RIS Ref: QH0081-0919
File Ref: DOC19/3075

7 January 2020

Ms Louise Ballinger
Manager
Queensland Health
33 Charlotte Street
BRISBANE QLD 4000

Dear Ms Ballinger

Consultation Regulatory Impact Statement—Regulatory Fees and Licensing Framework for Pharmacy Ownership in Queensland

Thank you for your enquiry of 1 August 2019 and further information provided to 3 January 2020, seeking advice on the adequacy of the Consultation Regulatory Impact Statement 'Regulatory Fees and Licensing Framework for Pharmacy Ownership in Queensland' (consultation RIS).

Background

The objective of the *Pharmacy Business Ownership Act 2001* (the Act) is to provide for the promotion of safe and competent provision of pharmacy services to maintain public confidence in the profession. The Act places restrictions on the ownership of pharmacy businesses including limiting ownership of community pharmacies to pharmacists, limiting the number of pharmacies that may be owned by a person, and provides for compliance with the Act to be monitored and enforced. The Department of Health (the department) is responsible for administering the Act.

The department advises that the regulatory environment does not effectively provide for the ongoing monitoring of compliance within the Act—once a pharmacy owner has notified the department of a transfer of pharmacy ownership, there is no further requirement for the owner to demonstrate whether they continue to maintain their pharmacy business or comply with other requirements under the Act. Further, the Act limits the department's ability to enforce compliance with the Act.

In May 2018, the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee (Committee) was asked to inquire into the establishment of a pharmacy council and the transfer of pharmacy ownership in Queensland. The Committee made 11 recommendations relating to the establishment of a pharmacy council; regulation of pharmacy ownership; changes to pharmacy ownership legislation and improved transparency of compliance outcomes in the pharmacy industry.

In response to the Committee report, the Queensland Government accepted recommendation 9—that the pharmacy ownership requirements of the Act be retained. All other recommendations were accepted in full or in-principle. The recommendations relevant to this consultation RIS are as follows:

- establish a Queensland Pharmacy Advisory Council to advise the department in its administration of the Act and provide expert advice on ownership and premises matters (recommendation 6)

- amend the Act to enable the department to more effectively manage the pharmacy ownership notification process, including establishment of offence provisions for breaches (recommendation 8)
- the department improve transparency regarding the compliance of pharmacists with the Act, the *Health Regulation 1996* and the *Health (Drugs and Poisons) Regulation 1996* by publishing its compliance audit results, at least annually (recommendation 10)
- the department investigate ways to improve communication to consumers about the services individual pharmacies provide, such as vaccinations (recommendation 11).

Proposal

The department has prepared this consultation RIS to assess options to:

- ensure the efficient and equitable administration of the Act, improve transparency of compliance activities undertaken by the department, and improve communications to health consumers about the services provided by community pharmacies, as recommended by the Committee's report (Part A below)
- address the requirement for the department to implement a mechanism, underpinned by legislation, that will support the department in fulfilling its regulatory responsibilities to proactively monitor and enforce compliance with the Act (Part B below).

The consultation RIS presents the following options:

Part A – Monitoring and enforcement of pharmacy ownership legislation

Option 1 Maintain the status quo. Under this option, legislation would not be updated, nor would a Queensland Pharmacy Advisory Council and a licensing framework be established.

Option 2 Retain the current notification approach and make minor amendments to the Act to improve compliance processes and establish the Queensland Pharmacy Advisory Council. Under this option, the Act would be amended to:

- improve the department's ability to obtain information to monitor and enforce compliance
- establish offences for entering into certain commercial arrangements, which provide for the pharmacy business to be controlled by a third party
- establish a Queensland Pharmacy Advisory Council (refer Part B).

Option 3 Establish a licensing framework for pharmacy businesses. The Act would be amended to:

- establish a licensing framework
- provide for a fee framework. Three options are considered:
  - a one size fits all fee structure (flat fee scheme)
  - a tiered fee scheme based on complexity of business structure
  - a fee framework that includes fees per application related to pharmacy businesses as well as additional fees based on business complexity and the number of financial interests' individuals hold in a pharmacy business
- establish a register to record the services provided by individual community pharmacies
- establish the Queensland Pharmacy Advisory Council (refer Part B).

This is the department's preferred option.

Part B – Establish a Queensland Pharmacy Advisory Council, funded by community pharmacy owners

Option 1 Maintain the status quo—the Queensland Pharmacy Advisory Council would not be established.

Option 2 Establish a Queensland Pharmacy Advisory Council to be funded by community pharmacy owners:

- the Queensland Pharmacy Advisory Council would be established
- a fee would apply to all Queensland pharmacies, on a cost recovery basis

- the purpose of the Council would be to provide expert advice to the Minister on ownership and any relevant standards
- members would be appointed by the Minister and comprise of experts in law, accounting, business management and representatives of the pharmacy industry and health consumers.

This is the department's preferred option.

Option 3 Establish a voluntary advisory Pharmacy Round Table

- the Round Table would provide advice on the Committee recommendations
- it may have up to eight members with expertise in law, business management, community pharmacy, hospital pharmacy as well as consumer representatives
- members would not be remunerated
- the round table would be time limited and would not provide for ongoing advice to support the compliance monitoring stages and 'business as usual.'

Option 4 Establish a Queensland Pharmacy Council as a Regulatory Authority

- the Queensland Pharmacy Council would be established as an independent pharmacy authority (the Authority)
- the Authority would have regulation functions of ensuring compliance with the pharmacy ownership restrictions and pharmacy premises regulation.

Consultation

The Consultation RIS follows initial consultation between May 2018 and October 2018, as part of the inquiry. The Committee accepted and published 210 written submissions from community pharmacists and pharmacy assistants, medical and pharmacy peak bodies, pharmacy franchise organisations, patient advocates and members of the public. The Committee also held public hearings in Brisbane, Toowoomba, Cairns and Townsville.

As part of the inquiry, the Queensland Audit Office (QAO) conducted an audit of the administration of transfers of pharmacy ownership by the department for compliance with the Act. In relation to the QAO report, the Queensland Productivity Commission (the Commission) notes that:

- the QAO report examined the effectiveness of the current systems and processes in regulating pharmacy business ownership in Queensland and the compliance with the Act of pharmacy ownership
- the Committee agreed with the QAO report recommendation to strengthen the Act to enable the department to more effectively manage the pharmacy ownership notification process.

The Commission notes that the QAO report did not seek to identify whether there is evidence of a public health problem or heightened risk associated with non-compliance with the Act, or the current level of oversight.

At the request of the Committee, the Commission was directed to conduct an independent cost benefit analysis of establishing a pharmacy council. Three options were assessed:

- Option 1: Continued regulation by the department
- Option 2: Establish a pharmacy council with a regulatory role
- Option 3: Establish a pharmacy council with a regulatory, advisory and educational role

Based on the available data, the Commission found no evidence that:

- other Australian states with pharmacy councils have better outcomes for producers and consumers than Queensland
- the existing premises regulation is resulting in unsafe conditions in pharmacies
- more intensive enforcement of the ownership restrictions would provide greater consumer benefits.

The Commission found that administering the ownership regulations more intensively, as proposed by creating a pharmacy council, is unlikely to produce material benefits. Rather, it adds to the general cost of regulation.

Assessment

In undertaking its assessment of a Consultation RIS, the Commission has regard to 'adequacy criteria' in the Queensland Government Guide to Better Regulation (the guidelines). Key elements include the identification of a policy problem, rationale for government action and analysis of costs and benefits.

The Commission acknowledges the effort made by the department in this document to allow the broader community to assess the merits of adding regulation to an already heavily regulated industry. In this context, the department, through consultation with this RIS, must establish that:

- the community will be better off if the preferred option is implemented
- the potential reduction in competition proposed by the preferred option is more than outweighed by the benefits of restricting competition
- the development of a new advisory institution will deliver a net benefit to consumers.

The Commission recognises that the scope for this RIS is defined by the objective to implement recommendations set out in the Committee report, including that the pharmacy ownership requirements of the Act be retained.

Given this context, the Commission has concluded that the RIS is adequate for the purposes of public consultation. The RIS adequately presents the department's assessment of the issues including analysis and quantification of the estimated impacts of the options on affected pharmacy owners, and a qualitative assessment of the impacts to community and industry stakeholders.

Consultation with stakeholders will likely assist the department to further develop the policy, including:

- whether and to what extent the proposed amendments will further restrict competition
- whether the proposed amendments will have any unforeseen adverse impacts
- whether any alternative options, which achieve the aims of the policy, should be considered.

Consistent with the guidelines, once a Consultation RIS has been approved for release it is published on the Commission's website along with this letter. After consultation has concluded, a Decision RIS, incorporating the consideration of public comments should be provided to the Commission for assessment before the matter is finally referred to Cabinet for decision.

Please contact Robert Sugden, Senior Analyst on (07) 3015 5113 if you require any additional information or guidance in relation to the above comments or the guidelines in general.

Yours sincerely

Sean Mackay
Acting Team Leader