Medicines, Poisons and Therapeutic Goods Bill 2014 - Consultation feedback

The consultation survey for the draft Medicines, Poisons and Therapeutic Goods Bill is divided into a number of sections:
1. 7 general questions (10-20 minutes)
2. 2 questions about offences and penalties (5 minutes)
3. 5 questions about licences, approvals and other authorisations (10-20 minutes)
4. 3 questions about the adoption of the *Therapeutic Goods Act 1989 (Commonwealth)* (5-minutes)
5. 3 questions about scheduled substance management plans (5 minutes)
6. 2 questions about monitoring and enforcement (3 minutes)
7. 1 question about standards and regulations (1 minute)

The online survey will be active for 45 minutes. After this time you can select the option to continue or you can save the survey and email yourself a link and password which will allow you to complete it later.

General questions

Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

Are there any additional controls that need to be provided for in the legislation to protect public health and safety? This Bill forms part of the framework of legislation and practice that ensures patient safety. It will also expressly allow for innovation of the health model. This innovation will include independent prescribing for suitably qualified health workers.

Patient safety would be enhanced should this Bill provide for independent prescribing by suitably qualified health practitioners. The APA submits that independent prescribing by physiotherapists would protect public health and safety by reducing treatment delays and improving specificity and responsiveness of prescribing.

Are there any omissions or gaps in the proposed legislative framework? What are they and how should they be addressed? The APA welcomes regulatory reform that allows Australia's health system to be flexible enough to build on and fully use health practitioners' expertise so they can contribute to improving the patient experience. This Bill should enable continued evolution of scope to meet patient needs and promote collaboration across traditional professional boundaries.

The APA is seeking the Physiotherapy Board of Australia's endorsement of physiotherapists for independent prescribing to achieve this goal. Independent prescribing is a model in which the

practitioner is responsible for the clinical assessment of the patient and diagnosis of the condition and then prescribes therapy, without the requirement for supervision by another healthcare professional. Independent prescribing creates new ways of working to improve quality of services and the patient experience. It helps form partnerships across professional and organisational boundaries and builds care pathways that are cost-effective and sustainable, for example improving the transition from acute to community care.

The Health Practitioner Regulation National Law (National Law) regulates certain health practitioners and Section 94 provides for National Boards to endorse the registration of health practitioners to administer, obtain, possess, prescribe, sell, supply or use a scheduled medicine or class of scheduled medicines. At present, physiotherapists are not endorsed practitioners.

Endorsement for prescribing supports innovation in line with the outcomes of this Bill. Commonwealth and State and Territory legislation needs to enable the implementation of this mechanism, so there is no unreasonable regulatory barrier to improvement.

Further, the Pharmaceutical Benefits Scheme (PBS) does not make allowance for physiotherapists to prescribe medicines. Authorised PBS prescribers are medical practitioners, dentists, optometrists, midwifes and nurse practitioners.

Since Queensland will adopt the classification (schedules) for medicines and poisons under the national Poisons Standard, this alone might impact on whether non-medical practitioners can supply or administer drugs.

Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions? The APA believes that reform should remove barriers to innovation. To allow for this, we suggest that amendment be made to allow for independent prescribing by suitably qualified allied health practitioners, as well as under direction. We seek greater clarity about the Bill's definition of 'regulated activity': "lawful direction to, authorisation or request that another person supply or administer the substance."

Are you aware of any other standards or codes that apply to your industry and are relevant to public safety and protecting the public from harm?

Offences and penalties

Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Licences, approvals and other authorisations

In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

Are the proposed licences, approvals and other authorisations appropriate?

Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth?

In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

Therapeutic Goods Act 1989 (Commonwealth)

Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

Scheduled substance management plan

The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity\'s processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a management plan (e.g. quality assurance plan, accreditation documents)?

What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

Monitoring and enforcement

Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

Standards and regulations

The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

The Queensland Government is bound by the Information Privacy Act 2009.
The information you provide on this form will only be used for the purpose of informing the State Government's final position on Medicines, Poisons and Therapeutic Goods Bill. We will not share your name or contact details with anyone without your consent. This consultation is a public process and any comments you provide may be published and/or online and may be transmitted outside of Australia. You may wish to bear this in mind when providing your comments.
You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.
Read our privacy statement for details.

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Publishing your response

Publish my response

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