Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2023

Explanatory notes for SL 2023 No. 51

made under the

Medicines and Poisons Act 2019

General Outline

Short title

Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2023

Authorising law

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

Policy objectives and the reasons for them

The *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation) regulates medicines and complements the *Medicines and Poisons Act 2019* (Act) by:

- ensuring regulated substances are used safely and effectively to reduce harm;
- setting out the 'authorised way' for a person to perform regulated activities with medicines; and
- providing flexible requirements for several authorised activities, such as storage and disposal, that are commensurate with the approved person's qualifications and activities and the public health and safety risk of the medicines.

The *Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2023* (Amendment Regulation) amends the Medicines Regulation to:

- remove barriers and facilitate ease of access to naloxone;
- enable psychiatrists to prescribe, administer, give a purchase order and possess N, α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA) for post-traumatic stress disorder (PTSD) and psilocybine for treatment resistant depression, to align with changes to the Commonwealth *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard) in down-scheduling MDMA and psilocybine from a schedule 9 to a schedule 8 medicine;
- restrict follitropin delta, sitaxentan and alefacept to prescribers with the same qualifications as those in Appendix D of the Poisons Standard;

- update a reference to a new version of the Departmental Standard – *Storage Standard for S8 Medicines* (Storage Standard) to clarify storage requirements in operational Queensland Ambulance Service vehicles; and
- update a reference to a new version of the Registered Nurses Extended Practice Authority to clarify approved courses in sexual and reproductive healthcare and to facilitate registered nurses administering the Japanese encephalitis virus vaccine.

Naloxone

Drug overdose is a leading cause of death for Australians of all ages. According to Australia's *Annual Overdose Report 2022*, compiled by the Penington Institute, unintentional drug-induced deaths in Australia have surpassed the number of deaths from road-related incidents for the past five years. For over 10 years, there have been over 2,000 overdose deaths per annum in Australia. Opioids are the most common drug group associated with unintentional drug-induced deaths, with deaths nearly trebling since 2006. Most of these deaths are related to pharmaceutical opioids, with ongoing increases in fentanyl overdose.

Queensland consistently has some of the largest increases in the rates of unintentional drug-induced deaths for different drug types. In Queensland, deaths due to pharmaceutical opioid overdose more than doubled between 2006-10 and 2016-2020. However, most overdose deaths can be prevented through a range of options including improving access to naloxone.

Naloxone is a medicine that works by blocking prescription and non-prescription opioid drugs, such as heroin and oxycodone, from attaching to opioid receptors in the brain. There is no evidence of significant adverse reactions to naloxone. Administering naloxone in cases of opioid overdose can cause withdrawal symptoms when the person is dependent on opioids, which is uncomfortable without being life threatening. The risk that a person overdosing on opioids will have a serious adverse reaction to naloxone is far less than their risk of dying from overdose. Naloxone works if a person has opioids in their system and has no harmful effect if opioids are absent. It can be administered by injection or via a nasal spray.

Take Home Naloxone (THN) programs are publicly funded in Canada, Scotland, Northern Ireland, Wales and Italy. These jurisdictions with broadly comparable health systems provide THN for free from community organisations, harm reduction and addiction services, and outreach services. These international THN programs have been evaluated with no significant issues reported as long as naloxone was provided free of charge with high levels of accessibility. In the United States, a large-scale national study showed that opioid overdose deaths decreased by 14 per cent after they enacted naloxone access laws.

From December 2019 to June 2022, the Australian Government funded a Pilot program to provide THN subsidised through the Pharmaceutical Benefits Scheme. This was in response to rising concerns over the rate of opioid overdose deaths in Australia. The THN Pilot allowed people at risk of experiencing or likely to witness an opioid overdose or adverse reaction to access naloxone without cost, and without a prescription. THN was available from a variety of settings, including pharmacies and other authorised alternative sites in New South Wales, South Australia and Western Australia. The evaluation of the Australian THN Pilot found that the program achieved at least 1,649 overdose reversals, saving an estimated three lives per day.

In response to the success of the THN Pilot, the Australian Government committed $19.6 million over four years from 2022-2023 (and $4.9 million per annum recurrently) to support the implementation of the program nationally, by continuing to fund the cost of naloxone.

Under the national THN program, naloxone (as either Naloxone Hydrochloride (DBL), Naloxone Juno, Nyxoid, and Prenoxad) is available for free in all Australian States and Territories through participating providers and in line with the THN program rules. The THN program is for:

- people who are at risk of an opioid overdose or adverse reaction, their carers, friends and family members;
- approved providers such as community pharmacists, dispensing doctors and hospital pharmacists; and
- authorised alternative suppliers such as needle and syringe programs, alcohol and other drug treatment centres and outreach services.

The Medicines Regulation creates barriers to implementing the national THN program. It is an offence to supply or administer naloxone unless the person is authorised to deal with that medicine and complies with the requirements in the regulation. For example, pharmacists must label the naloxone with the individual patient's name prior to dispensing, creating barriers to access due to the stigma associated with people who use opioids. Organisations seeking to participate in the program must obtain an approval to supply the naloxone to persons. For example, where a person is experiencing an opioid overdose, it is unlikely the person will be able to administer naloxone to themselves or even ask for assistance to administer naloxone, so a person may potentially commit an offence by administering naloxone to save another person's life. The Amendment Regulation facilitates ease of access to naloxone and removes these barriers to implementing the national THN program in Queensland.

MDMA and Psilocybine

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

On 3 February 2023, the Therapeutic Goods Administration announced that a change to the scheduling for the Schedule 9 prohibited substances MDMA and psilocybine would take effect on 1 July 2023. The change will down-schedule each substance to Schedule 8 in certain specific circumstances:

- MDMA in preparations for human therapeutic use for the treatment of PTSD; and
- psilocybine in preparations for human therapeutic use for the treatment of treatment-resistant depression.

Both medicines will be subject to further restrictions by having entries included in Appendix D of the Poisons Standard, limiting them to supply on prescription or instruction of a registered psychiatrist who has been given an authority under the *Therapeutic Goods Act 1989* (Cwlth), or under the auspices of a National Health and Medical Research Council approved clinical trial.

The Medicines Regulation does not automatically adopt the restrictions in Appendix D of the Poisons Standard. Amendments to the Medicines Regulation are required to ensure that appropriate controls are maintained over these medicines in Queensland.

Updating controls for other medicines in Appendix D of the Poisons Standard

A review of the Poisons Standard identified three medicines with restrictions in Appendix D of the Poisons Standard that require further controls in the Medicines Regulation:

- Follitropin Delta (a recombinant human follicle-stimulating hormone) for human use – The prescription of this medicine is restricted to authorised medical practitioners in Appendix D of the Poisons Standard. This medicine is in the same therapeutic class as Follitropin Alpha and Follitropin Beta, which are already in the Medicines Regulation; and
- Sitaxentan and Alefacept – These medicines are not currently commercially available and were not picked up as a regulated restricted drug under the repealed *Health (Drugs and Poisons) Regulation 1996*, and therefore did not transition to the Medicines Regulation.

Storage Standard

Section 233 of the Act enables the chief executive or their delegate to make a departmental standard and states that the departmental standard must be approved by regulation.

Schedule 1, part 2 of the Medicines Regulation lists the approved departmental standards by name and version number. When a new version of the departmental standard is made by the chief executive or their delegate, the Medicines Regulation requires an amendment to reflect the new version so it can take effect. The Act provides that the departmental standard does not take effect until it is approved by the Medicines Regulation or a date stated in the standard, and it is published on the Queensland Health website.

The Storage Standard describes the requirements for safe and secure storage of Schedule 8 (S8) medicines. The intent of the Storage Standard is to allow flexible, minimum requirements for the storage of S8 medicines across various practice contexts while preventing the unauthorised removal of, or interference with, these medicines.

Under the Storage Standard, Queensland Ambulance Service (QAS) officers (ambulance officers) are required to remove S8 medicines when an operational vehicle is parked overnight or left unattended. In operational QAS vehicles, S8 medicines are kept within a Primary Response Kit that is stored within a metal compartment in the vehicle. The Primary Response Kit is not visible to the public.

The QAS service delivery model includes after-hours on-call services in regional and remote communities. An ambulance officer providing an on-call service is considered operational and must be available to respond rapidly. The on-call ambulance officer usually responds from their personal residence, where a marked vehicle containing a Primary Response Kit is left operational overnight. The vehicle is always locked when unattended. Operational QAS vehicles containing a Primary Response Kit are also left locked but unattended when the ambulance officer is transferring patients to a hospital or other health facility.

There is a need to clarify how the Storage Standard applies to QAS vehicles, while balancing the safe storage of S8 medicines and the need to provide timely health responses to the community.

Registered Nurses Extended Practice Authority

Schedules 3 to 15 of the Medicines Regulation provide authorisations for certain classes of persons to deal with certain medicines. Extended practice authorities provide additional authorisations for a specific class of person to deal with certain medicines beyond the authorisations in the Medicines Regulation.

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.

Schedule 1, part 1 of the Medicines Regulation lists the approved extended practice authorities by name and version number. When a new version of the extended practice authority is made by the chief executive or their delegate, the Medicines Regulation requires an amendment to reflect the new version so it can take effect. The Act provides that the extended practice authority does not take effect until it is approved by the Medicines Regulation or a date stated in the extended practice authority, and it is published on the Queensland Health website.

Education requirements of sexual and reproductive health nurses

Specific post graduate sexual and reproductive health study is undertaken for a registered nurse to be qualified to practice as a sexual and reproductive health nurse.

The study requirements listed in part C of the Registered Nurses Extended Practice Authority are no longer available, meaning there is no ability for newly qualified sexual and reproductive health registered nurses to practice under part C of the Registered Nurses Extended Practice Authority.

Decisions regarding appropriate courses of study are determined locally, by either the employing Hospital and Health Service, a health service that provides services under a sexual and reproductive health program that was certified under the previous legislative framework until the date stated in the program to be the end of the certification, or a health service that holds a general approval given for a sexual and reproductive health program under the Act. Employing organisations are required to review the qualifications of an applicant nurse (such as the academic transcript and course modules), to ensure the program content includes knowledge of the appropriate use of medicines relevant to registered nurses working in a sexual and reproductive health program. The program content will need to align with the internal clinical guides of the employing organisation.

There are many courses available through creditable educational institutions, for example:

- Graduate Certificate in Sexual Health, The University of Melbourne;
- Graduate Certificate in Science in Medicine (HIV, STIs and Sexual Health), University of Sydney;
- Reproductive and Sexual Health – Clinical Accreditation Program: Family Planning Australia, affiliated with the University of Technology, Sydney;
- particular courses listed on the Queensland Health website; and
- particular courses through True Relationships and Reproductive Health.

Administration of Japanese encephalitis virus vaccines

The Japanese encephalitis virus is an arbovirus transmitted by mosquitoes. Arboviral diseases are caused by a group of viruses spread to people by the bite of infected arthropods (insects) such as mosquitoes and ticks. Japanese encephalitis is a vaccine-preventable disease caused by infection with the Japanese encephalitis virus.

The Japanese encephalitis virus has a fatality rate of up to 30 per cent. Up to 60 per cent of survivors experience neurological and neuropsychiatric outcomes. There is no cure once infected, so preventative measures are crucial. Previously, the virus has been isolated to Asia and the Torres Strait. The virus has recently been found in mainstream Australia. As of 26 September 2022, there were 40 human cases of Japanese encephalitis in Australia associated with the 2022 outbreak. Nationally, six people died from Japanese encephalitis during this outbreak.

On 4 March 2022, Australia's Acting Chief Medical Officer declared the virus outbreak a Communicable Disease Incident of National Significance. The recommended national response is adequate access to the Japanese encephalitis virus vaccine. There are currently 150 vaccine services able to provide the Japanese encephalitis virus vaccine in Queensland.

The Australian Immunisation Handbook recommends the vaccine for:

- routine vaccination of laboratory workers who may be exposed to the virus;
- routine vaccination of travellers spending one month or more in endemic areas during the Japanese encephalitis virus transmission season; and
- routine vaccination of people who live or work on the outer islands of the Torres Strait.

The Japanese encephalitis virus vaccine eligibility has been expanded to 23 local government authorities. Priority groups are spread geographically across the state, and include many rural and remote areas. Priority groups are encouraged to access Queensland Health immunisation clinics staffed by registered nurses who have authority under the Registered Nurses Extended Practice Authority to immunise. However, immunisation clinics are often not present in rural and remote areas. In rural and remote areas, many clinics are serviced by registered nurses rather than general practitioners.

Authorisation to provide immunisation services is restricted to registered nurses working under a Japanese encephalitis immunisation program approved by either the chief executive or the Public Health Medical Officer of the Torres and Cape Hospital and Health Service. This does not meet the geographical spread of the vaccine eligibility and coupled with the risk of outbreaks particularly in the wet season, is likely to increase community demand for the vaccine.

Victoria and New South Wales recently expanded the eligibility for the Japanese encephalitis virus vaccine after new cases were reported in December 2022 and January 2023.
A number of jurisdictions have the following requirements in place for registered nurses administering the Japanese encephalitis vaccine:

- New South Wales – an authority is issued for a person to supply and administer specified vaccines in accordance with any requirements set out in the authority. To administer the vaccine, an authorised nurse immuniser must have completed a course hosted by the

National Centre for Immunisation Research and Surveillance and meet requirements specified in the authority.

- South Australia – a registered health practitioner is authorised to administer the vaccine without a medical order. The vaccination must be administered in accordance with the Vaccine Administration Code, which requires a registered nurse to have completed an approved immunisation education program and administer the vaccine as part of a specified immunisation program.
- Western Australia – registered nurses administer Japanese encephalitis virus vaccines under a structured administration and supply arrangement issued by the Chief Executive Officer of the Health Department as part of a targeted public health response the virus.
- Tasmania – a medical order is required for a registered nurse to administer the vaccine. There is a legislative function available to enable registered nurses to administer vaccines without a medical order if circumstances require it, and this approval is given by the Director of Public Health.
- Australian Capital Territory – registered nurses require a prescription or medical order to administer the vaccine

Achievement of policy objectives

Naloxone

The Amendment Regulation provides a low-risk exemption for Schedule 3 naloxone when used for the treatment of opioid overdose. This ensures naloxone is easily available for supply to the at-risk population by organisations that interact with these persons or their carers, family, friends or peers. The controls of the *Therapeutic Goods Act 1989* (Cwlth) still apply to naloxone products, which must be registered on the Australian Register of Therapeutic Goods, supplied in suitable packaging and labelled appropriately. Pharmacies and wholesale suppliers can supply to these organisations, and the requirement to label the dose with a patient name is removed.

Authorised alternative suppliers participating in the THN program, such as needle and syringe providers and other alcohol and other drug services will no longer need to apply for a general approval to buy, possess and supply naloxone. However, they will still be required to comply with the THN program rules and will still be required to register with Queensland Health.

The Amendment Regulation amends the Medicines Regulation to:

- allow for access to naloxone without an approvals process by any organisation, including registered and unregistered healthcare workers, social services, QAS, police and justice services;
- allow both pharmacies and wholesale suppliers to supply naloxone to these organisations;
- remove the requirement for pharmacists to label with a patient's name; and
- exempt naloxone from offences for supply and administration and any other requirements allowing peer-to-peer distribution.

MDMA and Psilocybine

The Amendment Regulation ensures the Medicines Regulation reflects the additional controls on the possession or supply of medicines recommended in Appendix D of the Poisons Standard by including MDMA and psilocybine as restricted medicines in schedule 2 of the Medicines Regulation. The Amendment Regulation also enables psychiatrists to prescribe, administer, give a purchase order and possess MDMA in preparations for human therapeutic use for the treatment of PTSD and psilocybine in preparations for human therapeutic use for the treatment of treatment-resistant depression.

The specific health risks posed by these medicines are mitigated by restricting availability to prescribe through appropriately qualified specialist medical practitioners.

Updating controls for medicines in Appendix D of the Poisons Standard

The Amendment Regulation imposes controls on dealings with medicines in Appendix D of the Poisons Standard by including follitropin delta, sitaxentan and alefacept as restricted medicines in schedule 2 of the Medicines Regulation and enables:

- endocrinologists, gynaecologists and obstetricians to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess follitropin delta;
- cardiologists, respiratory and sleep medicine specialists, rheumatologists, and specialist physicians to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess sitaxentan; and
- dermatologists to prescribe, give a treatment dose, dispense, administer, give a purchase order and possess alefacept.

Storage Standard

Table 3 (Other acceptable S8 safes) of the Storage Standard is updated to enable the storage of S8 medicines in locked but unattended operational QAS vehicles by inserting a separate provision for ambulance officers. This will enable ambulance officers to continue to provide services to the community while adhering to the storage requirements for S8 medicines in operational QAS vehicles.

The Amendment Regulation updates the reference to the new version of the Storage Standard in schedule 1, part 2 of the Medicines Regulation.

Registered Nurses Extended Practice Authority

<u>Education requirements of sexual and reproductive health nurses</u>

The Amendment Regulation updates the reference to the new version of the Registered Nurses Extended Practice Authority in schedule 1, part 1 of the Medicines Regulation, which maintains the ability for sexual and reproductive health nurses that were previously authorised under grandfathered sexual and reproductive health courses to continue to practice under the Registered Nurses Extended Practice Authority.

The updated extended practice authority provides that a registered nurse may work under part C of the extended practice authority if they have completed a sexual health program of study

approved by the employing relevant health service or non-government organisation that holds a general approval to conduct a sexual and reproductive health program. The program must encompass, as a minimum, knowledge appropriate for the use of medicines relevant to registered nurses working in sexual and reproductive health programs.

Administration of Japanese encephalitis virus vaccines

The Amendment Regulation updates the reference to the new version of the Registered Nurses Extended Practice Authority in schedule 1, part 1 of the Medicines Regulation, which enables the provision of the Japanese encephalitis virus vaccine by registered nurses in accordance with the Australian Immunisation Handbook and the Queensland Government eligibility requirements. It removes the requirement for registered nurses to work under an immunisation program and means more access for consumers in rural and remote areas that are serviced by nurse-run clinics.

Registered nurses will be required to have successfully completed a Health Education Services Australia approved immunisation training program and be approved by their employing hospital and/or health service to administer Japanese encephalitis virus vaccines.

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 in relation to naloxone, MDMA, psilocybine, amendments to controls in Appendix D of the Poisons Standard and the Storage Standard.

Registered Nurses Extended Practice Authority

Education requirements of sexual and reproductive health nurses

An alternative way of achieving the policy objective is that Hospital and Health Services that employ sexual and reproductive health nurses who have completed appropriate extra training courses could credential the nurse under part A of the Registered Nurse Extended Practice Authority. The process of credentialing under part A requires the health service to define a credentialed scope of practice for each nurse using a credentialing process that meets the requirements of the current Health Service Directive: *Credentialing and defining the scope of clinical practice* or the current Australian Commission of Safety and Quality in Health Care *Standard for Credentialing and Defining the Scope of Clinical Practice*.

The credentialling framework under part A of the extended practice authority creates an administrative and bureaucratic burden on the health service. It also increases risk and regulatory issues due to inconsistency between the credentialling of sexual and reproductive health nurses across the state by different health services.

Administration of Japanese encephalitis virus vaccines

An alternative way of achieving the policy objective is an authorisation scheme. An ongoing authorisation scheme would require individual Hospital and Health Services and non-governmental organisations to produce Standing Orders. Standing Orders for organisations that do not meet the definition of a *relevant institution* under the Medicines Regulation would require approval from the Director-General of Queensland Health. While this option provides an immediate solution by improving access to the Japanese encephalitis virus vaccine, it is administratively burdensome and is not an efficient long-term solution.

Benefits and costs of implementation

The Amendment Regulation does not impose significant costs on persons or organisations. The cost of implementing the amendments will be met within existing budget allocations. The amendments do not impose any new or increased fees.

Naloxone

The proposed amendments for naloxone facilitate access to this life-saving medicine. Removing regulatory barriers to the supply and use of naloxone will allow for the widest and most cost-effective uptake of the national THN program, providing access to naloxone where it is needed. Evaluation of the THN pilot program across three states found that free access to naloxone saved an estimated three lives per day.

MDMA and Psilocybine

The proposed amendments are an opportunity to maintain a uniform national approach to medicines as recommended by the Galbally Review undertaken by the Council of Australian Governments in 2000.

The proposed amendments clarify that the prescription of MDMA and psilocybine is restricted to approved psychiatrists and for the treatment of specified conditions. This will maintain public safety by ensuring that only appropriately qualified prescribers are able to prescribe MDMA and psilocybine. Psychiatrists are required to apply for Authorised Prescriber status and obtain approval from a Human Research Ethics Committee.

Updating controls for other medicines in Appendix D of the Poisons Standard

The proposed amendments clarify that the prescription of the S4 medicines follitropin delta, sitaxentan and alefacept are restricted to approved clinicians. The proposed amendments remove the potential for stakeholders to interpret the Poisons Standard to mean that all prescribers have authority to prescribe the medicines.

Storage Standard

Access to healthcare in rural and remote areas can be challenging due to geographical location, isolation and distances between healthcare centres. QAS is critical in providing primary health care and connecting the community with other health services such as aeromedical transport in time critical cases.

The proposed amendment clarifies the requirements for ambulance officers, reduces the burden and minimises potential delays associated with having to remove and return S8 medicines from the QAS vehicle while it is operational. The amendments support the rapid responses required by ambulance officers to serve the community and provide quality patient-centred care, while promoting the safe storage of S8 medicines.

Registered Nurses Extended Practice Authority

Education requirements of sexual and reproductive health nurses

The proposed amendments reduce the administrative burden on health services by clarifying the suitability of qualified sexual and reproductive health nurses and expediting the employment of appropriately trained staff.

Registered nurses who choose to complete a sexual and reproductive health course will be required to self-fund the education and any associated expenses. The employing health service will be required to review and approve the course of study undertaken by the registered nurse.

Administration of Japanese encephalitis virus vaccines

The proposed amendments increase the availability of healthcare practitioners authorised and trained to administer the Japanese encephalitis virus vaccine. This improves the ability to scale a vaccination program based on need and reduce the number of cases through preventative vaccination of people in high-risk categories. Increased Japanese encephalitis virus vaccine services provided through Queensland Health would need to consider staff and resource implications.

The training requirements are consistent with other types of vaccination training. Registered nurses who choose to complete an accredited Health Education Services Australia immunisation program course will be required to self-fund the education and associated expenses.

Consistency with fundamental legislative principles

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

Institution of Parliament

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

Section 232 (making extended practice authorities) of the Act empowers the chief executive or their 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.

Section 233 (making departmental standards) of the Act empowers the chief executive or their delegate to make a departmental 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 provide task-specific guidance for professionals 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.

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. A departmental standard provides task-specific guidance for professionals and industry about interacting 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, to align with best clinical 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. 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.

Departmental standards provide guidance, allow flexibility of activities and apply to individuals and entities. The standards are monitored and updated when necessary, align with industry best practice and are published on the Queensland Health website. When making or amending a standard, relevant individuals and organisations with expertise in, or experience of, the matters under consideration will be consulted.

Departmental standards are updated regularly, with consideration given to setting the minimum safety and accountability criteria that must be met in relation to particular activities. Consideration is given to changes in technology, changes to clinical treatment with medicines, for example monitored medicines, and changes at a national level in relation to the monitored medicine database systems. Departmental standards are outcome focused and list options to achieve the desired outcomes, which would not be suitable for inclusion in a prescriptive requirement in a regulation. Schedule 1, part 2 (Approved departmental standards) of the Medicines Regulation details the name of each departmental standard made by the chief executive and its version number. The regulation is updated to reflect the name and new version

number of the departmental standard each time a new version is made. A copy of the updated departmental standard is tabled as extrinsic material each time the regulation is amended.

Including a list of extended practice authorities and departmental standards in the schedule of the Medicines Regulation creates certainty for the relevant professions and the public about the status of extended practice authorities and departmental standards published on the Queensland Health website and the date these took effect.

It is considered the rigour surrounding the development of extended practice authorities and departmental standards, and the level of parliamentary oversight afforded by the requirement that extended practice authorities and departmental standards must be approved by regulation justifies the need to sub-delegate by referring to external documents in the Medicines Regulation. Queensland Health has made a commitment to table any extrinsic material referenced in legislation in the Legislative Assembly. Tabling the updated extended practice authority or departmental standard provides the Legislative Assembly with an opportunity to consider the extended practice authority or departmental standard and any conditions imposed under it when scrutinising the Regulation.

Consultation

Naloxone

A consultation paper on the proposed naloxone amendments was disseminated to key stakeholders through various networks across the health system. Responses to consultation were received from stakeholders including the Australian Medical Association Queensland (AMAQ), Pharmaceutical Society of Australia – Queensland Branch (PSAQ), Pharmacy Guild of Australia (Queensland Branch) (Pharmacy Guild), Queensland Injectors Health Network, Queensland Network of Alcohol and Other Drug Agencies, Queensland Nurses and Midwives' Union (QNMU), Queensland Police Service and the Royal Australian and New Zealand College of Psychiatrists (Queensland Branch).

Most stakeholders support the amendments to facilitate ease of access to naloxone.

Initial feedback from the Pharmacy Guild and AMAQ was not supportive of the amendments. Further consultation occurred with these stakeholders in the form of meetings and correspondence. As a result of the further consultation, both stakeholders are supportive of the amendments.

The AMAQ noted that data from the Commonwealth trial that saved three lives per day is a compelling argument to support the proposal. The AMAQ indicated a preference for labelling the naloxone with a patient's name as a S3 medicine but acknowledged that that is not possible in every scenario where a person needs access to naloxone (such as an overdose).

The Pharmacy Guild indicated a preference for keeping a record of the doses dispensed to each patient. It did not support community pharmacies supplying naloxone to Authorised Approved Suppliers, such as needle and syringe programs, alcohol and other drug treatment centres and outreach services. The Amendment Regulation empowers pharmacies to supply naloxone to Authorised Approved Suppliers but does not mandate that supply. It is not a requirement for community pharmacies to supply Schedule 3 naloxone to Authorised Approved Suppliers under the THN program.

MDMA, psilocybine, and updating the controls for other medicines in Appendix D of the Poisons Standard

The Therapeutic Goods Administration consulted with its Advisory Committee in relation to updating the controls for medicines in Appendix D of the Poisons Standard. The Advisory Committee advised the Commonwealth Department of Health that there was support for MDMA and psilocybine to be down-scheduled from a schedule 9 to a schedule 8 medicine.

The Advisory Committee consists of appointed members selected from employees of a broad range of government agencies, academic institutions, healthcare, consumer and industry groups, and the public and nominated members who are nominated by each state and territory on the basis of their knowledge and experience in regulation of scheduled medicines and poisons and are independent and not as a representative of government. States and Territories are required to update their legislation to reflect the scheduling change, as the Poisons Standard is not automatically adopted by State and Territory legislative schemes.

Registered Nurses Extended Practice Authority

Education requirements of sexual and reproductive health nurses

The AMAQ, Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine, Health Consumers Queensland, QNMU, Royal Australian College of General Practitioners (RACGP), Royal Flying Doctors Service (Queensland) (RFDS), and TRUE Relationships and Reproductive Health were consulted on the amendments relating to the accreditation of sexual and reproductive health nurses.

TRUE Relationships and Reproductive Health support the amendments. No response was received from Health Consumers Queensland, RFDS, RACGP and the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine. QNMU support the amendment but sought clarification on the decision-making framework to be used by chief executives to determine the appropriateness of a potential credentialing course, and how Queensland Health will implement safeguards to ensure consistency. QNMU would like Queensland Health to consider the centralisation of the credentialling process and an external review process. Queensland Health is considering the standardisation of credentialing processes rather than centralisation. Credentialing is the responsibility of individual Hospital and Health Services.

The AMAQ advised that while it supported temporary amendments, it did not consider the proposed changes were clinically urgent. Therefore, the AMAQ did not support an immediate and permanent amendment of the extended practice authority. Queensland Health notes that there is a shortage of specialists, both medical and nurse practitioners, who can carry out sexual and reproductive health services, particularly in populations in rural and regional locations. Queensland Health considers the changes to the extended practice authority are appropriate as they will increase the availability of healthcare practitioners who are authorised and trained to deliver sexual and reproductive health services.

Administration of Japanese encephalitis virus vaccines

The AMAQ, Australian College of Nursing, Health Consumers Queensland, Pharmacy Guild, PSAQ, QNMU, RACGP and RFDS were consulted on the amendments relating to the administration of the Japanese encephalitis virus vaccine by registered nurses.

The Australian College of Nursing, Pharmacy Guild, PSAQ and QNMU support the amendments. The Australian College of Nursing noted the current course does not specifically cover the Japanese encephalitis virus vaccine. No response was received from Health Consumers Queensland, RFDS and RACGP.

The AMAQ advised that while it supported temporary amendments, it did not consider the proposed changes were clinically urgent. Therefore, the AMAQ did not support an immediate and permanent amendment of the extended practice authority. Vaccination programs have been identified as a key part of the national approach to Japanese encephalitis virus, particularly for identified priority groups. Queensland Health considers it appropriate to support broader access to the vaccine by enabling registered nurses working under the extended practice authority to administer the Japanese encephalitis virus vaccine across Queensland, rather than just in specified areas.

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 (No. 2) 2023*.

Commencement

Clause 2 provides for the commencement of the regulation on 1 July 2023.

Regulation amended

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

Insertion of new s 6A

Clause 4 inserts new section 6A (Exemption for S3 naloxone treatment programs —Act, s 7) which creates an exemption for naloxone when used for opioid overdose as part of a naloxone treatment program.

Clause 4 exempts naloxone used for opioid overdose from the operation of section 7 of the *Medicines and Poisons Act 2021*. The amendment supports the take home naloxone program by facilitating easier access to S3 naloxone, provided the person performing the following functions is appropriately qualified and gives instructions about recognising signs and symptoms of suspected opioid overdose and how to administer the S3 naloxone:

- wholesale supply of stock of S3 naloxone for a naloxone treatment program;
- giving one or more doses of S3 naloxone obtained under a naloxone treatment program;
- administering S3 naloxone obtained under a naloxone treatment program.

Amendment of s 161 (Selling S3 medicine with instructions for use)

Clause 5 amends section 161(3) by replacing the note from 'naloxone to treat opioid overdose' with 'an adrenaline (epinephrine) autoinjector to treat an anaphylactic reaction'. This amendment provides a clearer example of an S3 medicine that a pharmacist must give instructions in relation to the appropriate way to use the medicine.

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

Clause 6 amends schedule 1, parts 1 and 2, by replacing the version numbers for the registered nurses extended practice authority and Secure storage of S8 medicines departmental standard with new version numbers.

Amendment of sch 2 (Categories of medicines)

Clause 7 amends schedule 2, part 1, division 1 to insert alefacept, follitropin delta, MDMA, psilocybine and sitaxentan.

Amendment of sch 6 (Medical practitioners and assistants)

Clause 8 amends schedule 6 to clarify the dealings authorised by particular practitioners, such as cardiologists, dermatologists, endocrinologists, gynaecologists and obstetricians, psychiatrists, respiratory and sleep specialists, rheumatologists, and specialist physicians.

Clause 8(1) amends schedule 6, section 20, items 1 to 4, by omitting 'macitentan or riociguat' and inserting 'macitentan, riociguat or sitaxentan'.

Clause 8(2) amends schedule 6, section 22, items 1 to 4, by inserting 'alefacept' before 'bexarotene'.

Clause 8(3) amends schedule 6, section 26, items 1 to 4, by inserting 'follitropin delta' before 'luteinising hormone'.

Clause 8(4) amends schedule 6, section 30, items 1 to 4, by inserting 'follitropin delta' before 'luteinising hormone'.

Clause 8(5) omits schedule 6, section 50, items 1, 4 and 5, 'clozapine', and inserts 'clozapine, MDMA or psilocybine'.

Clause 8(6) amends schedule 6, section 50, item 6 to omit 'clozapine, amfetamine or methylphenidate' and insert 'a medicine mentioned in this column'.

Clause 8(7) amends schedule 6, section 52, items 1 to 4, by omitting 'riociguat' and inserting 'riociguat, sitaxentan'.

Clause 8(8) amends schedule 6, section 54, items 1 to 4, by omitting 'riociguat' and inserting 'riociguat, sitaxentan'.

Clause 8(9) amends schedule 6, section 58, items 1 to 4, before 'teriparatide' and inserting 'sitaxentan'.

Amendment of sch 12 (Other health practitioners)

Clause 9 amends schedule 12, section 12 by omitting '*Public Service Act 2008*, section 24' and inserting '*Public Sector Act 2022*, section 276'.

Amendment of sch 22 (Dictionary)

Clause 10 inserts a new definition for MDMA to mean the substance N, α-dimethyl-3,4-(methylenedioxy)phenylethylamine.