Pharmaceutical Society of Australia

Queensland Medicines and Poisons Bill 2019

Pharmaceutical Society of Australia - submission

June 2019

Purpose of this submission

The Pharmaceutical Society of Australia (PSA) makes this submission to the State Development, Natural Resources and Agricultural Industry Development Committee on the *Medicines and Poisons Bill 2019* and associated draft *Medicines and Poisons (Medicines) Regulation 2019.*

About PSA

PSA is the only Australian Government-recognised peak national professional pharmacy organisation representing all of Australia's 31,000 pharmacists working in all sectors and across all locations.

PSA is committed to supporting pharmacists in helping Australians to access quality, safe, equitable, efficient and effective health care. PSA believes the expertise of pharmacists can be better utilised to address the health care needs of all Australians.

PSA works to identify, unlock and advance opportunities for pharmacists to realise their full potential, to be appropriately recognised and fairly remunerated.

PSA has a strong and engaged membership base that provides high-quality health care and are the custodians for safe and effective medicine use for the Australian community.

PSA leads and supports innovative and evidence-based healthcare service delivery by pharmacists. PSA provides high-quality practitioner development and practice support to pharmacists and is the custodian of the professional practice standards and guidelines to ensure quality and integrity in the practice of pharmacy.

Background

PSA understands the purpose of the *Medicines and Poisons Bill 2019* (Bill) and associated draft Regulations, *Medicines and Poisons (Medicines) Regulation 2019* (Medicines Regulation) and *Medicines and Poisons (Pest Management, Poisons and Other Regulated Substances) Regulation 2019* is to repeal and replace the existing legislation with a new regulatory framework. We further understand that this is needed to modernise and streamline the regulation of medicines and poisons in Queensland, and that this framework has been designed to ensure the requirements are easier for industry and the community to understand and apply in practice.

General comments

Overall, PSA views the Bill and draft Medicines Regulation 2019 as positive in balancing the management of public health and safety risk with a more contemporary approach to regulation of medicines and poisons. This also allows for a more responsive and outcomes-focussed regulatory framework to meet the needs of the health care industry and provide greater assurance to the community.

Specific comments

In this submission to the consultation on the Bill and the draft Medicines Regulation 2019, PSA makes comment on the following aspects:

- National Uniformity
- Extended Practice Authorities
- Substance Management Plans
- Monitored medicines and real-time prescription monitoring
- Pharmaceutical services
- Requirements for supply only
- Registers
- Standards
- Medicinal cannabis

In the following section of this submission, where possible, relevant sections from the Bill and/or draft Medicines Regulation are referenced.

National Uniformity

National Reforms

PSA supports the Bill's alignment with the Council of Australian Governments' commitment to adopt a nationally-consistent approach to the management of medicines, poisons and therapeutic goods. The need for a nationally consistent approach has been a longstanding view held by PSA, and ultimately, we believe it is in the best interests of patients and health practitioners.

Adoption of the Poisons Standard

PSA supports the proposed adoption of schedules, parts and appendices of the Poisons Standard by reference. This will ensure consistency of regulatory controls governing the availability and accessibility of medicines and poisons with that of other states and territories. PSA believes this will complement and better support professional practice by pharmacists who are already regulated nationally (through the Pharmacy Board of Australia) and comply with nationally endorsed standards developed or promulgated by PSA including, currently, the *Professional Practice Standards* (2017), *Code of Ethics for Pharmacists* (2017) and the *National Competency Standards Framework for Pharmacists in Australia* (2016).

Terminology

PSA supports the introduction of terminology that is consistent with the Poisons Standard, aligning Queensland with other states and territories. With a workforce that is nationally registered, pharmacists are able to move between jurisdictions, and consistent terminology will support the ease of transition. It will also improve clarity for health practitioners and health consumers.

Extended Practice Authorities

Bill s232-235* and *Regs s138

Specifically, PSA notes the ability of the chief executive to make an Extended Practice Authorities (EPAs) by "adopting all or part of another entity's code, guideline, protocol or standard". This, PSA believes, is not dissimilar to existing arrangements whereby government agencies may adopt or cite profession specific standards or guidelines developed by professional associations such as PSA. Importantly, PSA notes that this does not preclude the ability for any consultations to be undertaken with stakeholders or professions that may be impacted by a new or revised EPA. As the peak body for pharmacists and the recognised standards-setting body for the pharmacy profession, PSA welcomes the opportunity to be consulted on the development and on-going review of any EPAs and departmental standards associated with the legislation in Queensland.

PSA supports the intent of the proposal of the EPAs in place of the current Drug Therapy Protocols. We believe this is appropriate where the EPA applies to a genuinely extended scope of practice eg. *Rural and Isolated Practice Area – Endorsed Nurses*.

We note however that the proposed EPAs would replace current Drug Therapy Protocols (DTPs) such as the *Pharmacist Vaccination Program.* The provision of vaccination services by pharmacists, including the administration of vaccines, is within the scope of practice of a pharmacist, not an extension of scope.

PSA therefore proposes that an alternative authorisation such as a *'Structured Practice Authority'* should be developed.

Substance Management Plans

Bill s92-94* and *Regs s108-110

PSA has no objections to the implementation of Substance Management Plans (SMPs) as a way to manage known and foreseeable risks associated with regulated activities related to regulated substances and to encourage shared responsibility for risk reduction. PSA supports an outcomes-focussed approach which is dynamic and proportionate to risk by setting minimum risk management, accountability and governance criteria.

PSA notes that the Bill and draft Medicines Regulation specify the entities which are required to have a SMP. However, PSA recommends that this should extend to any entity that carries out a regulated activity with a regulated substance.

Many pharmacies will already have similar risk management strategies or arrangements in place through relevant accreditation processes such as the Quality Care Pharmacy Program in community pharmacies. Therefore, PSA believes that the transition for pharmacies is not likely to be overly onerous, and that the proposed timeframe of one year for implementation seems reasonable. Consideration of a staged approach may also be beneficial. PSA encourages Queensland Health to undertake early consultation with relevant stakeholders, including the provision of sample templates and substance management plans and guidance on the new arrangements in order to minimise resource impact during the transition.

Monitored medicines and real-time prescription monitoring

Bill s41, s224-227, s228* and *Regs s9, s31, s49 Schedule 2

PSA supports the Bill establishing a head of power for Queensland Health to implement a real-time prescription monitoring system to manage the use of dependence-forming medicines, replacing the current reporting system which is generally up to 14 days out of date and only contains information on Schedule 8 medicines.

PSA has long advocated for the implementation of a national recording and reporting system which will enable real-time monitoring to address the increase in harm resulting from inappropriate use of certain prescription and over-the-counter medicines.

To facilitate an effective monitoring system which maximises benefits to patients and is in the best interest of the Australian community, PSA suggests a real-time monitoring system should be compulsory and include all drugs of dependence, not just substances included in Schedule 8 of the Poisons Standard (i.e. Controlled Drugs). It is also vital that the system has flexibility to allow for the inclusion of other medicines as future trends in abuse and misuse emerge.

PSA welcomes the establishment of a 'monitored medicines' list within the Regulation which will include Schedule 8 medicines and other medicines associated with abuse, and potential for misuse and harm.

PSA welcomes this as a mandatory requirement for prescribers and dispensers of monitored medicines and supports the need for a transition period until the database is fully operational.

PSA also continues to strongly advocate for a system that overcomes interoperability issues across states and territories to be able to function nationally.

A real-time monitoring system must be effectively integrated with medicine prescribing and dispensing systems and be functional for genuine real-time use. It should operate in a way that supports clinical decision making by prescribers and pharmacists to facilitate safe and optimal use of medicines with the potential for addiction without posing a barrier to legitimate therapeutic need.

The implementation of a real-time monitoring system must be accompanied by a robust implementation plan which includes appropriate workforce training. Establishing appropriate referral pathways for pharmacists will also be important so that patients with specific health concerns or chronic conditions can be supported in a timely manner.

PSA believes that nationally uniform regulatory controls for drugs and poisons will further enhance the efficiency and operation of real-time monitoring.

Pharmaceutical Services (Regulations Schedule 9)

Part 2 Division 1 section 3: Selling S2 and S3 medicines

Subsection 2(a) concludes with 'or' and PSA seeks clarity as to whether this should state 'and'. The use of the word 'or' implies that an S3 medicine can be sold to a patient with no therapeutic need provided it is sold in a manufacturer's pack.

PSA also notes the requirement in this section, and chapter 6 part 1 section 133, to sell an S3 medication in a manufacturer's pack. PSA believes this may not be practical as there may be situations when a pharmacist may choose to sell an S2 or S3 medicine in a smaller quantity and thus would not be practical to sell in a manufacturer's pack.

Part 2 Division 1 section 4: Labelling S3 medicines

PSA notes the change of labelling requirements and age restrictions for the sale of S3 medicines to bring Queensland into line with other jurisdictions. In subsection 2(a) PSA questions whether it is the contact details of the 'pharmacist' or 'pharmacy' that would be required, and suggests it is the latter.

In subsection 3, PSA suggests that the word 'ask' be replaced with 'confirm' in order to ensure the person has received the proper training.

Part 2 Division 1 section 6: Supply of S4 medicines in urgent circumstances

> *4(b) for another S4 medicine – 3 days supply of the medicine.*

PSA proposes deleting '*3 days supply' and replacing with* '*the minimum standard pack'* of the medicine so the patient has adequate time to access their prescriber, and for consistency with 4(a).

PSA notes in submissions to, and evidence provided at the public hearings on the recent *Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland*, that in rural areas patients are unable to access prescribers in short time frames due to distance and waiting times for consultation. Thus we strongly advocate for the above amendment to be considered in the best interest of patient care and would seek to discuss how it could be implemented without compromising patient safety.

Part 2 Division 1 section 10: Record keeping for pseudoephedrine

PSA notes that this section only applies to the sale of pseudoephedrine as an S3 medicine and questions whether best practice would indicate that this should apply to the supply of pseudoephedrine by a pharmacist regardless of its schedule. This would allow the real-time data to be collected on all supplies of pseudoephedrine, not just S3 supply.

Part 2 Division 2 section 12: Administering under an extended practice authority

> *A pharmacist may administer a medicine to a patient under 'Extended practice authority 5: Vaccinations by pharmacists.*

PSA proposes removal of "*Vaccinations by"* as this will become a barrier to evolving scope, and for consistency with other extended practice authorities.

As mentioned previously, PSA notes, that the use of the term 'extended' may raise concerns among some health professions if it is considered in relation to scope of practice. The provision of vaccination services by pharmacists, including the administration of vaccines, is within the scope of practice of a pharmacist, not an extension of scope. PSA proposes that an alternative term be used. A *'Structured Practice Authority'* may be a more appropriate alternative term to consider.

Part 2 Division 2 section 13: Administering approved opioids

PSA notes that this section restricts the administration of a medicine by a pharmacist to only approved opioids. We note that this does not adequately cover all medicines, regardless of their schedule, that a pharmacist would be able to administer within their scope of practice. Examples of this include, but are not limited to, daily dosing of non-opioid medicines or application of topical medicines in wound care services.

Part 2 Division 2 section 15: Compounding

PSA notes that the draft Regulation limits the compounding of medicines to patients only and thus appears to exclude compounding for animals. PSA seeks clarity whether compounding for animals should be included in the draft Regulation.

Part 2 Division 2 section 16: Disposing of waste

The explanatory notes to the draft Regulations indicates that the Regulations are designed to provide greater flexibility and more timely destruction of S8 medicines by extending the authority to destroy medicines to a broader range of people including pharmacists. PSA supports the proposed changes that allows for destruction of S8 medicines by pharmacists. More efficient destruction will result in harm minimisation of the public and health professionals by reducing stockpiling. However, PSA notes that if this is the intent of the draft Regulations, it is not clear that such is the case. The draft Regulations state that:

> A pharmacist may dispose of waste from a medicine by giving it to another person-
>
> (a) Who is authorised to dispose of the waste under the Act or another law.

The draft Regulations do not specifically say 'a pharmacist may dispose of waste from an S8 medicine' as it does with other health practitioners in the Regulations.

The draft Regulations also do not specifically indicate whether pharmacists are authorised to administer S8 medicines.

PSA recommends that the draft Regulations be amended to include pharmacists as authorised persons to administer, and dispose of waste from, an S8 medicine.

PSA seeks clarity on whether waste from an S8 medicine only relates to the particular S8 medicine being administered.

PSA also recommends that the draft Regulation be amended, in line with the explanatory notes, to include pharmacists as authorised persons to destroy S8 medicines (not just waste from an S8 medicines) thus including the authorisation to destroy expired S8s or S8s returned by patients to a pharmacy.

Part 3: Hospital pharmaceutical technicians* and *Part 4: Pharmacy employees

PSA notes the differences in the Regulation between the two types of employees and suggests that the latter is not consistent with contemporary pharmacy practice.

> *s44 (2) The pharmacy employee may possess a medicine to assist a pharmacist at the pharmacy to dispense the medicine only if the employee is acting under the direct supervision of the pharmacist.*

PSA proposes removal of *'to assist a pharmacist', and 'to dispense the medicine only if the employee is acting', and 'direct'* for consistency with Part 3 of this division.

Requirements for supply only

Chapter 2 Part 2 Division 3 subdivision 3 section 32: Generation of paper prescriptions using computer

PSA notes the removal of the requirement for a prescriber to handwrite particular details of the prescription on computer generated prescriptions other than the prescriber's handwritten signature.

Chapter 2 Part 2 Division 3 subdivision 3 section 35: Oral or informal prescribing

PSA notes that in subsection 3 it states that '*If a prescriber supplies the medicines…'* and queries whether *'prescriber' should be replaced with 'person'* for consistency with the rest of that section when referring to a 'person authorised to supply'.

PSA also seeks clarity on what is referred to by 'another record' in 3(b).

Chapter 2 Part 2 Division 8 section 74: Disposal of S8 medicine waste

PSA questions whether subsection 2(a) and 2(b) are required, or whether it should state 2(a) or 2(b). As it is currently stated, this would create a very onerous task for disposal of S8 medicine waste.

Chapter 5 Part 2 Division 3 section 123: Information for register

PSA notes the current *Health (Drugs and Poisons) Regulation 1996* allows for opioid replacement therapy to be recorded in the register no later than 7 days after the end of the month in which the final dose of the administration or supply is carried out. There is no such specification in the draft Regulation which only specifies that an S8 medicine must be recorded no later than 24 hours after it is supplied. PSA seeks confirmation that this is an intended change to Regulation with respect to Pharmacist Opioid Treatment Program.

Registers

Bill s228-231

PSA supports the provision in the Bill for the chief executive to keep and publish the following registers relating to substance authorities as well as administrative action taken in relation to substance authorities and authorisations.

These registers will increase transparency for patients and health practitioners allowing enhanced public confidence that the licence or approval holder, or the approved person they are dealing with holds the appropriate authority for the activity they are carrying out. Currently this is not able to occur in Queensland.

Standards

Bill s233-235

PSA supports the development and use of departmental standards as a way of regulating the activities of regulated substances as well as other matters related to the Act. In addition, PSA supports the requirement of the chief executive to consult with entities that have expertise about the matters proposed to be dealt with by the standard. As the peak body for pharmacists and the recognised standards-setting body for the pharmacy profession, PSA welcomes the opportunity to be consulted on the development and on-going review of any standards associated with the legislation in Queensland.

Medicinal cannabis

PSA welcomes the streamlining of the legislative framework and the reduction of the regulatory burden associated with the prescribing of medicinal cannabis in Queensland, allowing it to be regulated and treated in the same manner as other Schedule 4 or Schedule 8 medicines.

Other

Throughout the draft Regulations, the term ‘signature’ is used and is a requirement of records eg records for giving a treatment dose, marking dispensed prescriptions, information for S8 register. PSA seeks clarity on the definition of ‘signature’ as in many cases, a pharmacist would sign using written or electronic initials.

Summary

PSA notes the complexity of the implementation of legislative changes in practice for health care practitioners and as such the need for not only relevant training and information sessions for practitioners, but also the need for supporting guidance documents and resources for use in practice. PSA, as the peak body for pharmacists, welcomes the opportunity to work with Queensland Health in the development and delivery of these training and educational resources recognising this as an important process for supporting practitioners to transition to the new legislation.

PSA would be happy to provide any further information or clarification on this submission and can also assist with other profession-specific matters such as impact on the professional practice of pharmacists as custodians of medicines and poisons.

Submitted by:

Pharmaceutical Society of Australia
Level 2, 225 Montague Road
West End, Qld 4101
PO BOX 6120
Wolloongabba, Qld, 4102
Tel: 07 3186 2800
www.psa.org.au

Contacts:

Mark Lock, State Manager – Queensland
[redacted]
[redacted]

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