Health (Drugs and Poisons) Amendment Regulation (No. 2) 2020

Explanatory notes for SL 2020 No. 90

made under the

Health Act 1937

General Outline

Short title

Health (Drugs and Poisons) Amendment Regulation (No. 2) 2020

Authorising law

Section 180 of the *Health Act 1937*

Policy objectives and the reasons for them

On International Women's Day 2020, the Premier and Minister for Trade announced the Government would make the oral hormonal contraceptive pill and urinary tract infection (UTI) medications more easily accessible for Queensland women over the counter at pharmacies.

The *Health (Drugs and Poisons) Amendment Regulation (No. 2) 2020* (Amendment Regulation) implements the Premier and Minister for Trade's commitment by amending the *Health (Drugs and Poisons) Regulation 1996* (HDPR) to:

- enable a pharmacist to supply an oral hormonal contraceptive (OHC) to women who are currently being treated, without a prescription; and
- include an authority for pharmacists to sell a restricted drug under a Drug Therapy Protocol (DTP).

The Amendment Regulation also amends the HDPR to reduce the regulatory burden on medical practitioners, pharmacists and community by:

- removing the requirement for non-specialist medical practitioners to obtain a state-based approval to prescribe controlled drug medicinal cannabis products;
- enabling certain staff of Queensland pathology providers and the national blood product supplier, Australian Red Cross LifeBlood, as categories of persons exempted from requiring endorsements to carry out certain activities with restricted drugs that are immunoglobulin blood products listed on the National Product Price List for blood and blood products; and
- enabling the chief executive to exempt a package from the labelling requirements in part 2 of the Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard).

Pharmacist supply of oral hormonal contraceptive

In October 2018, the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (the Committee) recommended 'that the Department of Health develop options to provide low-risk emergency and repeat prescriptions (for example, repeats of the contraceptive pill) through pharmacies subject to a risk-minimisation framework'. This recommendation formed part of the *Report on the inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland* (Report No. 12, 56th Parliament).

On 8 March 2020, the Premier and Minister for Trade announced the Government would make legislative changes which would allow women to obtain an interim supply if their prescription for the OHC had expired.

Under schedule 1 of the *National Health (Continued Dispensing) Determination 2012* (Cth) (Continued Dispensing Determination) a pharmacist can continue the supply of a medicine in accordance with the criteria set out in the determination. The Continued Dispensing Determination allows the supply of a single full pack (four months' supply) of an eligible medicine (currently limited to statins and OHCs), subsidised under the Pharmaceutical Benefits Scheme (PBS) once in any 12-month period.

The existing supply provisions for OHCs without a prescription are inequitable and impractical. Women who need an urgent supply of an OHC can be given a four-month supply if they are taking a brand that is subsidised under the PBS. However, for the approximately 40 per cent of women who are taking a brand that is not subsidised under the PBS, the legislation limits supply to three tablets only. The provision of three tablets is impractical because OHCs are supplied in calendar packs where each foil strip is organised in the sequence necessary to suppress ovulation to promote their safe and proper use. Depending on the brand, there may be up to four different tablets in a 28-day foil strip of OHC, each of which must be taken in the correct order to provide effective contraception. The pharmacist would need to identify the necessary tablets that correspond to the stage of the woman's menstrual cycle. Also, in some rural areas with limited access to prescribers, three days' supply may not give enough time for the patient to obtain a prescription for the medicine.

Pharmacist urinary tract infection trial

On 8 March 2020, the Premier and Minister for Trade announced that the Government had engaged a consortium led by the Queensland University of Technology (QUT) to manage the development and implementation of a state-wide trial of the management of UTIs by pharmacists. The trial, which will start mid-2020 and run until 2023, involves a pharmacist selling a course of one of three antibacterial drugs to a consumer, if appropriate according to the trial protocol, without a prescription. The pharmacist would select the most appropriate treatment after talking to the consumer about their medical history, including history of antibiotic use, medical conditions and other medicines. Participating pharmacists will be required to successfully complete the online training program developed by QUT before participating in the trial and be practising at a site that is enrolled in the trial.

UTIs are very common in women, with one in three women experiencing a UTI in their lifetime. UTIs are considered uncomplicated when they occur in non-pregnant, pre-menopausal women between the ages of 18 and 65 with no relevant underlying conditions or urinary tract abnormalities.

Currently, the HDPR does not allow a pharmacist to sell these antibacterial drugs to a person without a prescription. Typically, restricted drugs can only be dispensed by a pharmacist with a valid prescription. The ability for pharmacists to provide this acute primary care helps to ensure Queenslanders have access to timely treatment of uncomplicated UTIs and continuity of care.

Prescribing medicinal cannabis

Access to, and prescribing of, medicinal cannabis to patients in Queensland is regulated by both the Australian Government and State Government. Most medicinal cannabis products are unregistered medicines in Australia and only available for access using special access schemes administered by the Therapeutic Goods Administration (TGA). Controlled drug medicinal cannabis products are listed in Appendix D of the Poisons Standard, meaning that products (including registered products) are available only from, or on the prescription or order of, an authorised medical practitioner. State and Territory governments may place additional controls in defining who is an authorised medical practitioner and the conditions that may be treated.

Section 78A of the HDPR requires Queensland Health to approve applications by non-specialist medical practitioners to prescribe controlled drug medicinal cannabis products. Only specialist medical practitioners hold an as-of-right authority to prescribe without a state-based approval. This currently means that non-specialist medical practitioners must obtain dual approvals from both the Commonwealth and the State.

Streamlined blood supply arrangements

In 2003, the National Blood Supply Arrangements were established through the National Blood Agreement, signed by all health ministers. The National Blood Agreement facilitates the Commonwealth, States and Territories adopting a coordinated approach to the funding, administration and management of the blood sector, policy setting and governance arrangements. The National Blood Supply Arrangements is the national scheme for the subsidised supply of blood products into the Australian health sector, as established by the National Blood Agreement and overseen by the National Blood Authority.

To enable better management and visibility of the national blood supply, the National Blood Authority introduced BloodNet as the national online ordering system used by pathology laboratories for managing and ordering of blood and blood products (including immunoglobulins) and to ensure sufficient blood stock is available for patient needs.

In 2016, the National Blood Authority introduced the Blood System for Tracking Authorisation and Reviews (BloodSTAR), a national online system developed on behalf of all Australian governments to efficiently facilitate authorisation for access to, and management of, funded immunoglobulins for treatment of conditions identified in the *Criteria for clinical use of Immunoglobulin in Australia*.

Under the National Blood Supply Arrangements, eligible patients can access immunoglobulin products at no cost, however the product must be obtained via Australian Red Cross LifeBlood, as the authoriser, through BloodSTAR and BloodNet.

Supplies of restricted drugs that are immunoglobulin blood products are currently being double handled by pathology laboratories and pharmacies in Queensland hospitals due to a lack of clarity about how the National Blood Supply Arrangements interact with the HDPR. The double handling of these products ties up valuable pharmacy resources, creates longer wait times for treating clinicians and patients and may impact on a hospital's ability to appropriately manage immunoglobulin inventory.

Double handling of the dealings with these blood products also increases the risk of pandemic coronavirus transmission to pathology staff and pharmacy staff, as well as immunosuppressed patients who receive double handled product. In addition, double handling of these blood products is an inefficient use of staff resources and may cause delays in the supply chain for patients getting treatment.

Labelling exemptions

Section 131I of the *Health Act 1937* requires that every package containing a drug or poison for sale must include a label which complies with requirements prescribed by regulations. Also, a person must not sell a package containing a drug or poison unless the package includes the required label.

Section 11 of the HDPR prescribes that a package containing a controlled drug, restricted drug or a poison must include a label that complies with part 2 of the Poisons Standard.

Part 2 of the Poisons Standard details the labelling requirements and types of containers needed for various scheduled substances. One of the purposes of the Poisons Standard is for the provisions for labelling and packaging to be adopted for use in each jurisdiction of Australia to promote uniformity across Australia.

Paragraph 1.5.5 in part 2 of the Poisons Standard, allows for an appropriate authority to grant exemptions from labelling requirements in certain circumstances. Although the chief executive of Queensland Health has been named as an appropriate authority in Queensland to grant an exemption to labelling requirements, there is no statutory provision in either the Health Act or the HDPR, which provides for such an exemption to be made, or for an exemption granted in another jurisdiction to be legally recognised. Consequently, in Queensland a drug or poison must be labelled strictly in accordance with the Poisons Standard in order to comply with the HDPR and to satisfy the Health Act.

Achievement of policy objectives

Pharmacist supply of oral hormonal contraceptive

The Amendment Regulation inserts new section 194A into the HDPR to allow a pharmacist to supply the smallest available manufacturer's pack of a PBS subsidised and non-PBS subsidised OHC to a patient who presents to a pharmacy without a prescription.

Under the new provision, pharmacists are required to take reasonable steps to satisfy themselves that a patient has recently been reviewed by a prescriber, for example, by sighting an expired prescription or phoning the last pharmacy who supplied the medicine on a prescription.

The pack size varies between brands of OHC from one month to four-months, with some brands available in more than one pack size. The pharmacist must supply the smallest manufacturer's pack of the requested OHC that they keep in stock. The maximum quantity that could be given is four-months' supply, equivalent to the maximum quantity that is permitted to be supplied under the Continued Dispensing Determination.

The pharmacist is required to appropriately label the supplied medicine and keep records that includes the evidence they obtained to satisfy themselves that the patient has been prescribed the OHC, that their therapy is stable, and they have recently had a clinical review by a prescriber, which are equivalent to the requirements under the Continued Dispensing Determination. It is expected that pharmacists will follow the Pharmaceutical Society of Australia "*Guidelines for the continued dispensing for eligible prescribed medicines by pharmacists*".

Pharmacist urinary tract infection trial

The Amendment Regulation amends section 171 of the HDPR to include an authority for pharmacists to supply a restricted drug under a new DTP. The DTP will be called the Drug Therapy Protocol – Pharmacist UTI Trial (UTI DTP) and will allow patients to be provided with timely treatment for uncomplicated UTIs directly from a pharmacist without consulting a medical practitioner.

The UTI DTP will give effect to the requirements of the trial and include the requisite training, model of care and antibacterial drugs approved for use during the trial.

Prescribing medicinal cannabis

The Amendment Regulation amends section 78A of the HDPR to remove the requirement for non-specialist medical practitioners to obtain a state-based approval to prescribe controlled drug medicinal cannabis products.

Medical practitioners will continue to require an approval from the TGA to prescribe unapproved therapeutic goods (including medicinal cannabis) for patients. The amended provision in the HDPR will remove the dual approval process for medicinal cannabis in Queensland, improving access for patients, reducing the regulatory burden on medical practitioners and the administrative burden on the Department. Removing duplication and streamlining access is a key driver in facilitating access to medicinal cannabis.

Streamlined blood supply arrangements

The Amendment Regulation amends section 183 of the HDPR to streamline the supply of restricted drugs that are immunoglobulin blood products to patients. Pathology staff working under the National Blood Supply Arrangements need to be able to provide prescription only blood products directly to doctors or nurses to supply or administer to patients without needing to go through the pharmacy.

The amendment will provide that certain staff of Queensland pathology providers and the national blood product supplier, Australian Red Cross LifeBlood, be included as categories of persons exempted from requiring endorsements to carry out certain activities with restricted drugs that are immunoglobulin blood products listed on the National Price List for blood and blood products, when these activities are undertaken in accordance with the National Blood Supply Arrangements.

The exemption to possess and use restricted drugs that are immunoglobulin blood products will extend, to persons engaged to transport and deliver restricted drugs that are immunoglobulin blood products under the National Blood Supply Arrangements, to the extent necessary to facilitate the transportation and delivery of these products.

Queensland pathology providers are entities which provide pathology services to Queensland healthcare organisations under the National Blood Supply Arrangements. Current providers include Pathology Queensland, QML Pathology and Sullivan Nicolaides Pathology. Certain staff for pathology providers, primarily scientists, are required to undertake certain dealings, such as wholesaling, supplying, obtaining, possessing and issuing, with immunoglobulins under the National Blood Supply Arrangements. At Australian Red Cross LifeBlood, a range of staff members undertake similar dealings in carrying out their duties under the National Blood Supply Arrangements. Couriers are engaged by manufacturers, Queensland pathology providers and Australian Red Cross Lifeblood to transport and deliver blood and blood products, including immunoglobulin products, under the National Blood Supply Arrangements. These individuals are therefore required to possess restricted drugs that are immunoglobulin blood products for the purposes of transporting and delivering them to the ordering pathology provider or health care setting.

The Amendment Regulation also amends section 200 of the HDPR to provide that ordering restricted drugs that are immunoglobulin blood products through the National Blood Supply Arrangements' blood product ordering and authorisation systems (BloodNet or BloodSTAR) satisfies the purchase order requirements within that section. Section 200 requires restricted drugs to be obtained via a purchase order.

Labelling exemptions

Medicines that do not meet the labelling requirements in part 2 of the Poisons Standard are not permitted to be supplied in Queensland. Examples of when a product may not meet the specific requirements of the Poisons Standard include if a medicine is rescheduled or if stock is obtained from overseas such as the UK market, where it was labelled in accordance with local requirements. Time limited exemptions are granted by the TGA and other States and Territories. However, there is no power to grant an exemption in Queensland. Without the power to provide an exemption, as intended by part 2 of the Poisons Standard, access to some medicines in Queensland can be delayed until new stock with compliant labels are made, despite being available in other States and Territories through exemption.

The Amendment Regulation amends section 11 of the HDPR to provide that the chief executive may certify an exemption to the labelling requirements in part 2 of the Poisons Standard. The chief executive must be reasonably satisfied that the exemption is unlikely to adversely affect public safety, having regard to the nature of the drug or poison and the purpose for which it is to be used. The authority will be similar to the chief executive's power to grant an exemption to the packaging requirements of part 2 of the Poisons Standard. The authority is to extend to controlled drugs, restricted drugs and Schedule 2 and 3 poisons, as labelling exemptions are not needed as urgently for S7 poisons. Packaging provisions in section 10 will continue to apply to controlled drugs, restricted drugs or poisons.

The Amendment Regulation will also allow the chief executive to certify an exemption in force under a law of the Commonwealth, or of another State or a Territory, corresponding to section 11. Any labelling exemption certified by the chief executive is to be published on the Queensland Health website.

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

Pharmacist supply of oral hormonal contraceptive

This amendment will improve both the timeliness of care delivery and access to care, resulting in fewer costs from delays, improved health outcomes and greater public satisfaction with the care provided by pharmacists.

Allowing pharmacists to supply a standard manufacturer's pack of PBS and non-PBS subsidised OHCs will ensure that access is equitable for all women. It will also benefit pharmacy businesses as they won't have to break packets of medicines which usually leads to significant medicine wastage.

This amendment addresses concerns from the medical fraternity about the risks associated with delaying clinical review of patients by requiring that pharmacists take reasonable steps to determine that therapy is stable and limiting repeated supply of non-PBS OHCs without a prescription from a particular pharmacy. This limit is similar to the limits under the Continued Dispensing Determination.

The amendment promotes national consistency by better aligning Queensland with most other Australian States and Territories.

Pharmacist urinary tract infection trial

This amendment will allow pharmacists that have successfully completed the required training and signed up to the UTI trial with QUT to participate without the need to apply to Queensland Health for an individual approval. This will enable timelier uptake and provision of treatment and will enable a more effective use of workforce, freeing up medical practitioners for other work. Patients will also benefit by having more timely access to treatment for uncomplicated UTIs directly from a pharmacist without consulting a medical practitioner.

Prescribing medicinal cannabis

This amendment provides Queensland doctors and patients with a more streamlined process to access medicinal cannabis in Australia, while providing a regulatory framework that is in line with other controlled drugs.

Queensland Health will retain the ability to monitor the prescribing and dispensing of controlled drug medicinal cannabis using the current systems used to monitor other controlled drugs. Doctors that prescribe controlled drug medicinal cannabis for drug dependent persons will still require an approval under section 122 of the HDPR.

Streamlined blood supply arrangements

Streamlining the supply of immunoglobulin products to clinical areas will reduce the unnecessary double-handling of the products, thereby reducing risk of pandemic coronavirus transmission to immunosuppressed patients who are receiving the double handled product. It also means that staff in these areas are at reduced risk of coronavirus transmission. The current double handling of these blood products is an inefficient use of staff resources and may cause delays in the supply chain for patients getting treatment.

If double handing continues, there may be an impact on a pathology laboratory's ability to effectively anticipate immunoglobulin stock requirements and it increases the risk of wastage of this high cost product. This could result in patients being unable to access immunoglobulin products when needed, which could subsequently require immunosuppressed patients to re-present to the clinic or hospital pharmacy, thereby increasing their risk of COVID-19 transmission. Streamlining the supply process will ensure all blood and blood product inventory management is occurring out of the pathology laboratory, reducing the risk of wastage and short supply.

Labelling exemptions

This proposal will facilitate the granting of exemptions to the labelling requirements to improve deployment of medicines that come into short supply and are sourced from overseas. For example, a COVID-19 vaccine or medicines used to ventilate patients in intensive care may be imported, but as they do not meet the labelling requirements cannot be supplied to health professionals to be administered, impacting greatly on treatment options available to clinicians to treat the community effectively.

Consistency with fundamental legislative principles

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

Delegation of administrative power only in appropriate cases and to appropriate persons

<u>Drug Therapy Protocol</u>

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

Clause 5 (Amendment of s 171 (Pharmacists)) of the Amendment Regulation provides that a pharmacist can supply a restricted drug to a person under the Pharmacist UTI Trial Drug Therapy Protocol.

The Drug Therapy Protocol takes into consideration the healthcare needs of specific patient populations, how care can be provided in a timely and safe manner, requirements for medical advice or referral to higher levels of care, and specific training the pharmacist must have completed to act under the Drug Therapy Protocol. It is considered that the technical clinical nature of the Drug Therapy Protocol, justifies the need to sub-delegate by referring to an external document in the HDPR.

Prescribing requirements by reference to an external document may be seen to breach section 4(5)(e) of the Legislative Standards Act. A Drug Therapy Protocol is a document certified by the chief executive of Queensland Health that sets out matters of technical detail for the possession, administration and supply of substances. The Pharmacist UTI Trial Drug Therapy Protocol includes the conditions for treatment, process for drug selection, circumstances for referral to a medical practitioner, as well as the specific drugs and form of drugs to be supplied. The Drug Therapy Protocol is monitored and updated when necessary, aligns with the trial and clinical best practice, is published on the Queensland Health website (www.health.qld.gov.au) and a copy will be tabled as extrinsic material.

Poisons Standard

Clause 3 (Replacement of s 11 (Labelling of controlled or restricted drugs or poisons—Act, s 131I)) of the Amendment Regulation inserts new section 11. Section 11(1) provides that for section 131I of the Health Act, a package containing a controlled drug, restricted drug or a poison must have a label that complies with part 2 of the current Poisons Standard. *Current Poisons Standard* has the meaning given by section 52A of the *Therapeutic Goods Act 1989* (Cth). Section 52A defines the current Poisons Standard as the *Standard for the Uniform Scheduling of Drugs and Poisons* published by the Australian Health Ministers' Advisory Council and updates to that document published by the Commonwealth.

This provision may be seen to breach the principle that subordinate legislation should allow the subdelegation of a power delegated by an Act only in appropriate cases and if authorised by an Act (section 4(5)(e) of the Legislative Standards Act). Adopting the current version of the Poisons Standard will ensure key regulatory controls governing the availability and accessibility of drugs and poisons in Queensland will continue to be consistent with those in other States and Territories. Reference to the Poisons Standard provides national consistency. There are representative from each State on the scheduling committee to ensure the Poisons Standard is applicable in all jurisdictions. Additionally, the committee meets three times per year to discuss updates to be made to the Poisons Standard.

By referencing the Poisons Standard, which is made under section 52D of the *Therapeutic Goods Act 1989* (Cth), as opposed to stating the requirements directly in the Regulation, ensures the Regulation will always be consistent with the Poisons Standard and relevant to national requirements. Each labelling exemption must be published on the Queensland Health website (www.health.qld.gov.au) and specify the alternative way certified under section 11(3), the day the certification takes effect and the period for which the certification has effect.

Penalties of appropriate level

Fundamental legislative principles recognise that a penalty should be proportionate to the offence, and penalties within a legislative instrument should be consistent with each other.

Clause 8(4) inserts new section 194(5) to provide that it is an offence if a pharmacist fails to keep the record for at least two years after the date a restricted drug is sold by a pharmacist. The offence carries a maximum penalty of 20 penalty units. The maximum penalty of 20 penalty units is equivalent to other offences under the HDPR, including the recording of sales of S3 pseudoephedrine in section 258A. The penalty has been reviewed and is proportionate to the seriousness of the offence and is justified due to the need to ensure accurate records for the sale of restricted drugs are kept.

Clause 9 inserts new section 194A (Sale of oral hormonal contraceptives by pharmacist for immediate need). New section 194A(2) provides that it is an offence for a pharmacist to sell the person more than a manufacturer's pack of the restricted drug. New section 194A(3) provides that it is an offence for a pharmacist to sell the restricted drug in a container that does not have a securely attached label with specific information written on it. New section 194A(4) provides that it is an offence for a pharmacist selling a restricted drug under this section to fail to make a record of the sale. These offences carry a maximum penalty of 40 penalty units.

The maximum penalty of 40 penalty units, is equivalent to other offences under the HDPR. These offences include sections 194, 198, 199 and 277. The above penalty has been reviewed and is proportionate to the seriousness of the offence and is justified due to the need to limit access to restricted drugs.

Consultation

Pharmacist supply of oral hormonal contraceptive

On 3 May 2018, the Legislative Assembly referred to the Committee, an inquiry into the establishment of a pharmacy council and the transfer of pharmacy ownership in Queensland. The Committee process involved broad consultation with relevant stakeholders. The Committee received submissions from pharmacists, University of Queensland, QUT School of Pharmacy, pharmacy peak bodies and professional organisations, including Pharmacy Guild of Australia (Queensland Branch) and Pharmaceutical Society of Australia and professional bodies representing medical practitioners, including Australian Medical Association Queensland (AMAQ), Royal Australian College of General Practitioners, Australian College of Rural and Remote Medicine, Rural Doctors Association of Queensland and other non-government organisations including Diabetes Queensland, Asthma Australia and Health Consumers Queensland.

The Pharmaceutical Society of Australia and Pharmacy Guild of Australia are supportive of the proposal.

The AMAQ did not support any expansion of a pharmacist's scope of practice in their submission to the Committee, highlighting the missed opportunity for general practitioners to add value during an appointment for a repeat prescription and the potential conflict of interest issues when the pharmacist is both the prescriber and dispenser.

As outlined above, the Amendment Regulation addresses the concerns of medical practitioners about the risks associated with delaying clinical review of patients by requiring that pharmacists take reasonable steps to determine that therapy is stable and limiting repeated supply of non-PBS OHCs without a prescription from a particular pharmacy. This limit is similar to the limits under the Continued Dispensing Determination.

Pharmacist urinary tract infection trial

In Report No. 12, 56th Parliament – *Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland*, the Committee made 11 recommendations relating to pharmacist and pharmacy assistant scope of practice; the establishment of a pharmacy advisory council; the regulation of pharmacy ownership in Queensland; and communication to consumers about services offered by pharmacies.

On 16 April 2019, the Government accepted the Committee's 11 recommendations in full or in principle. In the response to recommendation 2, which states that Queensland Health develop options to provide low-risk emergency and repeat prescriptions through pharmacies, subject to a risk-management framework, Queensland Health will develop, implement and evaluate a state-wide pilot program to provide antibacterial drugs for UTIs and, separately, develop options for extended supply of the contraceptive pill.

The Pharmacy Guild and the Pharmaceutical Society of Australia have been consulted and provided with a draft copy of the proposed UTI DTP for review and input. They are supportive of both the implementation of the trial and the draft UTI DTP. The AMAQ does not support the introduction of this trial and the increase in scope of practice for pharmacists. This trial will run until 2023, at which time the outcomes of the trial will be reviewed and a decision about its future will be made.

Prescribing medicinal cannabis

The AMAQ, Royal Australian College of General Practitioners (Queensland Branch) and the Pharmaceutical Society of Australia were supportive of broadening the eligibility to prescribe medicinal cannabis to all registered medical practitioners.

Streamlined blood supply arrangements

Queensland Health consulted with key stakeholders including the National Blood Authority, TGA, Pathology Queensland and Queensland clinicians. These stakeholders provided a broad picture of current practices and needs regarding Immunoglobulin supply in Queensland. Stakeholders outlined the need to maintain pathology involvement in Immunoglobulin supply and for regulatory arrangements for pathology providers to obtain and deal with these blood products in order to better streamline supply to patients.

No direct consultation was required with Australian Red Cross LifeBlood as the amendments do not materially affect current practices. Rather, the amendments clarify that the National Blood Supply Arrangements are sufficient regulatory oversight of Immunoglobulin supply and that no additional regulatory requirements are needed for these products in Queensland.

General discussions with Australian Red Cross LifeBlood emphasised the importance of consistency of practices across State and Territories in dealing with blood and blood products under the National Blood Supply Arrangements. The Amendment Regulation will improve national consistency by clarifying the interaction between the National Blood Supply Arrangements and the HDPR.

Labelling exemptions

No formal external consultation has been undertaken about the labelling exemptions amendment. Given the Poisons Standard includes the ability for labelling exemptions to be granted, stakeholders expect Queensland to be able to grant labelling exemptions in circumstances where there would otherwise be a shortage of the medicine with compliant labelling. Individual companies have indicated to Queensland Health that some medicines will not be available to Queenslanders unless a labelling exemption is granted.

Office of Best Practice Regulation

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 *Health (Drugs and Poisons) Amendment Regulation (No. 2) 2020*.

Regulation amended

Clause 2 provides that the regulation amends the *Health (Drugs and Poisons) Regulation 1996*.

Replacement of s 11 (Labelling of controlled or restricted drugs or poisons—Act, s 131I)

Clause 3 omits and replaces section 11 to refer to sections 131I and 132(n) of the *Health Act 1937*. This amendment provides for the chief executive to approve an alternative way for labelling controlled or restricted drugs or poisons. Section 131I of the Health Act requires every package containing a drug or poison for sale to have a label which complies with the requirements prescribed by regulation. Also, a person must not sell a package containing a drug or poison unless the package has such a label. Section 132(n) of the Health Act provides that a regulation may be made exempting a package, drug or article from the labelling requirements in the Health Act.

New section 11(1) provides that for section 131I of the Health Act, a package containing a controlled drug, a restricted drug or a poison must have a label that complies with part 2 of the current Poisons Standard. *Current Poisons Standard* has the meaning given by section 52A of the *Therapeutic Goods Act 1989* (Cth).

New section 11(2) provides that for section 132(n) of the Health Act, a package is exempt from section 131I of the Health Act if the package is labelled in an alternative way certified for the package under subsection (3).

New section 11(3) provides that the chief executive may certify an alternative way for labelling a package if the package is for containing a controlled drug, restricted drug or an S2 or S3 poison and the alternative way, and either an appropriate authority, has authorised by approval, exemption or some other way, the package to the labelled in the alternative way for the purpose or other State, or the chief executive is satisfied the alternative way is unlikely to adversely affect public safety, having regard to the nature of the drug or poison and the purpose for which it is to be used.

New section 11(4) provides that the chief executive must publish on the Queensland Health website the alternative way certified under subsection (3), the day the certification takes effect and the period, if any, for which the certification has effect.

Replacement of s 78A (Medicinal cannabis)

Clause 4 replaces section 78A to provide that, subject to section 74(3), it is an offence for a person to dispense, obtain, prescribe, sell or use a controlled drug that is medicinal cannabis unless the person is a doctor and the doctor is dispensing, obtaining, prescribing or supplying the drug for another person being medically treated by the doctor. A doctor is only able to dispense medicinal cannabis to a person they are treating. The offence carries a maximum penalty of 80 penalty units.

The amendment removes the requirement for non-specialist medical practitioners to obtain a state-based approval to prescribe a controlled drug that is medicinal cannabis.

Amendment of s 171 (Pharmacists)

Clause 5 amends section 171 to provide for the urinary tract infection (UTI) trial for pharmacists.

Clause 5(1) amends section 171(2) to include a cross-reference to subsection (6).

Clause 5(2) inserts new subsection (5A) which provides for a new drug therapy protocol titled 'pharmacist UTI trial DTP' and that a pharmacist is authorised to supply a restricted drug specified in the drug therapy protocol (a UTI drug) to a person in accordance with the requirements of the pharmacist UTI trial DTP.

Clause 5(3) renumbers sections 171(5A) and (6) to 171(6) and (7).

Clause 5(4) inserts new definitions of *pharmacist UTI trial DTP* and *UTI drug*. *Pharmacist UTI trial DTP* is defined as the drug therapy protocol called 'Drug Therapy Protocol—Pharmacist UTI Trial'. *UTI drug* is defined as a restricted drug that is for the treatment of a urinary tract infection stated in the pharmacist UTI trial DTP.

Amendment of s 183 (When endorsement is not needed)

Clause 6 amends the heading of section 183 to replace 'When endorsement is not needed' with 'When endorsement is not needed—delivery agents and carers'.

Clause 6(2) omits section 183(3) as the exemption from needing an endorsement to administer, dispense, issue, manufacture, obtain, possess, prescribe, supply or use a restricted drug for an approved clinical trial is not relevant for agents and carers.

Insertion of new s 184

Clause 7 inserts new section 184 (When endorsement is not needed—approved arrangements). New section 184(1) provides that a person does not need an endorsement to administer, dispense, issue, manufacture, obtain, possess, prescribe, supply or use a restricted drug for an approved clinical trial.

New section 184(2) provides that a person does not need an endorsement to issue, obtain, possess, sell by wholesale, supply or use a restricted drug that is a listed immunoglobulin blood product for carrying out the person's functions or duties under the national blood supply arrangements.

The terms *listed immunoglobulin blood product*, *National Blood Agreement*, *national blood supply arrangements* and *national product price list* are defined in appendix 9 (Dictionary), as inserted by clause 11.

Amendment of s 194 (Emergency sale of restricted drugs)

Clause 8 amends section 194 to improve record keeping for the emergency sale of restricted drugs by pharmacists.

Clause 8(1) omits section 194(3) as recording in the emergency supply book is addressed in section 194(4).

Clause 8(2) amends section 194(4) by replacing the phrase 'record in the emergency supply book' with 'make a record of'.

Clause 8(3) amends section 194(4)(e) by replacing 'doctor or nurse practitioner' with prescriber. A prescriber is defined as a person who is endorsed under the *Health (Drugs and Poisons) Regulation 1996* to prescribe a stated controlled or restricted drug or a stated poison. The amendment also recognises that there may be other authorised prescribers treating the patient, such as dentists.

Clause 8(4) inserts new section 194(5) to provide that it is an offence if a pharmacist fails to keep the record for at least two years after the date the restricted drug was sold. The offence carries a maximum penalty of 20 penalty units.

Clause 8(5) renumbers sections 194(4) and (5) to 194(3) and (4).

Insertion of new s 194A

Clause 9 inserts new section 194A (Sale of oral hormonal contraceptives by pharmacist for immediate need). New section 194A(1) provides that despite section 193(1)(a), a pharmacist may sell a person a restricted drug that is an oral hormonal contraceptive without a prescription if the pharmacist reasonably believes:

- the person has been treated by a prescriber with the drug for a continuous period of a reasonable length before seeking the drug from the pharmacist;
- it is not practicable for the person to obtain a prescription for the drug before needing to continue treatment with the drug; and
- the person has not, in the year before seeking the drug from the pharmacist, been sold the drug without a prescription from the dispensary at which the drug is sought.

New section 194A(2) provides that it is an offence for a pharmacist to sell the person more than a manufacturer's pack of the restricted drug. The offence carries a maximum penalty of 40 penalty units.

New section 194A(3) provides that it is an offence for a pharmacist to sell the restricted drug in a container that does not have a securely attached label with the following information written on it:

- 'Keep out of reach of children' in red on a background of contrasting colour and in bold-faced sans serif capital letters with a face depth of at least 1.5mm;
- 'Immediate need' in a colour contrasting with the background colour and in bold-faced sans serif capital letters with a face depth of at least 1.5mm;
- the name of the person;
- the name and address of the pharmacy;
- the date of the sale;
- the approved name, or the trade name, of the drug.

The offence in section 194A(3) carries a maximum penalty of 40 penalty units.

New section 194A(4) provides that it is an offence for a pharmacist selling a restricted drug to a person under this section to fail to make a record of the following:

- the name and address of the person;
- the date of the sale;
- the description and quantity of the drug;
- the directions given for the use of the drug;
- the name of the prescriber who last prescribed the drug;
- a brief description of why the pharmacist is selling the drug to the person under this section.

The offence in section 194A(4) carries a maximum penalty of 40 penalty units.

New section 194(5) provide that it is an offence if a pharmacist fails to keep the record for at least two years after the date the restricted drug was sold. The offence carries a maximum penalty of 20 penalty units.

New section 194A(5) inserts definitions of *manufacturer's pack* and *oral hormonal contraceptive*. *Manufacturer's pack* of a restricted drug is defined as a primary pack of a drug supplied by the manufacturer of the drug. *Oral hormonal contraceptive* is defined as an oral preparation of a drug for preventing pregnancy by interrupting ovulation.

Amendment of s 200 (Authorised persons to obtain restricted drugs on purchase order)

Clause 10 inserts new sections 200(5) and (6). New section 200(5) provides that an order placed on a national blood tracking system for a restricted drug that is a listed immunoglobulin blood product is taken to be a purchase order complying with section 200.

New section 200(6) inserts a definition of *national blood tracking system*, which is defined as an electronic system for ordering, or authorising orders for, blood or blood-related products, established for facilitating the national blood arrangements.

Amendment of appendix 9 (Dictionary)

Clause 11 inserts definitions of the terms *listed immunoglobulin blood product*, *National Blood Agreement*, *national blood supply arrangements* and *national product price list*.