The Pharmacy Guild of Australia

4th June 2019

Dr Jacqui Dewer
Committee Secretary
State Development, Natural Resources and Agricultural Industry Development Committee
Parliament House
George Street
Brisbane Qld 4000
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Dear Dr Dewar

Submission regarding the Draft Medicines and Poisons (Medicines) Regulation 2019

Thank you for the opportunity to provide feedback on the proposed Medicines and Poisons Regulatory Scheme 2019 of which the Medicines and Poisons Regulation forms part.

The Pharmacy Guild of Australia, Queensland (Guild) has previously provided extensive feedback regarding the proposed regulations and is disappointed the majority of the feedback has not been accepted at this point in time.

We have concerns that key issues have not been addressed which will impede the provision of medicines in a way that will address the current and future health of Queenslanders.

These issues include:

- Limitation in supply quantities of important medications in urgent situations such as natural disasters
- The terminology and use of extended practice authorities hindering their potential benefit in utilising existing capacity in health professions.

The Guild wishes to appear as a witness at the public hearing scheduled for the legislative package on Thursday 20th June 2019 so it can explain to the Committee in greater detail the areas that the Regulation can be improved before it commences operation.

A representative sample of the concerns of the Guild are attached to this letter.

The Guild looks forward to continued collaboration with the Queensland Government on this important piece of legislation.

Should you have any queries, please contact me on 07 3831 3788 or [redacted]

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Kind regards

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Branch President
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Draft of the Medicines and Poisons (Medicines) Regulation 2019

Chapter 2 Approved persons Part 2 Requirements for dealings – Act, section 91 [s 33]	Content of prescriptions other than medication chart prescriptions
The Regulation states that if the medicine is an s8 and is a monitored medicine, the patient's date of birth is to be included on the prescription. The Guild notes that there are also monitored s4 medicines listed in Schedule 2 Part 4. The Guild suggests the Committee inquire into whether this requirement to include date of birth should be required on all s4 prescriptions.	
Chapter 2 Approved persons Part 2 Requirements for dealings – Act, section 91 [s 33] (l)	Content of prescriptions other than medication chart prescriptions Animal Prescriptions
The Regulation states that if the medicine is for an animal, that the address of the owner is required. However in [s 37] (f) Content of prescriptions for administration, the <u>name</u> and address of the owner is required. The Guild suggests the Committee inquire into whether these requirements should be consistent.	
Chapter 2 Approved persons Part 2 Requirements for dealings – Act, section 91 [s 50]	Dispensing diversion-risk medicines If the dispenser is dispensing a diversion-risk medicine on a prescription, the dispenser must take reasonable steps to ensure the prescription has been given by a prescriber. Example of reasonable steps – attempting to contact the person who gave the prescription.
The Guild requests further information on other examples of reasonable steps. The list of diversion-risk medicines in Schedule 2 Part 3 is extensive and the Guild has concerns in relation to the practicality of contacting prescribers in each instance that these medicines are prescribed.	
Chapter 2 Approved persons Part 2 Requirements for dealings – Act, section 91 [s 54]	Marking dispensed prescriptions (b) the dispenser's contact details and signature (d) if the last repeat was dispensed – that the prescription is cancelled;
In practice these requirements place additional administrative steps that are not needed. *The dispenser's initials and pharmacy contact details should be sufficient in relation to (b).* *In the context of (d) If the last repeat is dispensed, the pharmacy retains the paper prescription or if the item is on a prescription listing other medicines and does not have a repeat prescription attached, the item is not dispensed.* *More generally, the Guild requests the Committee inquire into what steps the Government took to ensure that unnecessary red tape has not been included in the Regulation.*	
Chapter 2 Approved persons Part 2	Disposal of s8 medicine waste (2) The destruction must be witnessed by –

Requirements for dealings – Act, section 91 [s 74]	(a) another person who is authorised under the Act to dispose of waste AND (b) an inspector or police officer.
The Guild has concerns with the limitations (especially in regional and remote regions) of requiring an authorised person AND an inspector or police officer to witness destruction of s8 medicines (e.g. how often are inspectors available to visit a pharmacy? Is the pharmacy able to request visits when needed?). *The Guild asks the Committee to recommend that provisions similar to section 390 of the Australian Capital Territory's Medicines, Poisons and Therapeutic Goods Regulation 2008 be included in the Regulation.*	
Chapter 3 Substance authorities Part 4 Retail licences	S2 retail licence
The Guild asks the Committee to inquire how the criteria for these licences were formulated. The previous regulation mentions that licence holders need to be a minimum distance away from a pharmacy, however this has appeared to be removed in the proposed regulation.	
Chapter 4 Substance management plans Part 6 Dealings under substance authorities [s108]	(1) For section 92 of the Act, definition *regulated place*, paragraph (b), the places stated in schedule 16, section 2, column1 are prescribed.
The Guild supports the implementation of substance management plans as an important risk management tool that should be used by all entities dealing with medicines. The Guild requests the Committee inquire as to why some entities are listed as a regulated place (and hence must have a substance management plan) and other entities which also deal with medicines are not listed (e.g. medical practices).	
Chapter 5 Requirements for establishing systems Part 2 Storage systems [s 118]	This part applies to a person (the storage system controller) who is responsible for setting up a system for storing stock of a medicine at a specified place.
The Guild recommends the Committee inquire into who is considered the 'storage system controller' and how is this different to the 'responsible person' stated in schedule 16 of the Regulations.	
Schedule 1	Extended practice authorities
The Guild has concerns with the use of term 'extended' in relation to practice authorities. Extended gives the impression that the approved person is working outside their scope of practice however this is not the case. The Guild recommends the term 'extended' should be removed. *Extended practice authorities state the circumstances in which an approved person may deal with a regulated substance. The Guild notes that other extended practice authorities list only the approved persons role in the title e.g. midwives, registered nurses however with pharmacists it specifies the type of regulated substance i.e. vaccination being dealt with. The Guild has concerns*	

that this variation specific to pharmacists creates limitations on enabling change in future practice. The Guild therefore recommend removing the terms 'Vaccinations by' in the title of the practice authority for pharmacists.	
Schedule 9 Part 2 (4)	Labelling s3 medicines (2) The pharmacist must – (a) Ensure a label is attached to the medicine with the contact details of the pharmacist
In relation to 'contact details of the pharmacist' on the label, the Guild recommends that the Committee review the requirements of the NSW Poisons and Therapeutic Goods Legislation. Pharmacy contact details provided on the label in addition to a system used by the pharmacy identifying which pharmacist authorised the supply should be sufficient.	
Schedule 9 Part 2 (5)	Continued supply
The Guild has concerns that this section only refers to Commonwealth regulation and does not reference or allow state identified instances where this measure could be applied to.	
Schedule 9 Part 2 (6)	Supply of s4 medicines in urgent circumstances
These emergency supply arrangements are not practical for pharmacists and are inadequate in effectively supporting patients in the event of a catastrophe such as fire or flood, when people can be displaced, essential medical services can be disrupted and people are at their most vulnerable. *The limit of three days' supply is demonstrably inadequate – as natural disaster emergency situations can and do continue for much longer periods. In less catastrophic situations, it may take longer than three (3) days for a patient to be able to attend their usual doctor, requiring patients to attend emergency departments or unfamiliar doctors. Such appointments can be both costly and inconvenient to patients and does not make efficient use of our health systems.* *The Guild accordingly recommends an expansion of supply provisions to enable urgent supply of the smallest available manufacturer pack in the absence of a prescription.* *The Guild also notes [s52] which states if the dispenser reasonably believes the patient has a therapeutic need for a medicine on a prescription which may be fraudulently prepared, they can supply a maximum of two (2) days supply. This may be confusing to practitioners.* *The Guild recommends the Committee particularly inquire as to the way in which the supply of s4 medicines in urgent circumstances contained in the Regulation was designed in the manner it was.*	
Schedule 9 Part 3 and Part 4	Hospital pharmaceutical technicians and pharmacy employees
The Guild notes the difference in authorities for hospital pharmaceutical technicians and pharmacy employees although they deliver similar roles and are always ultimately the responsibility of the supervising pharmacist.	

The Guild strongly recommends that the authorities are the same with these persons and that they both can possess an s4 or s8 under the supervision of a pharmacist.	
Schedule 9 Part 2	Pharmacists
We note that other health practitioners have it specifically mentioned in the regulation that they can dispose of s8 medicine waste e.g. Dentists, Schedule 4 [6] and Medical Practitioners Schedule 6 [8]. However this clause has not been included under Pharmacists in Schedule 9. The Guild requests confirmation that pharmacists will be able to dispose of s8 medicine waste.	
	Quality standards
In the previous regulation, pharmacists were required to implement a quality standard for dispensing. We note that there is currently no mention of this requirement in the proposed Regulation. The Guild recommends the Committee inquire how the matters managed by way of a quality standard for dispensing will be managed through the proposed regulation.	
	Manufacturing licences
There are certain activities that pharmacists in pharmacies do on a day to day basis including but not limited to: repackaging supply of medicines into Dose Administration Aids for RACF imprest etc. The Guild recommends the Committee inquire that the definitions relating to manufacturing does not include these types of activities.	