

Enquiries to:

Dorothy Vicenzino Executive Director Chief Medical Officer and Healthcare Regulation Branch

Telephone:

Our ref:

CAPS1692

Queensland Health

The Honourable Mr Aaron Harper MP
Chair
Health, Communities, Disability Services and Domestic
and Family Violence Prevention Committee
Parliament House
George Street
BRISBANE QLD 4000

Email: health@parliament.qld.gov.au

Dear Mr Harper

The Department of Health (the Department) remains committed to implementing the Queensland Government's response to the recommendations of the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee's (the Committee) Report No. 12, 56th Parliament – Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland (Inquiry Report), including the recommendations of the related Queensland Audit Office Report No. 4: 2018-9 – Managing transfers in pharmacy ownership (Audit Report).

The COVID-19 pandemic has placed additional pressure on the pharmacy industry and the health sector more broadly. As a result, the Department has temporarily suspended a number of activities during the COVID-19 pandemic crisis, including a number of activities under the Government's response to the Inquiry Report.

I have attached a progress report for your information on the implementation of the Government's response, highlighting progress to date and activities temporarily suspended. Once the COVID-19 pandemic is averted, the Department will recommence implementation of all outstanding recommendations and provide further advice to the Committee.

Should you require further information, the Department's contact is Ms Dorothy Vicenzino, Executive Director, Chief Medical Officer and Healthcare Regulation Branch, Prevention Division on telephone

Yours sincerely

Dr John Wakefield PSM Director-General

11 May 2020

April 2020 Progress Report on the Delivery of Queensland Government Response to the Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee's Report No. 12 – Inquiry into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland

Recommendation	Commitments in Government Response	Progress
Recommendation 1: The Committee recommends that the Department of Health lower the minimum patient age requirement for pharmacist-administered vaccinations to 16 years of age	This recommendation is accepted and has been implemented.	In March 2016, the Queensland Government supported a change to the Health (Drugs and Poisons) Regulation 1996 to allow pharmacists to provide nominated vaccinations to adults aged 18 years and over. This included influenza, diphtheria-tetanus-acellular pertussis vaccine and measles-mumps-rubella vaccine, and adrenalin for treatment of anaphylaxis only. A further amendment was supported on 5 April 2019 to lower the age for pharmacist administered vaccinations to persons aged 16 years and older. The Committee's recommendation that the minimum age for pharmacist-administered vaccination be lowered to 16 years has been implemented.
Recommendation 2: The Committee recommends the Department of Health develop options to provide low-risk emergency and repeat prescriptions (for example, repeats of the contraceptive pill) and low-risk vaccinations (including low risk travel vaccinations) through pharmacies subject to a risk-minimisation framework. The framework could include: • consultation with a GP utilising 13HEALTH; • limitations on the number of times a prescription can be issued within a period of time (e.g. only once in a six-month period); • on-site testing; and	This recommendation is accepted in principle. Queensland Health will develop, implement and evaluate a state-wide trial to provide low-risk emergency and repeat prescriptions for the contraceptive pill and antibiotics for urinary tract infections. To support this recommendation, Queensland Health will: 1. review and evaluate proven models from similar health systems for relevance to Queensland and/or trial new models of care and determine training and governance; and 2. establish a multidisciplinary group to consider the outcomes of the Australian Health Protection Principal Committee	Status: IN PROGRESS – Continuing during the COVID-19 pandemic in part, with delay to longer term solution regarding introduction of continued supply provisions for oral hormonal contraceptives. However, supply provisions within the Drug Therapy Protocol – Communicable Diseases Program (were enacted late March) to give effect to continued supply arrangements for oral hormonal contraceptives during a public health emergency until the emergency declaration finalises. Provision of antibiotics for urinary tract infections by community pharmacists: The Department of Health has engaged the Queensland University of Technology (QUT) to manage the development, implementation and evaluation of a state-wide pilot of the provision of antibiotics for urinary tract infections by community pharmacists.

Recommendation	Commitments in Government Response	Progress
 a requirement that the pharmacist consult a 13HEALTH GP or have regard to the patient's medical record via MyHealthRecord. 	(AHPPC) working group, and if necessary, develop further options in accordance with the recommendation.	 QUT has established a steering advisory group to provide advice, as required, on matters related to the determination of the model of care and implementation of the pilot. The advisory group meets monthly.
Any change in pharmacists' scope of practice should be underpinned by appropriate credentialing and training for the services to be delivered.		 QUT have proposed a model of care for the pilot that would enable a community pharmacist to provide empirical treatment in accordance with the Therapeutic Guidelines using a hierarchal decision-making protocol to select the most appropriate treatment for the woman from a choice of three antibiotics.
		QUT have received ethics approval for the evaluation of the pilot.
		The education and training module for pharmacists to participate in the trial has been developed and was made available online in early April 2020.
		 An appropriate temporary legislative mechanism to allow pharmacists participating in the trial to provide antibiotics, is yet to be determined.
		Continued provision of the contraceptive pill:
		• The Medicines and Poisons Bill 2019 was passed. The subordinate legislation is being drafted and includes provisions for continued supply of the contraceptive pill through community pharmacies where a woman has an immediate need for the medicine and cannot obtain a prescription. However, the commencement of this legislation will be delayed by the COVID19 response.
,		 Ministerial approval was granted on 5 February 2020 to prepare a paper for the COAG Heath Council seeking jurisdictional support for a request to the Secretary to the Department of Health to approve the down-scheduling of oral hormonal contraceptives from Schedule 4 (Prescription-only) to Schedule 3 (Pharmacist only) with an Appendix M listing.

Recommendation	Commitments in Government Response	Progress
		 Approval was also granted to engage an industry expert to prepare the Application to Amend the Poisons Standard as required by the Advisory Committee on Medicines Scheduling. A request for quote has been released to identify an industry expert to complete this work. Applications closed COB Friday 10 April 2020.
		Options to provide low-risk vaccinations (including low-risk travel vaccinations:
		 On 12 November 2019, the multidisciplinary group provided inprinciple support of the Australian Health Protection Principal Committee (AHPPC) working group's draft categorisation of low risk vaccines. To deliver on this recommendation, on 20 February 2020 the Health (Drugs and Poisons) Regulation 1996 was amended to lower the age for pharmacist administered vaccines to persons who are 10 years or more and allow trainee pharmacists to administer vaccines and adrenaline. The legislative amendment enabled the <i>Drug Therapy Protocol (DTP) – Pharmacist Vaccination Program</i> to be amended to: allow pharmacists and trainee pharmacists to administer influenza vaccine only to persons who are 10 years or more and expand the range of low risk vaccines pharmacists and trainee pharmacists can administer to persons who are 16 years or more to include those that have been categorised as low risk in the draft report of the AHPPC working group. Additional low risk vaccines are cholera, Haemophilus influenzae type B, hepatitis A, meningococcal ACWY and poliomyelitis. The <i>Queensland Pharmacist Vaccination Standard</i> has also been amended to reflect these changes.

Recommendation	Commitments in Government Response	Progress
,		Stakeholder communication advising of the changes was distributed on 21 February 2020.
Recommendation 3: The Committee recommends the Minister for Health seek support through the COAG Health Council for nationally consistent education and training requirements and scope of practice for pharmacists administering vaccinations.	This recommendation is accepted. This will be considered once AHPPC has endorsed the report from the working group on a nationally consistent approach to pharmacy delivered vaccination programs.	The Commonwealth Department of Health has authorised Health Education Services Australia (HESA), a subsidiary of the Australian Nursing and Midwifery Accreditation Council, to act as the single point of entry for immunisation education provider courses seeking to be accredited against the Immunisation Education Framework for Health Professionals.
		 Queensland education providers whose courses meet the Australian Pharmacy Council's (APC) 'Standards for the accreditation of programs to support pharmacist administration of vaccines', may continue to deliver immunisation training, subject to state and territory legislation, as the APC vaccination standards have been revised to align to the National Framework.
Recommendation 4: The Committee recommends the Department of Health, in conjunction with the Pharmacy Advisory Council (if established), explore the benefits and risks of extending the scope of practice of community pharmacy assistants in relation to the handling of dangerous drugs	This recommendation is accepted in principle. Queensland Health is currently progressing legislative change that will allow community pharmacy assistants to participate in the receipt and stocking of scheduled drugs. This change will be introduced as part of the proposed Medicines and Poisons Bill.	Status: IN PROGRESS — Delayed during the COVID-19 pandemic Under the Health (Drugs and Poisons) Regulation 1996, pharmacy assistants are currently not authorised to handle Schedule 8 drugs. The new Medicines and Poisons Bill 2019 was passed. The subordinate legislation is being drafted that will permit pharmacy assistants to participate in the receipt and stocking of scheduled drugs. However, the commencement of this legislation will be delayed by the COVID19 response.
Recommendation 5: The Committee recommends the Department of Health, in conjunction with the Pharmacy Advisory Council (if established), explore whether community pharmacy assistants and hospital pharmacy assistants should undergo the same	This recommendation is accepted in principle. Queensland Health will engage with relevant stakeholders to review training requirements for community and hospital pharmacy assistants.	Status: IN PROGRESS - Continuing during the COVID-19 pandemic A review of the education and training programs and requirements for community and hospital pharmacy assistants has been undertaken. A background paper and report on pharmacy assistant education and training is being drafted and will be distributed to internal and external stakeholders for consultation in May 2020.

Recommendation	Commitments in Government Response	Progress
basic mandatory training, and whether this would provide benefits to the community.		A final project report, including feedback from the consultation, will be completed by June 2020.
Recommendation 6: The Committee recommends the establishment of a Queensland Pharmacy Advisory Council to advise the Department of Health in its administration of the Pharmacy Business Ownership Act (PBO Act) and the fulfilment of its regulatory responsibilities. The Queensland Pharmacy Advisory Council would: • provide expert advice to the Minister on ownership and premises standards, and would enhance the department's capacity to proactively monitor and enforce the pharmacy regulatory environment; • comprise members appointed by the Minister with expertise in law, accounting, and business management and members representing the pharmacy sector and consumers; • be funded on a cost recovery basis by the pharmacy sector (that is, no costs to be borne by government); and • be consulted by the Department of Health on matters including, but not limited to, managing transfers of pharmacy ownership and changes to scope of practice for pharmacists and pharmacy assistants.	This recommendation is accepted in principle. The Minister for Health and Minister for Ambulance Services will appoint an Interim Pharmacy Roundtable prior to the formal establishment of the Queensland Pharmacy Advisory Council to allow a smooth transition. Queensland Health will act as the secretariat for the Interim Pharmacy Roundtable in the short term, and for the formally established Council in the long term. Queensland Health will coordinate meetings, arrange travel (if required), maintain records, manage correspondence, ensure compliance with relevant governance and reporting requirements, and any relevant business functions (such as budget management).	Status: DELAYED – subject to change in legislation - Impacted by the COVID-19 pandemic The establishment of a Queensland Pharmacy Council will require amendments to the PBO Act to provide the appropriate authorising environment and governance structure to support the council. The department has been working to identify what may be required to underpin the establishment of the Council and planning toward its implementation. The Minister for Health and Minister for Ambulance Services has appointed an Interim Pharmacy Roundtable. The Roundtable has held six meetings and is currently developing an advice paper on policy considerations for the regulation of pharmacy ownership in Queensland. Representatives from the New South Wales Pharmacy Council and the Victorian Pharmacy Authority have provided the Roundtable with an overview of their systems and the function of their Councils. Queensland Health has utilised the expertise of the Roundtable to inform the implementation of the Government's response to recommendation's 7, 8, 9 and 10 of the Pharmacy Inquiry. The planning of future Roundtable meetings is impacted by the COVID-19 pandemic. The Chair is in discussions with members on the approach going forward, including what can be progressed without face-to-face meetings. As the establishment of the Council is subject to legislative changes, it is anticipated that this may result in the delivery of the Government response to recommendation 6 being extended beyond three years. Timeframes are unknown at this stage.

Recommendation

Recommendation 7: The Committee recommends that:

- 1. the Department of Health's development and implementation of a risk-based strategy for testing that existing commercial arrangements for pharmacy ownership in Queensland comply with sections 139B, 139H and 139I of the *PBO Act* be limited to transfers transacted since 03 May 2016, being a period of two years prior to the date the inquiry was referred to the committee;
- 2. by 16 October 2019, 12 months from the tabling of the report, the department request a review by the Queensland Audit Office of the implementation of part (1) above of this recommendation together with compliance by the department with the agreed recommendations in the office's Report No 4: 2018-19 Managing Transfers in Pharmacy Ownership, and request that the Queensland Audit Office, pursuant to the Auditor-General Act 2009, table in the Legislative Assembly the report from its review, and
- within six months of requesting the review recommended in part (2) above of this recommendation, the department provide the committee a written update of the review.

Commitments in Government Response

This recommendation is accepted.

Queensland Health will review all current commercial arrangements of pharmacy ownership, and all transfer arrangements that are still current. Notifications for arrangements that are no longer valid (for example, if a pharmacy has subsequently transferred ownership), will be considered out of scope.

In direct response to the recommendations contained in the QAO's report, and in the context of the Committee's endorsement of those recommendations, Queensland Health will deliver:

- a published policy document clarifying the role and obligations of Queensland Health;
- re-designed internal controls that are mapped and documented to administer the PBO Act based on the roles and obligations of Queensland Health under the PBO Act. The effectiveness of these internal controls is subject to the limitations of the PBO Act;
- Pharmacy Ownership Business Rules (work instructions) to support policy and business processes documented;
- documented specifications for a suitable electronic decision support tool;
- a software development or procurement activity undertaken to establish the decision support tool;

Progress

Status: DELAYED - Impacted by the COVID-19 pandemic

The department commenced a review of all current commercial arrangements of pharmacy ownership. The inclusion of all current ownership arrangements in this review was to promote equity across the industry by ensuring that all pharmacy owners are subject to the same scrutiny and enforcement actions.

The PBO Act currently does not provide any authorisation for the department to compel pharmacy owners to provide commercial or transactional documents to the department for any reason, and pharmacy owners have no legal obligation to respond to the department's requests for documentation. The department was planning to write to pharmacy owners seeking voluntary participation. The department has suspended writing to pharmacy owners due to the impact of the COVID-19 pandemic on the pharmacy industry. Requests to pharmacy owners will recommence once the COVID-19 pandemic impact is averted.

The department has implemented enhancements to the Monitoring of Drugs of Dependence System (MODDS) to better support the existing notification system and address issues raised by the QAO in their audit report. These enhancements improve the quality of information collected on pharmacy business ownership structures and allows better detection of pharmacists that may hold undeclared ownership interests in a pharmacy through corporate or trust structures. These enhancements were implemented as a mediumterm solution only, as it is anticipated that MODDS will be decommissioned following the implementation of Queensland's real-time reporting system.

In direct response to the recommendations contained in the QAO's report:

Recommendation	Commitments in Government Response	Progress
Recommendation	 guidelines to support pharmacy owners and their agents through the re-designed notification process; amended notification form/s to support and align with the re-designed notification process; a compliance monitoring plan developed and implemented to support the ongoing monitoring of compliance with the PBO Act; long-term arrangements for the ongoing administration of the PBO Act identified and established within Queensland Health; request a review by the Queensland Audit Office by 16 October 2019; and within six months of the review, provide the committee with a written update of the review. 	 A policy document clarifying the department's role and obligations in the administration of the PBO Act was published February 2020; Queensland Health has re-designed its internal controls to expand its assessment of pharmacy ownership notifications against the requirements of the PBO Act; MinterEllison was engaged to produce a procedure manual to document the new processes. This manual is supported by written instructions and checklists; Notification forms to support the PBO Act administration were amended to align with the new processes. New Guidelines: Pharmacy Business Ownership in Queensland have been published to assist pharmacy business owners to understand how to comply with the regulatory framework in Queensland under the PBO Act. A suite of tailored notification forms is under development to improve usability. The department is establishing a monitoring and compliance program to review pharmacy ownership arrangements at regular intervals. The monitoring and compliance program will be supported by Memorandums of Understanding (MOUs) with both the Commonwealth Department of Health and the Pharmacy Board of Australia. The MOUs will allow the department to gain valuable information in relation to Pharmaceutical Benefits Scheme approval ownership information and pharmacists' registration details. Queensland Health wrote the QAO on 17 October 2019 requesting a review of progress against the QAO's recommendations. This request included a progress report and a list of issues impacting on Queensland Health's ability to implement the recommendations. The QAO responded to advise that they would undertake a follow-up audit of how Queensland Health administers pharmacy ownership legislation 12 months after new legislation has been in force. Queensland Health will be

Recommendation	Commitments in Government Response	Progress
		 providing QAO with an update in the impact of COVID-19 on the implementation of the Government response in due course. The department has commenced an ICT project to procure a fit-for-purpose system to support the administration of the PBO Act in the long term. When assessing potential IT solutions, the project will also ensure any suitable ICT solution is flexible enough to deal with any successive legislation. To date, all planning documentation has been completed / endorsed by relevant approvers and a procurement strategy is being developed.
		It is anticipated that this impact of the COVID-19 pandemic as noted above will result in the delivery of the Government response to recommendation 7 being extended beyond three years. Timeframes are unknown at this stage.
Recommendation 8: The Committee	This recommendation is accepted in principle.	Status: DELAYED – Impacted by the COVID-19 pandemic
recommends that the <i>PBO Act</i> be amended to enable the Department of Health to more effectively manage the pharmacy ownership notification process, including the establishment of offence provisions for breaches of s 139(I).	Queensland Health will facilitate the amendment of the PBO Act to more effectively manage the pharmacy ownership notification process.	The department commenced work to define policy positions regarding the amendment of the PBO Act to deliver recommendation 8. This work was carried out in consultation with the Interim Pharmacy Roundtable.
	Queensland Health will consider amendments to the PBO Act in relation to: the Queensland Pharmacy Advisory Council,	The Government Response to other recommendations will also be considered when proposing amendments to the PBO Act, which is likely to result in more extensive amendments.
	to provide an authorising environment for the establishment of the council, the appointment of members and its role and responsibilities (see Recommendation 6);	This work has been temporarily suspended as a result of the COVID-19 pandemic impacts. This will recommence once the COVID-19 impact is resolved. It is anticipated that this may result in the delivery of the Government response to recommendation 8 being extended beyond three years. Timeframes are unknown at this stage.
	 the mechanism through which the pharmacy industry will fund the Queensland Pharmacy Advisory Council (see Recommendation 6); 	extended beyond three years. Himeframes are unknown at this stage.

Recommendation	Commitments in Government Response	Progress
	 definition of terms not currently defined in the PBO Act to improve consistent interpretation by Queensland Health; 	
	offence provisions for breaches of section 139I of the PBO Act;	
	 enforcement and penalty options to enable more effective management of the pharmacy ownership notifications; 	
	Queensland Health's ongoing monitoring of compliance with ownership provisions;	
	 public reporting of pharmacists' compliance with pharmacy ownership legislation and compliance activities undertaken by Queensland Health in relation to this legislation (see Recommendation 10); and 	
	the development of a public-facing register of pharmacies and the services they provide (see Recommendation 11).	
	Queensland Health will seek to amend the PBO Act to introduce a licensing and registration scheme to support the regulation of pharmacy ownership in Queensland as is common in other jurisdictions.	
Recommendation 9: The Committee	This recommendation is accepted.	Status: DELAYED – Impacted by the COVID-19 pandemic
recommends that the pharmacy ownership requirements of the <i>PBO Act</i> be retained.		The department will seek to ensure that the pharmacy ownership requirements of the PBO Act will be retained in any new legislation.
	,	This work has been temporarily suspended as a result of the COVID-19 pandemic impacts. It is anticipated the program of works will recommence once the COVID-19 impact is resolved. It is anticipated

Recommendation	Commitments in Government Response	Progress
		that this may result in the delivery of the Government response to recommendation 9 being extended beyond three years. Timeframes are unknown at this stage.
Recommendation 10: Based on the findings of the audit by the Queensland Audit Office, the Committee recommends that the Department of Health improve transparency regarding the compliance of pharmacists with the PBO Act, the Health Regulation 1996 and the Health (Drugs and Poisons) Regulation 1996 by publishing its compliance audit results, at least annually.	This recommendation is accepted in principle. Queensland Health, will establish a temporary inspectorate to facilitate a baseline review of all pharmacies in Queensland over a three-year period, using a combination of physical and desktop inspections of pharmacies. Queensland Health will work with Hospital and Health Services to develop and implement a robust statewide compliance plan and associated public reporting. In conjunction with the Interim Pharmacy Roundtable or the Pharmacy Advisory Council (once established), Queensland Health will consider options for ensuring ongoing monitoring of pharmacies' and pharmacists' compliance with the PBO Act, the Health Regulation 1996 and the Health (Drugs and Poisons) Regulation 1996 (or equivalent) is sufficient to maintain public confidence in the pharmacy industry.	Status: DELAYED – Impacted by the COVID-19 pandemic The Department of Health has reviewed data sources to support greater transparency in reporting of compliance, in consultation with Public Health Units in all Hospital and Health Service Districts. Public compliance reporting published by other jurisdictions have also been reviewed to support the development of a reporting framework. A temporary inspectorate has been established in the Department of Health to conduct baseline reviews of all community pharmacies in Queensland. The Community Pharmacy Compliance Survey (CPCS), looks at high risk areas for diversion, including Schedule 8 medicines, and also provides a mechanism for raising awareness of upcoming changes to medicines regulation as a result of the Medicines and Poisons Act 2019 being passed late last year. The CPCS was developed in consultation with the Interim Pharmacy Roundtable. A public facing webpage was developed along with other educational support materials such as 'Frequently asked Questions' to raise industry awareness about the CPCS. The CPCS team commenced site visits in February 2020, with 39 completed as at 17 March 2020. Due to the increased pressure on community pharmacies caused by the COVID-19 pandemic the CPCS site visits have been temporarily suspended. The CPCS site visits will recommence once the impact of COVID-19 is resolved. It is anticipated that this will result in the delivery of the Government response to recommendation 10 being extended beyond three years. Timeframes are unknown at this stage. Note: The CPCS was in addition and did not replace the regulatory activities undertaken by the Public Health Units in all Hospital and Health Service Districts.

Progress Report on Delivery of Government Response to the Pharmacy Inquiry

Recommendation	Commitments in Government Response	Progress
Recommendation 11: The Committee recommends that the Department of Health investigate ways to improve communication to consumers about the services individual pharmacies provide such as vaccinations.	This recommendation is accepted. Queensland Health will deliver a public-facing website that lists pharmacies and the services they provide.	Status: DELAYED – Impacted by the COVID-19 pandemic The Community Pharmacy Compliance Surveys (rec. 10) will collect preliminary information on services offered by community pharmacies. This will inform the planning of any future public facing website of pharmacies and any community support services they provide such as vaccines. It is anticipated that this delay in delivery of the Government response to recommendation 10 due to COVID-19 pandemic will result in the delivery of recommendation 11 being extended beyond three years. Timeframes are unknown at this stage.