Medicines and Poisons (Medicines) Amendment Regulation 2022

Explanatory notes for SL 2022 No. 77

made under the

Medicines and Poisons Act 2019

General Outline

Short title

Medicines and Poisons (Medicines) Amendment Regulation 2022

Authorising law

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

Policy objectives and the reasons for them

The medicines and poisons scheme commenced on 27 September 2021, comprising the *Medicines and Poisons Act 2019* (Act) and supporting regulations, including the *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation).

The medicines and poisons scheme was a major reform to modernise and streamline the medicines and poisons regulatory framework, ensuring the scheme is easier for industry and the community to understand and apply in practice. The scheme has largely been implemented without significant issues. However, a number of minor and technical issues have been identified during implementation by either stakeholders or Queensland Health.

The *Medicines and Poisons (Medicines) Amendment Regulation 2022* (Amendment Regulation) amends the Medicines Regulation to reflect changes to the Commonwealth *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard), updates references to external documents that have been revised since commencement on 27 September 2021 and makes the following minor and technical amendments:

- updates the references to a new version of the extended practice authority for Aboriginal and Torres Strait Islander health practitioners;
- updates the reference to a new version of the *Guidelines for use of scheduled medicines* made by the Optometry Board of Australia on 10 December 2021 (Optometry Guidelines) and updates a reference to the correct appendix;
- authorises specialist medical practitioners in respiratory and sleep medicine to prescribe, give a treatment dose, administer, give a purchase order and possess the restricted

medicines ambrisentan; bosentan; macitentan and riociguat, consistent with the approach that applied under the repealed *Health (Drugs and Poisons) Regulation 1996* (HDPR);

- ensures consistency with Appendix D of the Poisons Standard by specifying whether the restricted medicines in schedule 2, part 1 are for human use or for human oral use, and includes ivermectin in the list of restricted medicines;
- enables certain classes of approved person, including a new class of person (gastroenterologists and hepatologists), to deal with ivermectin for human oral use, to implement changes made to the Poisons Standard;
- updates the requirements for sending prescriptions electronically to ensure these apply to all prescriptions and not only prescriptions for diversion-risk medicines;
- amends the definition of *shared clinic* to ensure settings that supply or administer medicines to animals are required to prevent unauthorised access and manage inappropriate use and diversion risks for the medicines;
- streamlines the use of electronic prescription systems by removing the requirement for both words and numbers to be included in an electronic prescription, while retaining their use for written prescriptions to describe the quantity of medicine to be dispensed; and
- replaces the phrase 'minimum standard pack' with 'smallest available size of manufacturer's pack of the medicine'.

Extended practice authorities

Section 232 of the Act enables the chief executive or their delegate to make an extended practice authority and states that the extended practice authority must be approved by regulation (section 232(4)).

Schedule 1, part 1 of the Medicines Regulation lists the approved extended practice authorities (name and version number). When new versions of an extended practice authority are made by the chief executive or their delegate, the Medicines Regulation requires an amendment to reflect the new version so it can take effect.

Aboriginal and Torres Strait Islander health practitioners

Queensland Health's policy position is that Aboriginal and Torres Strait Islander health practitioners be authorised to administer or give a treatment dose of a medicine as specified in the extended practice authority, with or without a prescription from a medical practitioner, nurse practitioner or dentist.

An error was identified in the Aboriginal and Torres Strait Islander health practitioner extended practice authority (version 1), referring to physician assistants rather than dentists. The intent of the Aboriginal and Torres Strait Islander health practitioner extended practice authority is to provide comparable authorisations with medicines to those previously stated in the discontinued Drug Therapy Protocol for Aboriginal and Torres Strait Islander health practitioners made under the repealed HDPR. As such, the reference to physician assistants rather than dentists in the Aboriginal and Torres Strait Islander health practitioner extended practice authority is inconsistent with the department's policy position.

The Aboriginal and Torres Strait Islander health practitioners extended practice authority was approved by the chief executive on 12 September 2021 and took effect on 27 September 2021, on commencement of the Medicines Regulation.

Optometrists and endorsed optometrists

On 10 December 2021, the updated Optometry Guidelines made by the Optometry Board of Australia revoked the version referred to in the Medicines Regulation. The updated version of the Guidelines outlines the Optometry Board's expectations about the use of scheduled medicines by endorsed and non-endorsed optometrists and includes two additional Schedule 4 (S4) medicines in the approved list of medicines in Appendix B (ganciclovir and lifitegrast). The Optometry Guidelines apply to:

- optometrists with general registration who use scheduled medicines for diagnostic purposes; and
- optometrists whose registration is endorsed for scheduled medicines, who use scheduled medicines for the practice of optometry.

The Medicines Regulation specifies the authorisations for optometrists (schedule 8, part 2) and endorsed optometrists (schedule 8, part 3), as approved persons, to deal with S2, S3 or S4 medicines listed in Appendix A, Appendix B and Appendix C, as made by the Optometry Board, and stated to have effect from 10 September 2018.

Respiratory and sleep medicine specialist medical practitioners

The Medicines Regulation lists restricted medicines which can only be prescribed by a certain class of specialist medical practitioner or an individual who holds a prescribing approval. Restricted medicines include medicines whose use may cause birth defects (such as thalidomide), medicines with a higher risk of serious side effects (such as the antipsychotic medicine clozapine), or medicines that meet both these criteria (such as isotretinoin as treatment for severe skin conditions).

All restricted medicines categorised under the Medicines Regulation are listed in Appendix D of the Poisons Standard as medicines for a specific health risk, where the risks of use can be mitigated by restricting availability through specialist medical practitioners.

The Medicines Regulation states the restricted medicines that specialist medical practitioners in respiratory and sleep medicine, and their registrars, are authorised to deal with. Four restricted medicines, (ambrisentan; bosentan; macitentan and riociguat), indicated for respiratory and sleep disorders, were inadvertently not included when the Medicines Regulation was made.

As an interim measure, a prescribing approval was granted under section 67 of the Act, authorising all specialist medical practitioners in the field of respiratory and sleep disorders under the Health Practitioner Regulation National Law, and their registrars to prescribe, give a treatment dose, dispense, administer, buy and possess the restricted medicines (ambrisentan; bosentan; macitentan and riociguat).

Under the prescribing approval, specialist medical practitioners and their registrars are subject to standard conditions and requirements under the Medicines Regulation, including the requirement to include the prescribing approval number as proof of their authorisation on the prescription to enable pharmacists to lawfully dispense the restricted medicine.

Restricted medicines for human use or human oral use

Restricted medicines (schedule 2, part 1 of the Medicines Regulation) include S4 and S8 medicines, which are also listed in Appendix D of the Poisons Standard. Appendix D also denotes the medicines listed when the controls do not apply for animal use. These medicines are marked as 'for human use' or 'for human oral use'.

The controls on use for restricted medicines listed in the Medicines Regulation apply to both human and non-human use and do not align with the Appendix D entries for those medicines. When establishing the list of restricted medicines in the Medicines Regulation, the policy intent was to take a consistent approach to Appendix D of the Poisons Standard. That is, to place controls on these medicines for human use to safeguard public health. It was not the intention to exclude veterinary surgeons from dealing with these medicines, as non-restricted medicines, used for treating animals.

Ivermectin oral preparation for human use

In October 2021, in response to the COVID-19 pandemic, increasing public health risk and a supply shortage, the Commonwealth Government revised Appendix D of the Poisons Standard to include ivermectin (preparations for oral administration for human use) to control what it may be prescribed for.

As an interim measure, the emergency order – Authority to deal with oral preparations of ivermectin (https://www.health.qld.gov.au/__data/assets/pdf_file/0036/1129896/emergency-order-authority-oral-preparations-ivermectin.pdf) (made under section 58 of the Act) was made during the COVID-19 declared public emergency. The first emergency order came into effect on 3 December 2021. It has since been remade to reflect the relevant controls placed on ivermectin (oral preparations) under the Poisons Standard. The emergency order only has effect during the COVID-19 declared public health emergency and must be remade every 90 days. The emergency order overrides the authority for approved persons to undertake regulated activities detailed for oral preparations of S4 ivermectin (as a non-restricted medicine) in the current relevant schedules of the Medicines Regulation.

Sending prescriptions electronically

Section 84 of the Medicines Regulation sets out requirements that apply when sending a digital copy of a paper prescription for a medicine to be dispensed.

Section 84(2) of the Medicines Regulation provides the timeframes for when a paper prescription must be received by the dispenser after a digital copy is sent. It was intended that these requirements apply to all prescriptions. However, as drafted the provision only applies to diversion-risk medicines. A diversion-risk medicine includes all Schedule 8 (S8) medicines and some S4 medicines (as listed in schedule 2, part 3 of the Medicines Regulation).

Definition of shared clinic

Section 195 of the Medicines Regulation defines *shared clinic*, which means a place at which medicines are possessed by more than one person to use for supply or administration to more than one person. The definition *shared clinic* does not refer to animals but should apply to settings such as veterinary clinics and animal shelters. The relative risks associated with unauthorised access, inappropriate use and diversion risks associated with obtaining medicines

stored at a place for animals are comparable to places that use medicines for supply or administration for peoples.

Chapter 8, part 2 of the Medicines Regulation establishes the standards for storing medicines across a range of industries and settings, which are proportionate to the relative risks of storing the medicines. For the purposes of establishing stores and S8 safes for medicines, section 196 states the requirements for appointing establishers and managers at a shared clinic to prevent unauthorised access. Offence provisions apply to the person in charge of the shared clinic for non-compliance with the medicine storage requirements.

While chapter 8, part 2 does not apply to S4 medicines in animal feed, the policy position is for the provisions for storage and S8 safe requirements to apply across a range of industries and settings, including veterinary clinics and animal shelters where medicines, such as pentobarbital, are stored for supply or administration to an animal. This ensures the recommendations of the two Coronial reviews[1,2] of injectable pentobarbital related deaths and the need to ensure storage requirements are proportionate to prevent unauthorised access to medicines which may cause harm.

Electronic prescription content

Section 86 of the Medicines Regulation states the content that must be included on a written prescription, for it to be lawful when authorising the supply of medicines for the treatment of a person or an animal. Section 87 of the Medicines Regulation states the additional content that must be included on a written prescription for S8 medicines.

Section 87(2)(a) of the Medicines Regulation states a written prescription, including electronic prescriptions, for S8 medicines must contain both words and numbers to describe how much of the medicine may be dispensed or given. This requirement is consistent with the provisions under the HDPR, to mitigate misinterpretation of the paper prescription information and to reduce fraudulent behaviour, such as illegibility and making changes to the amount to be dispensed.

A prescription is a direction to another person to administer, dispense or give a treatment dose of a medicine for the treatment of a person or animal. A prescription may be given in writing (a written prescription), which includes paper prescriptions (handwritten or computer generated), electronic prescriptions or orally.

Section 83 of the Medicines Regulation provides that for an electronic prescription, a prescriber must not make an electronic prescription except by using an electronic prescription management system. The system manager of an entity's electronic prescription management system must take all reasonable steps to ensure the system complies with the *Requirements for an electronic prescription management system* departmental standard (the departmental standard) (see section 186 of the Medicines Regulation).
Clause 2a of the departmental standard states the electronic prescription management systems must use software products listed on the *Electronic prescribing – External conformance register* published by the Australian Health Digital Agency (AHDA), as meeting the national electronic prescription management conformance and technical requirements (nationally agreed conformance requirements). In April 2021, the revised AHDA national conformance

[1] Notice of interim decisions on proposed amendments to the Poisons Standard - ACMS/ACCS/Joint ACMS-ACCS meetings, March 2020: 3.3. Pentobarbital | Therapeutic Goods Administration (TGA) (https://www.tga.gov.au/book-page/33-pentobarbital)
[2] Coronial findings - Donna Cowley-Persch (courts.qld.gov.au) (https://www.courts.qld.gov.au/__data/assets/pdf_file/0020/510176/cif-cowley-persch-20170221.pdf)

requirements were released, with the technical specifications no longer requiring software products to include specific fields for words and numbers for S8 medicines, as the annotation fields could be used.

All Australian states and territories have made legislative changes to enable electronic prescriptions created, transferred, stored and retrieved for dispensing through AHDA conformant software products, to provide a nationally consistent digital health solution and medicines safety framework to maintain patient choice of prescriber and pharmacy for supply of their medicines; adhere to privacy and security principles, and alignment across relevant Commonwealth, state and territory legislation.

Queensland is now the only Australian jurisdiction that requires an electronic prescription to include both the word and number to describe the quantity being prescribed for S8 medicines. As a result, Queensland based pharmacists have raised concerns about whether electronic prescriptions generated by prescribers outside of Queensland may be dispensed as lawful prescriptions, placing patients at risk of not receiving S8 medicines in a timely manner.

The AHDA nationally agreed conformance requirements, including the security requirements for integration of the conformant software products that form an electronic prescription management system mitigates the likelihood of misinterpretation and unlawful changes, as only the prescriber who created the electronic prescription may make any changes in the system. In addition, the system records all activities made in the system, including user details, that may be retrieved for audit and investigation purposes. As such, the risks associated with misinterpretation of written content or making fraudulent changes on a prescription is more likely with paper prescriptions signed by hand.

Manufacturer's pack

Minimum standard pack is not defined in the Medicines Regulation and is a legacy term that was transferred from the HDPR. Manufacturer's pack, for a medicine, is defined in the Medicines Regulation as a primary pack of the medicine supplied by the manufacturer of the medicine. For example, by referring to the smallest available size will ensure that if a 10g tube of cream and a 100g tube of cream is available, the pharmacist must sell the 10g tube of the S4 medicine.

Achievement of policy objectives

Extended practice authorities

The Amendment Regulation amends schedule 1, part 1 of the Medicines Regulation to reflect new version 2 of the Aboriginal and Torres Strait Islander health practitioner extended practice authority, which refers to dentists rather than physician assistants.

Optometrists and endorsed optometrists

The Amendment Regulation amends schedule 8, part 1, section 1 of the Medicines Regulation to update the reference to the Optometry Guidelines made on 10 December 2021 to ensure optometrists and endorsed optometrists continue to deal with scheduled medicines in accordance with the Medicines Regulation and the expectations of the Optometry Board, as the profession's national regulatory authority.

Appendix A of the Optometry Guideline applies to optometrists and Appendix B and C apply to endorsed optometrists. The Amendment Regulation amends schedule 8, part 2, section 3 to reflect this by replacing the reference to Appendix B with Appendix A for optometrists. No changes to the appendices for non-endorsed optometrists are required.

Respiratory and sleep medicine specialist medical practitioners

The Amendment Regulation amends schedule 6, part 2, division 17 of the Medicines Regulation to enable specialist medical practitioners in respiratory and sleep medicine to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess the restricted medicines ambrisentan; bosentan; macitentan and riociguat, in addition to sodium oxybate, to mitigate any specific health risks so that persons with complex respiratory and sleep disorders will have access to these medicines.

Restricted medicines for human use or human oral use

The Amendment Regulation amends schedule 2, part 1 of the Medicines Regulation to update the list of restricted medicines to include two new divisions. Division 1 lists the medicines that are restricted for the purposes of human use. Division 2 lists the medicines that are restricted for human and animal use. These changes will enable the conditions applied on these medicines to be consistent with Appendix D of the Poisons Standard and authorise veterinary surgeons to deal with the medicines lists in new division 1 as non-restricted medicines for animal use.
If an amendment is not made to specify that a medicine is a restricted medicine only if the medicine is for human use, veterinary surgeons are not authorised to use medicines such as dinoprost to treat reproductive conditions in animals. Managing these reproductive conditions is a routine part of veterinary practice.

Ivermectin oral preparation for human use

The Amendment Regulation:

- amends schedule 6, part 2, division 3, section 22 of the Medicines Regulation to allow dermatologists to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess restricted ivermectin;
- amends schedule 6, part 2, division 10, section 36 of the Medicines Regulation to allow infectious diseases specialists to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess restricted ivermectin;
- amends schedule 6, part 2, division 15, section 47 of the Medicines Regulation to allow paediatricians to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess restricted ivermectin;
- inserts a new class of person (Gastroenterologist and hepatologist) into schedule 6, part 2. This class of person is a medical practitioner who is a specialist registrant in gastroenterology and hepatology. The amendments allow these specialist medical practitioners to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess restricted ivermectin; and
- amend schedule 2, part 1 to include an entry for ivermectin which means a restricted medicine that is ivermectin (oral preparation for human use).

The amendments are required to give effect to the controls in the Poisons Standard and are consistent with the authorisations stated in the emergency order. Until revisions are made to the Medicines Regulation, new versions of the emergency order need to be approved every three months (the maximum duration) by the chief executive or delegate, to retain the restrictions and authorisations to control dealings with ivermectin oral preparations for human oral use.

Sending prescriptions electronically

The Amendment Regulation amends section 84(2) and (3) of the Medicines Regulation to ensure the requirement to send a paper prescription to the dispenser within a specified time period after sending a digital copy of a prescription for the medicine to be dispensed applies to a prescription for any type of medicine. The additional requirement to include particular annotations on a paper copy of a prescription sent electronically will continue to apply to prescriptions for diversion-risk medicines only.

Definition of shared clinic

The Amendment Regulation amends the definition of *shared clinic* in section 195 of the Medicines Regulation by removing the phrase ‘to more than 1 person’, to ensure the requirements for S8 safes and medicines storage apply to all relevant treatment settings that use medicines for supply or administration, including animal settings such as veterinary clinics and animal shelters. These requirements include the appointment of establishers and managers, to set up S8 safes and medicines storage and maintain records appropriate to the types of medicines used at the shared clinic.

Electronic prescription content

The Amendment Regulation amends section 87(2)(a) to exclude the requirement for both words and numbers to be included in an electronic prescription, while retaining these for other written prescriptions to describe the quantity of medicine to be dispensed.

Manufacturer’s pack

The Amendment Regulation amends section 159(a) by replacing ‘the minimum standard pack’ with ‘the smallest available size of manufacturer’s pack of the medicine’.

Consistency with policy objectives of authorising law

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

Inconsistency with policy objectives of other legislation

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

Alternative ways of achieving policy objectives

The Amendment Regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The cost of implementing the amendments to the Medicines Regulation will be met within existing budget allocations, and the resources to manage and administer the existing regulation framework will continue to be used. The amendments do not impose any new or increased fees.

Extended practice authorities

The circumstances in which an approved person may deal with a regulated substance without a prescription are clarified under the Aboriginal and Torres Strait Islander health practitioner extended practice authority.

Optometrists and endorsed optometrists

The amendment will ensure optometrists and endorsed optometrists continue to deal with scheduled medicines in accordance with the Medicines Regulation and the expectations of the Optometry Board of Australia, as the profession's national regulatory authority.

Respiratory and sleep medicine specialist medical practitioners

The inclusion of ambrisentan, bosentan, macitentan and riociguat in the Medicines Regulation will reinstate the use of these medicines, which was authorised under the HDPR, and authorise respiratory and sleep medicine specialists and their registrars to continue dealing with these medicines without the need to include a prescribing approval as proof of authorisation. The inclusion of these medicines will ensure persons with complex respiratory and sleep disorders will have timely access to medicines through specialist medical practitioners to mitigate specific health risks.

Restricted medicines for human use or human oral use

The amendment will enable controls to be applied for restricted medicines in line with Appendix D of the Poisons Standard and authorise veterinary surgeons to deal with particular medicines as non-restricted medicines for animal use.

Ivermectin oral preparation for human use

Enabling certain classes of approved persons to deal with oral preparations of ivermectin for human use will give effect to the restrictions in Appendix D of the Poisons Standard and provide a safeguard for public health by restricting availability through specialist medical practitioners.

Sending prescriptions electronically

The amendment will improve clarity about the requirements for sending images of paper prescriptions.

Definition of shared clinic

The relative risks related to unauthorised access, inappropriate use and diversion risks associated with obtaining medicines stored at a place for animals are comparable to places that use medicines for supply or administration for people. Amending the definition for *shared*

clinic to include settings such as veterinary clinics and animal shelters will ensure regulated substances are used safely and effectively and will ensure the controls and requirements that apply are commensurate with the public health and safety risk of the medicines.

Electronic prescription content

Removing additional prescribing requirements for words and numbers to be included in an electronic prescription for an S8 medicines provides a consistent approach with other state and territory requirements, allowing prescriptions generated by prescribers outside of Queensland to be dispensed as lawful prescriptions in Queensland.

Manufacturer's pack

The amendment will improve clarity by using consistent language throughout the Medicines Regulation by referring to a manufacturer's pack, rather than using an undefined term.

Consistency with fundamental legislative principles

The Amendment Regulation is generally consistent with fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*.

Institution of Parliament

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

Extended practice authorities

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

Prescribing requirements by reference to an external document may be seen to breach section 4(5)(e) of the Legislative Standards Act. An extended practice authority is a document certified by the chief executive of Queensland Health (or delegate) that sets out matters of technical detail for how an approved person can carry out a regulated activity with a regulated substance. Extended practice authorities include details such as the route of administration, the specific dose, quantity, duration and restrictions placed on substances and the circumstances in which they may be administered. The extended practice authority is monitored and updated when necessary, aligns with clinical best practice and is published on the Queensland Health website. When making or amending an extended practice authority, relevant individuals or organisations with expertise in, or experience of, the matters under consideration are consulted.

Extended practice authorities are updated regularly, with consideration given to the healthcare needs of specific patient populations, how care can be provided in a timely and safe manner and requirements for medical advice, referral or transfer to other individuals qualified to provide higher levels of care, and the individual qualifications, skills and experience of the

class of health practitioners who will act under the particular authority. Schedule 1, part 1 (Approved extended practice authorities) of the Medicines Regulation details the name of each extended practice authority made by the chief executive and its version number. The regulation is updated to reflect the name and new version number of the extended practice authority each time a new version is made. A copy of the updated extended practice authority is tabled as extrinsic material each time the regulation is amended, to reflect the updated document. The Act provides that an extended practice authority has effect in relation to an approved person only if a provision of a regulation states it applies to the particular class of persons, as approved persons.

By including a list of extended practice authorities in the schedule of the Medicines Regulation, it creates certainty for the relevant professions and the public about the status of extended practice authorities published on the Queensland Health website and the date when these took effect.

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

External Standards and Guidelines

In some cases, it is necessary to adopt or specify standards that have been developed by relevant industry bodies, for example, the Optometry Board of Australia.

Schedule 8, section 3 (Dealing authorised) provides that an optometrist may administer a topical S2, S3 or S4 medicine mentioned in appendix A of the *Guidelines for use of scheduled medicines*, made by the Optometry Board, if the optometrist administers the medicine under the guidelines.

Schedule 8, section 5 (Dealing authorised) provides that an endorsed optometrist may prescribe, give a treatment dose of, and administer an S2, S3 or S4 medicine mentioned in appendix B and appendix C of the Guidelines for use of scheduled medicines made by the Optometry Board and the endorsed optometrist prescribes, gives a treatment dose of or administers the medicine under the guidelines.

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

The Optometry Board publishes lists of the endorsed classes of scheduled medicines, which are updated from time to time. To ensure the Medicines Regulation is up to date, it is amended to reflect the date of the new version. A copy of the new version of the guidelines is being tabled as extrinsic material.

There is a rigorous process that National Registration Boards must follow to amend guidelines. The process is governed by the Health Council (formerly known as the COAG Health Council)

and any amendments must be approved by the Minister for Health from each jurisdiction. The Ministerial Council may, at any time, ask a National Board to review an approved or proposed registration standard for the health profession for which the National Board is established. The guidelines are published online on the Optometry Board's website (https://www.optometryboard.gov.au).

This potential breach of the fundamental legislative principle is considered justified as it will support national consistency in the authorised scope of medicines dealings for optometrists and makes it clear the version of the guidelines these practitioners are authorised to use.

Consultation

Prior to commencement of the medicines and poisons scheme in September 2021, extensive review and consultation took place with stakeholders from a broad range of industries about the new legislation. Since commencement of the Medicines Regulation, stakeholders have sought clarification and feedback on the regulation, including some minor variations from the repealed HDPR. These stakeholders included the Optometry Board of Australia, Veterinary Surgeons Board Queensland and Royal Australian College of Physicians (Qld) (RACPQ).

The Optometry Board of Australia advised Queensland Health of their revised Guidelines, dated 10 December 2021, and the need to update this version in the Medicines Regulation, for optometrists and endorsed optometrists to deal with medicines in the 'authorised way'.

Queensland Health wrote to RACPQ and respiratory and sleep medicine specialists advising that due to an unintended oversight, these specialists were not currently authorised to deal with the specified restricted medicines, unless they had a prescribing approval. The RACPQ supports the amendment to the Medicines Regulation to include the 'as-of-right' authorisation for respiratory and sleep medicines specialists and their registrars to deal with the listed restricted medicines.

The Veterinary Surgeons Board of Queensland acknowledges the expansion of the definition of *shared clinics* to include clinical settings that treat animals; and supports the inclusion of two new divisions to denote the list of restricted medicines that are restricted from 'human use' or 'human use only', enabling veterinary surgeons to deal with these as non-restricted medicines to treat animals.

In general, stakeholders support the proposed amendments to the Medicines Regulation to further clarify the 'authorised way' to carry out activities with medicines and to rectify minor and technical issues identified during implementation.

The Amendment Regulation was assessed by the Office of Best Practice Regulation in accordance with *The Queensland Government Guide to Better Regulation* as being excluded from further regulatory impact analysis under category (k) – regulatory proposals designed to reduce the burden of regulation, or that clearly do not add to the burden, and it is reasonably clear there are no significant adverse impacts.

Notes on provisions

Short Title

Clause 1 states the short title is the *Medicines and Poisons (Medicines) Amendment Regulation 2022*.

Commencement

Clause 2 provides for the commencement of the regulation on 1 July 2022.

Regulation amended

Clause 3 provides that the regulation amends the *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation).

Amendment of s 84 (Sending prescription electronically)

Clause 4 amends section 84 which sets out the requirements that apply when sending a digital copy of a paper prescription.

Clause 4(1) amends section 84(2) by omitting the phrase 'for a diversion-risk medicine'. The intention is that subsection (2) applies to all prescriptions, and not only to diversion-risk medicines. The amendment will ensure the requirement to send a paper copy of a prescription within a specified time period after sending a digital copy of a prescription applies to a prescription for any type of medicine. Prescriptions are only required for S4 and S8 medicines.

Clause 4(2) amends section 84(3) by replacing 'Before sending the digital copy, the prescriber must take all reasonable steps' with 'If the medicine is a diversion-risk medicine, the prescriber must take all reasonable steps, before sending the digital copy,'. The additional requirement to include particular annotations on a paper copy of a prescription sent electronically will continue to apply to prescriptions for diversion-risk medicines only.

Amendment of s 87 (Additional content of written prescription for S8 medicine)

Clause 5 amends section 87(2)(a) by replacing 'both' with 'if the prescription is a paper prescription—both'. This amendment will streamline the use of electronic prescription management systems by removing the requirement for both words and numbers to be included in an electronic prescription, while retaining this requirement for written prescriptions to describe the quantity of medicine to be dispensed.

Amendment of s 159 (Amounts when selling S4 medicines)

Clause 6 amends section 159(a) by replacing 'the minimum standard pack' with 'the smallest available size of manufacturer's pack of the medicine'. Minimum standard pack is not defined in the Medicines Regulation and is a legacy term that was transferred from the repealed *Health (Drugs and Poisons) Regulation 1996*. Manufacturer's pack, for a medicine, is defined in the Medicines Regulation as a primary pack of the medicine supplied by the manufacturer of the medicine. For example, by referring to the smallest available size will ensure that if a 10g tube of cream and a 100g tube of cream is available, the pharmacist must sell the 10g tube of the S4 medicine.

Amendment of s 195 (Definitions for part)

Clause 7 amends the definition of *shared clinic* by omitting 'to more than 1 person'. This amendment will ensure settings that supply or administer medicines to animals are captured and they are required to prevent unauthorised access and manage inappropriate use and diversion risks for the medicines in the same way as places that supply or administer to people.

Amendment of sch 1 (Extended practice authorities and departmental standards)

Clause 8 amends schedule 1, part 1, by replacing the reference to version 1 of the extended practice authority with version 2 for the entry for Aboriginal and Torres Strait Islander health practitioners.

Amendment of sch 2 (Categories of medicines)

Clause 9 amends schedule 2, which lists the restricted medicines which can only be prescribed by a certain class of specialist medical practitioner or an individual who holds a prescribing approval. Restricted medicines include medicines whose use may cause birth defects (such as thalidomide), medicines with a higher risk of serious side effects (such as the antipsychotic medicine clozapine), or medicines that meet both these criteria (such as isotretinoin as treatment for severe skin conditions).

Clause 9 inserts in schedule 2, part 1, new divisions 1 (Medicines for human use) and 2 (Other medicines). The inclusion of division 1 specifies that particular medicines are restricted medicines only if the medicine is for human use. The amendment will ensure veterinary surgeons are authorised to use relevant medicines to treat animals and will also ensure consistency with Appendix D of the Poisons Standard. An entry for the restricted medicine 'ivermectin other than when prepared in oral tablet form for treating a condition shown as an approved indication on the Australian Register of Therapeutic Goods for treatment with ivermectin in oral tablet' has also been included in the list of medicines for human use. Division 2 is the remaining restricted medicines from the original list in schedule 2, part 1.

Amendment of sch 6 (Medical practitioners and assistants)

Clause 10 amends schedule 6 to include a new class of authorised person and enables specified health practitioners to deal with ivermectin (oral preparations).

Clause 10(1) omits all references to 'human' from schedule 6, sections 22, 32 and 58. This amendment is a consequence of the amendment in clause 9 which specifies the medicines that are for human use.

Clause 10(2) amends schedule 6, section 22, to enable a dermatologist to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess restricted ivermectin. This is in addition to a dermatologist already being able to deal with acitretin, bexarotene, etretinate, hydroxychloroquine, isotretinoin, thalidomide or tretinoin for oral use.

Clause 10(3) inserts new Division 5A (Gastroenterologists and hepatologists) in schedule 6. New Division 5A consists of sections 26A (Class of person) and 26B (Dealing authorised).

New section 26A provides that division 5A applies to a medical practitioner who is a specialist registrant in gastroenterology and hepatology.

New section 26B provides that gastroenterologists and hepatologists can perform the following regulated activities:

- prescribe restricted ivermectin;
- give a treatment dose of restricted ivermectin;
- dispense restricted ivermectin;
- administer restricted ivermectin;
- give a purchase order for stock of restricted ivermectin, if the stock is not for a specified place;
- possess restricted ivermectin.

Clause 10(4) amends schedule 6, section 36, to enable an infectious diseases specialist to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess restricted ivermectin. This is in addition to an infectious diseases specialist already being able to deal with hydroxychloroquine or thalidomide.

Clause 10(5) amends schedule 6, section 47, to enable paediatricians to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess restricted ivermectin. This is in addition to paediatricians already being able to deal with hydroxychloroquine or sodium oxybate.

Clause 10(6) amends schedule 6, section 52, to enable respiratory and sleep medicine specialists to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess ambrisentan, bosentan, macitentan, riociguat. This is in addition to respiratory and sleep medicine specialists already being able to deal with sodium oxybate. This amendment ensures respiratory and sleep medicine specialists can deal with the four restricted medicines, ambrisentan; bosentan; macitentan and riociguat, indicated for respiratory and sleep disorders, which were inadvertently not carried over from the *Health (Drugs and Poisons) Regulation 1996* to the Medicines Regulation.

Amendment of sch 8 (Ocular treatment professions)

Clause 11 amends schedule 8, which relates to ocular treatment professions.

Clause 11(1) amends the definition of optometry guidelines in schedule 8, section 1 to update the reference to the *Guidelines for use of scheduled medicines* (Guidelines) made on 10 December 2021 to ensure optometrists and endorsed optometrists continue to deal with scheduled medicines in accordance with the Medicines Regulation and the expectations of the Optometry Board of Australia, as the profession's national regulatory authority.

Clause 11(2) amends schedule 8, section 3, by replacing an incorrect reference to 'appendix B' with 'appendix A' for optometrists. Appendix A of the Guidelines applies to optometrists and appendices B and C apply to endorsed optometrists. No changes to the appendices for non-endorsed optometrists were required.

Amendment of sch 22 (Dictionary)

Clause 12 amends schedule 22 (Dictionary).

Clause 12(1) inserts definitions for *Australian Register of Therapeutic Goods* and *restricted ivermectin*. *Australian Register of Therapeutic Goods* means the Australian Register of Therapeutic Goods maintained under the *Therapeutic Goods Act 1989* (Cwlth). *Restricted ivermectin* means a restricted medicine that is ivermectin.

Clause 12(2) amends the definition *adrenaline (epinephrine) autoinjector* by omitting 'maintained under the *Therapeutic Goods Act 1989* (Cwlth)'. This amendment is a consequence of the inclusion of the definition of Australian Register of Therapeutic Goods in clause 12(1).

Clause 12(2) amends the definition *registered medicine* by omitting 'maintained under the *Therapeutic Goods Act 1989* (Cwlth)'. This amendment is as a consequence of the inclusion of the definition of Australian Register of Therapeutic Goods in clause 12(1).