* applies to an HDPR approval that, immediately before the commencement, authorised the treatment of a drug dependent person, or class of drug dependent persons, under the HDPR, section 120, 122, 213 or 213A. The HDPR approval continues in effect until the day the term of the approval ends under the HDPR, the day the approval is cancelled or surrendered under the HDPR, the day prescribed under clause 281 to be the day the monitored medicines database is fully operational, whichever is earliest.

The HDPR continues to apply to the HDPR approval as if this Act had not commenced. This clause applies despite clauses 246 to 248.

### **Authorised way for continued approvals**

*Clause 251* provides that a person who holds an HDPR approval or pest licence that is continued in effect under this part is taken to carry out a regulated activity with a regulated substance in the authorised way, if the person carries out the activity under the HDPR or the Pest Management Act.

### **Waiving fees for continued approvals**

*Clause 252* applies to a person who holds an HDPR approval or pest licence that is continued in effect under this part and, before the term of the approval or licence ends, applies for a substance authority that is equivalent to the approval. The chief executive may decide to waive all or part of a fee payable under this Act for the application.

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## **Subdivision 3      HDPR authorities**

### **Royal Flying Doctor Service**

*Clause 253* applies in relation to an HDPR authorisation that, immediately before the commencement, authorised a person from the Royal Flying Doctor Service of Australia to carry out an activity with a substance under the HDPR, section 54(1) or 157(1).

If, within 1 year after the commencement, an appropriately qualified officer of the Royal Flying Doctor Service of Australia applies for a substance authority equivalent to the HDPR authority, the HDPR authority continues in effect as if this Act had not commenced until the day the application for the substance authority is decided, or otherwise the day that is 1 year after the commencement.

### **St John Ambulance Australia – Queensland**

*Clause 254* applies in relation to an HDPR authority that authorised a person from St John Ambulance Australia – Queensland to carry out an activity with a substance under the HDPR, section 174B.

If, within 1 year after the commencement, an appropriately qualified officer of St John Ambulance Australia – Queensland applies for a substance authority equivalent to, or authorising more than, the HDPR authority, the HDPR authority continues in effect as if this Act had not commenced until the day the application for the substance authority is decided, or otherwise, the day that is 1 year after the commencement.

### **Universities**

*Clause 255* applies in relation to an HDPR authority that, immediately before the commencement, authorised the vice-chancellor of a university, or the vice-chancellor's delegate, to carry out an activity with a substance under the HDPR, section 179A or 265A.

If, within 1 year after the commencement, an appropriately qualified officer of the university applies for a substance authority equivalent to the HDPR authority, the HDPR authority continues in effect as if this Act had not commence until the day the application for the substance authority is decided, or otherwise the day that is 1 year after the commencement.

## **Division 3              Continued applications**

### **Existing applications for new interests**

*Clause 256* provides that this clause applies if before the commencement, a person applied for an approval, licence or permit (the *interest*) under the Health Act or Pest Management Act, and immediately before the commencement, the person's application had not been decided.

The person's application must be decided as if it were an application for the substance authority that is equivalent to the interest and made under this Act on the commencement.

For subsection (2), if a fee has been paid or waived for the interest, a fee payable under this Act for an application for the substance authority is waived.

### **Amendment or renewal applications for approvals**

*Clause 257* provides that this clause applies if before the commencement, a person applied to amend or renew an HDPR approval or pest licence and immediately before the commencement, the application had not been decided and the existing HDPR approval or pest licence is continued in effect under this part.

The person's application must be decided as if it were an application to amend or renew a substance authority that is equivalent to the HDPR approval or pest licence and made under this Act on the commencement.

For subsection (2), if a fee has been paid or waived for the application, a fee payable under this Act to amend or renew the substance authority is waived.

### **Amendment or repeal applications about suspension or cancellation decisions – HDPR authorities**

*Clause 258* provides that this clause applies if before the commencement, a person applied, under the HDPR, section 26A, for the amendment or repeal of a decision (the *original decision*) to suspend or cancel an HDPR authority and immediately before the commencement, the application had not been decided and on the commencement, a new authorisation that is an approved person's authorisation is equivalent to the HDPR authority and applies to the person.

The person's application must be decided as if it were a request to review administrative action under clause 105.

For considering the application under subsection (2), the original decision is taken to be the administrative action taken under this Act in relation to the equivalent new authorisation.

### **Amendment or repeal applications about suspension or cancellation decisions – HDPR approvals**

*Clause 259* provides that this clause applies if before the commencement, a person applied, under the HDPR, section 26A, for the amendment or repeal of a decision (the *original decision*) to suspend or cancel an HDPR approval and immediately before the commencement, the person's application had not been decided.

The person's application must be decided as if it were a request to review administrative action under clause 105.

For considering the application under subsection (2), the person is taken to be the holder of a substance authority that is equivalent to the HDPR approval and the original decision is taken to be administrative action taken under this Act in relation to the substance authority.

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## **Division 4      Continued processes and proceedings**

### **Subdivision 1   Former offences**

#### **Proceedings for former offences**

*Clause 260* provides that this clause applies in relation to an offence against a provision of the Health Act or Pest Management Act committed by a person before the commencement.

Without limiting section 20 of the *Acts Interpretation Act 1954*, the clause provides that a proceeding for the offence may be continued or started, and the person may be convicted of and punished for the offence, as if this Act had not commenced. This applies despite section 11 of the Criminal Code.

An analysis completed under clause 273 may be used in relation to the proceeding to the extent otherwise authorised under the Health Act or Pest Management Act.

#### **Applications for recovery of costs**

*Clause 261* provides if before the commencement, the chief executive applied to the court for the payment of costs under section 153ZL of the Health Act or section 119 of the Pest Management Act, and immediately before the commencement, the application had not been decided, the application may be decided as if this Act had not commenced.

If a person is convicted of an offence after the commencement of the Act because of a proceeding continued or started under clause 260, the chief executive may apply to a court for an order for the payment of costs under section 153ZL of the Health Act or section 119 of the Pest Management Act, and the application may be decided as if the Medicines and Poisons Act had not commenced.

### **Subdivision 2   Reviews and appeals**

#### **Review of HDPR decisions**

*Clause 262* provides that this clause applies if, before the commencement, a decision was made by the chief executive under the HDPR and immediately before the commencement, the period during which an application for a review of the decision may have been made to QCAT under the HDPR, section 33 had not ended, or an application was made to QCAT under the HDPR, section 33 for a review of the decision and the application had not been decided by QCAT immediately before the commencement.

The application may be decided, or made and decided, as if this Act had not commenced.

Subsection (4) applies if as a result of the QCAT's decision on the application, an approval, licence or permit (an *interest*) would have been granted under the HDPR but for the commencement of this Act.

The chief executive must grant the person a substance authority that is equivalent to the interest and is subject to the conditions that would have applied to the interest had it been granted under the HDPR before the commencement.

### **Review of Pest Management Act decisions**

*Clause 263* provides that this clause applies if, before the commencement, a person was given, or entitled to be given, an information notice for a decision under the Pest Management Act and immediately before the commencement, the period during which an application for a review of the decision may have been made under the Pest Management Act, part 4, had not ended, or an application was made under the Pest Management Act, part 4 for a review of the decision and the application had not been decided immediately before the commencement.

The application may be decided, or made and decided, as if this Act had not commenced.

Subsection (4) applies if, as a result of a decision on the application, a licence would have been granted under the Pest Management Act if this Act had not commenced.

The chief executive must grant the person a pest management licence that is equivalent to the licence under the Pest Management Act and is subject to the conditions that would have applied to the licence, if it had been granted under the Pest Management Act before the commencement.

### **Appeals against forfeiture decisions under Health Act**

*Clause 264* provides that if, before the commencement, a thing was forfeited to the State under the Health Act, repealed section 153G(1)(c) and immediately before the commencement:

- the period during which the owner may have started an appeal to a Magistrates Court under the Health Act, part 4A, division 7 had not ended; or
- the owner had started an appeal (the *first appeal*) that had not been decided by the Magistrates Court;
- the period in which the owner may have started an appeal to the District Court from a decision of the Magistrates Court on the first appeal had not ended;
- the owner started an appeal (the *second appeal*) to the District Court from a decision of the Magistrates Court on the first appeal and the second appeal was not decided.

The first appeal and second appeal may be decided, or started and decided, as if this Act had not commenced. Furthermore, the owner may start an appeal to the District Court from a decision of the Magistrates Court as if this Act had not commenced.

## **Subdivision 3 Other continued processes**

### **Show cause notices**

*Clause 265* provides that if before the commencement, a person was given either a show cause notice under the Pest Management Act, section 44 that was in effect immediately before the commencement or a written notice for a suspension or cancellation under the HDPR, section 24 that was in effect immediately before the commencement, and on the commencement, the person has a new authorisation that is equivalent to the former authorisation, the notice is taken

to be a show cause notice for administrative action taken under this Act in relation to the new authorities.

### **Suspension of former authorisations**

*Clause 266* applies if, immediately before the commencement, a suspension (the *former suspension*) of a person's former authorisation was in effect. The former suspension is taken to be administrative action.

If the former authorisation was an HDPR approval or HDPR authority, the suspension notice day for the former suspension is taken to be the review day for the administrative action.

In this clause, *suspension notice day*, for a suspension means the day stated in the notice under the HDPR, section 24 for the suspension before which the person was not permitted to apply to the chief executive for an amendment or repeal of the chief executive's decision under the HDPR, section 26A.

### **Cancellation of HDPR authority**

*Clause 267* applies if immediately before the commencement, a cancellation (the *former cancellation*) of a person's former authorisation that was an HDPR authority was in effect. The former cancellation is taken to be administrative action.

The cancellation notice day for the former cancellation is taken to be the review day for the administrative action.

In this clause, *cancellation notice day*, for a cancellation, means the day stated in the notice under the HDPR, section 24 for the cancellation before which the person was not permitted to apply to the chief executive for an amendment or repeal of the chief executive's decision under the HDPR, section 26A.

### **Surrender of HDPR authority**

*Clause 268* applies if immediately before the commencement, a surrender (the *former surrender*) under the HDPR, section 32 was in effect for a person's HDPR authority and on the commencement, a new authorisation that is an approved person's authorisation and is equivalent to the HDPR authority applies to the person.

The former surrender is taken to be agreed administrative action.

### **Compliance notices**

*Clause 269* provides if a compliance notice is given to a person under the Pest Management Act, section 89 that was in effect immediately before the commencement, the compliance notice is taken to be a compliance notice under this Act.

### **Warrants**

*Clause 270* provides that a warrant issued under the Health Act or the Pest Management Act, that was in force immediately before the commencement, continues in force until the warrant

is executed or cancelled, or the period during which the warrant can be executed ends, whichever occurs earliest.

For this clause, the Health Act or Pest Management Act, as the case may be, continues to apply to the warrant as if this Act had not commenced.

### **Requirements made by Health Act inspectors**

*Clause 271* states that a requirement made by an inspector under the Health Act for a person to do a thing under any of the following provisions (each an *enforcement provision*) of that Act continues to apply until it has been satisfied or otherwise ends under the terms of the requirement:

- section 151 (General powers after entering a place);
- section 153E (Powers to support seizure);
- section 153N (Power to require production of documents);
- section 153Q (Power to require information); or
- section 153R (Compliance notice).

The Health Act continues to apply to the requirement as if this Act had not commenced.

### **Requirements made by Pest Management Act inspectors**

*Clause 272* states that a requirement made by an inspector for a person to do a thing under any of the following provisions (each an *enforcement provision*) of the Pest Management Act continues to apply until it has been satisfied or otherwise ends under the terms of the requirement:

- section 69 (General powers after entering place);
- section 76 (Powers to support seizure);
- section 83 (Power to require name and address);
- section 85 (Power to require production of documents);
- section 88 (Power to require information); or
- section 89 (Compliance notice).

The Pest Management Act continues to apply to the requirement as if this Act had not commenced.

### **Analysis by State analysts**

*Clause 273* states that if a State analyst under the Health Act or Pest Management Act was undertaking analysis of a thing (whether under the Health Act, Pest Management Act or another Act), immediately before commencement, and had not completed the analysis or certificate for the analysis, a State analyst under this Act may continue to analyse the thing and give a certificate of analysis for the thing.

The Health Act continues to apply to the analysis as if the Health Act were not repealed.

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## Division 5            Transition of other matters

### Subdivision 1        Documents

#### Prescriptions

*Clause 274* states that a prescription that was given under the Health Act for the supply or administration of a substance before the commencement, and immediately before the commencement, the substance had not been dispensed, supplied or administered will continue in force until the earliest of the following:

- the substance is dispensed, supplied or administered;
- the prescription is cancelled by a person with authority to cancel prescriptions under the Health Act;
- the period stated on the prescription or provided for under the Health Act during which the substance must be supplied or administered ends.

The Health Act continues to apply in relation to the prescription as if this Act had not commenced. In this clause, a *prescription* means any instrument under the Health Act, other than an HDPR standing order, that, immediately before the commencement, permitted a substance to be dispensed or supplied for, or administered to, a stated person or animal.

#### Purchase orders

*Clause 275* states that if before the commencement, a purchase order was given under the Health Act for the supply of a substance and immediately before the commencement, the substance had not been supplied under the purchase order then the order continues in force until the earliest of the following if the purchase order was for the supply of a substance other than medicated animal feed:

- the substance is supplied under the order;
- the order is cancelled by a person who had the authority to cancel the order under the Health Act;
- the period, stated on the order or provided for under the Health Act, during which the substance must be supplied ends.

If the purchase order is for the supply for medicated animal feed, the order continues in force until the day that is 6 months after the commencement, or until the day a circumstance mentioned in subsection (2)(a) or (b) applies to the order, whichever is first.

The Health Act continues to apply to the purchase order as if this Act had not commenced.

#### Standing orders

*Clause 276* provides that an HDPR standing order that was in effect immediately before the commencement continues in force until the day that is 6 months after the commencement.

The Health Act continues to apply to the HDPR standing order as if this Act had not commenced.

## References to repealed Acts

*Clause 277* provides that a reference in a document to the Health Act or Pest Management Act, may, if the context permits, be taken to be a reference to this Act.

## Subdivision 2 Offices and functions

### Inspectors

*Clause 278* states a person who held office as an inspector under the Health Act or Pest Management Act immediately before the commencement, is taken to hold office as an inspector under this Act on the conditions, if any, stated in the person's instrument of appointment. This clause stops applying to the person on the day that is 6 months after the commencement.

### State analysts

*Clause 279* states that a person who held office as a State analyst under the Health Act or Pest Management Act immediately before the commencement is taken to hold office as a State analyst under this Act on the conditions, if any, stated in the person's instrument of appointment.

This clause stops applying to the person on the day that is 6 months after the commencement.

## Division 6 Extended periods for compliance

### Substance management plans

*Clause 280* provides that a responsible person who, on the commencement, would be required under clause 93 to make a substance management plan for a regulated place does not need to comply with the requirements of chapter 4, part 2 until one year after the commencement (the *transition period*).

If the responsible person becomes subject to the requirements in chapter 4, part 2 because a former authorisation is replaced with a substance authority during the transition period, the responsible person must comply with chapter 4, part 2 when the transition period ends, regardless of when the substance authority is granted.

### Procedure until monitored medicines database operational

*Clause 281* provides that this clause applies for the period (the *transition period*) starting on the commencement and ending on the day prescribed by regulation to be the day the monitored medicines database is fully operational.

In the transition period, a person is not liable to be prosecuted for a contravention of clause 41 or 226 and a person to whom the HDPR, sections 84(2) to (10), 84A(3) and (4), 120, 122, 213

of 213A applied immediately before the commencement must continue to comply with the section as if this Act had not commenced.

This clause does not prevent a person complying with this Act to the extent practicable if, during the transition period, the monitored medicines database is able to be used.

## **Division 7 Miscellaneous**

### **Transitional regulation-making power**

*Clause 282* allows a *transitional regulation* to make a saving or transitional provision about any matter necessary to make provision to allow or facilitate the doing of anything to achieve the transition from the Health Act or the Pest Management Act to this Act, and for which this Act does not already make provision or sufficient provision.

A transitional regulation must declare it is a transitional regulation, may have retrospective operation to a day that is not earlier than the day on which this provision commences, and expires 2 years after this clause commences. The power to make a transitional regulation also expires at that time.

## **Chapter 9                    Acts amended**

### **Part 1                        Amendment of this Act**

#### **Act amended**

*Clause 283* provides that this part 1 amends this Act.

#### **Amendment of long title**

*Clause 284* amends the long title of this Act.

### **Part 2                        Amendment of Drug Misuse Act 1986**

#### **Act Amended**

*Clause 285* provides that chapter 9, part 2 amends the *Drugs Misuse Act 1986*.

#### **Amendment of s 4 (Definitions)**

*Clause 286* omits the definition for *chief executive for health, environmental health officer* and *official identity card*.

It also amends the definition for *prosecution information notice*.

#### **Omission of ss 43H – 43Q**

*Clause 287* omits sections 43H to 43Q.

### **Omission of s 43T (Compensation)**

*Clause 288* omits section 43T.

### **Amendment of s 125 (Prescribed persons permitted to receive and dispose of dangerous drugs)**

*Clause 289* amends section 125 to remove references to the *Health Act 1937* and insert references to the *Medicines and Poisons Act 2019*.

## **Part 3                      Other Acts amended**

### **Acts amended**

*Clause 290* provides that Schedule 2 amends the Acts mentioned in it.

### **Schedule 1**

*Schedule 1* contains definitions for terms used in the Bill.

### **Schedule 2**

*Schedule 2* contains consequential amendments to various Acts.