

Pharmacy Remuneration and Regulation Review

28 May 2018

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In brief

On 3 May 2018, the Federal Government released its highly anticipated response to the Independent Review of Pharmacy Remuneration and Regulation. The Government has accepted three of the 45 recommendations made by the Review on potential reforms to regulations for the dispensing of medicines by pharmacies and wholesalers under the Pharmaceutical Benefits Scheme (PBS).

This LegalTalk Alert explores the Government's responses to key areas including digital health, minimum service standards, location rules and the harmonisation of pharmacy legislations, and the impacts of these decisions on Australian individuals.

In detail

Overview of the Independent Review

The pharmacy industry is heavily regulated, with specific rules governing how pharmaceuticals can be dispensed. Some of these rules are determined in the Community Pharmacy Agreements (CPA), periodically entered into between the Federal Government and the Pharmacy Guild of Australia. The Sixth CPA commenced on 1 July 2015 and will conclude on 30 June 2020.

A feature of the Sixth CPA was a commitment to an independent review of pharmacy remuneration and regulation. The Health Minister appointed a panel of expert reviewers comprising Professor Stephen King, Ms Jo Watson, and Mr Bill Scott (Review Panel) in November 2015, and following extensive stakeholder engagement, the Review Panel issued its report (Review Report) in September 2017.

The Review Report made 45 recommendations focused on improving consumer access to reliable and affordable medicines. Some key recommendations include:

- reform of pharmacy location rules
- harmonisation of pharmacy legislation around Australia
- regulation of consumer pricing of PBS-listed medicines
- promotion of the use of electronic prescriptions and medication records
- mandating minimum service levels in PBS pharmacies, and
- banning the sale of homeopathic products in PBS pharmacies.

The Government accepted, to some degree, nine of the recommendations, rejected three and noted the remainder. A comparatively small number of the recommendations were the subject of outright acceptance or rejection however, the detail of the Government response may provide insight into the

future of pharmacy regulation and the future negotiation of the Seventh CPA. We explore below three key themes arising from the Review:

- use of automation in pharmacy
- changing role of community pharmacy, and
- legislative reform.

Use of automation in pharmacy

A key set of recommendations put forward by the Review Panel centred on the use of technology and automation to improve customer awareness and access to medicines. The Government has accepted, in principle, Recommendation 2-6 that an integrated system for electronic prescriptions and medicine records be developed, removing the need for a paper prescription.

The Government noted that an Electronic Prescribing Working Group is developing a framework, and \$28.2 million has been allocated to upgrading the e-prescribing system in the most recent budget. Importantly, participation in the system will be voluntary and doctors will retain full control over prescriptions.

The Government accepted Recommendation 2-7 that a central electronic medications record should be established, noting that the existing 'My Health Record' system allows health care recipients to register their health information and medications history with doctors and pharmacists, and that an estimated 98 percent of Australians will have a My Health Record by 2018.

The Government also referred to the Australian Digital Health Agency's initiatives in exploring the use of digital health programs such as medication monitoring systems to improve the safe use of medicines. There is potential for further developments as pharmacy IT providers such as the Fred IT Group develop real-time prescription monitoring products and services.

The Government's support for automation of pharmacy stopped short of trialling the use of machine dispensing in remote locations which did not have adequate access to community pharmacy, which had been suggested by the Review Panel in Recommendation 3-4. The Government rejected this recommendation on the basis that it might limit patient access to the necessary advice and support provided by pharmacists.

We recognise that industry participants are actively trialling machine dispensing technology and we expect that this will not be the final word on the matter.

Changing role of community pharmacy

The Review Panel put forward various recommendations aimed at developing more patient-focused and evidence-based pharmacy services. In particular, Recommendation 4-1 suggests a minimum set of services should be delivered by PBS pharmacies, and Recommendation 7-1 proposes a Community Service Obligation which requires PBS medicines to be available within 24 hours. The Government noted both of these recommendations. If implemented, the impact on the industry would be significant given the current lack of service standards adopted, aside from the Pharmacy Guild's Quality Care Pharmacy Program.

The Review Panel proposed that PBS pharmacies discontinue offering homeopathy services and the sale of homeopathic products in Recommendation 4-4, due to concern that consumers may interpret the sale of such products in a community pharmacy as an endorsement of efficacy (the 'halo' effect) where there may be a lack of evidence to substantiate efficacy. The Government did not accept this recommendation, but did confirm that consumers should be provided with information of all medicines and health care products stocked within community pharmacies.

The Review Panel made a number of recommendations in relation to the remuneration of pharmacists in Recommendations 5-1 to 5-4, although there was a split in the Review Panel with different members advocating different views. Ideas centred on comparison to best practice models and included:

- remuneration for dispensary activities in community pharmacies based on the activity and cost inputs as reported through pharmacy accounting data, and

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- remuneration based on reported cost inputs as well as maintaining a sustainable community pharmacy sector.
 - The Government noted these recommendations and indicated that it will work with the Guild and other stakeholders to determine the appropriate scheme of remuneration as part of the Seventh CPA, negotiation of which is due to commence by 30 June 2019.

Legislative reform

The Review Panel advocated reform of the Pharmacy Location Rules, which regulate the location of community pharmacies, in Recommendation 6-1. The Review Panel presented the view that the current location rules are anti-competitive, and that barriers to competition between pharmacies should be removed to ensure that consumers receive affordable access to medicines.

The Government has not adopted this recommendation and further noted that changes to location rules will require the express agreement between the Guild and the Government under the CPA. Therefore, location rules will remain, at least until the end of the Sixth CPA in mid-2020. The sunset provision in the National Health Act 1953 (Cth), which would have resulted in the expiry of the location rules, was removed in early 2018.

The Review Panel proposed measures to restrict concentration of ownership of pharmacies where this resulted in a substantial lessening of competition, relative to independent ownership, in Recommendation 6-2. The Government noted the recommendation but observed that ownership rules are a responsibility of State and Territory governments.

The Review Panel advocated harmonisation of State, Territory and Commonwealth pharmacy regulation in Recommendation 6-5. As part of this recommendation the Review Panel proposed that a single pharmacy regulator be adopted as a long-term goal, and suggested greater co-ordination between jurisdictions in the meantime. The Government supported this initiative but noted that it would be a complex process, requiring cooperation from all Government levels.

The takeaway

While a number of recommendations have the potential to result in significant change to the delivery of community pharmacy services in Australia, the Government is considering the options presented and is unlikely to change the existing model in the foreseeable future. The commentary provided by the Government does indicate a desire and willingness to take an evidence-based approach to the negotiations for the Seventh CPA which will start next year.

As we look ahead, it will be prudent for all community pharmacy stakeholders to invest in demonstrating the value they are delivering to the health system and the Australian population. This could include the adoption of new technology and digital health solutions, the breadth of professional services delivered through a pharmacy, and the products sold through pharmacies that improve consumer's health and wellbeing.

Let's talk

For a deeper discussion of how these issues might affect your business, please contact:

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