The Pharmacy Guild of Australia

5 October 2017

Red Tape Committee
Department of the Senate
PO Box 6100
Canberra ACT 2600

SUBMISSION: THE EFFECT OF RED TAPE ON PHARMACY

On behalf of The Pharmacy Guild of Australia (the Guild), I am pleased to provide this submission to the Red Tape Committee on 'The Effect of Red Tape on Pharmacy Rules'.

The Guild represents the owners of community pharmacies which are small businesses and provide a range of professional health services to the community. These owners of Australia's 5,700 community pharmacies need to strike a balance between running a successful small business and providing primary and preventative health care to their patients.

The Guild has been involved in several other small business reviews. This submission outlines the Guild's concerns about the effect of red tape on community pharmacy and their patients:

- **Retail Leasing**

  The community pharmacy sector is an industry where inflated occupancy costs are placing serious and detrimental pressures on pharmacy small businesses. Pharmacy is the largest single retail channel in Australia with in excess of 5,700 outlets, located in all forms of retail property. A high percentage of these are under retail lease. As a result, pharmacy owners have a limited ability to pass on fixed underlying costs such as rent because prices in the industry are largely regulated, in particular for dispensed items under the Pharmaceutical Benefits Scheme (PBS). This area (PBS) specifically relates to approximately 70% of the revenue for each business.

- **Workplace Relations Compliance**

  There is an increased compliance obligation on small businesses in relation to record keeping, employment arrangements and directors' liabilities are a concern. In addition, the highly complex and continuously changing industrial relations landscape places a significant burden on small business, with a high risk of inadvertent non-compliance. The rigidity and lack of flexibility in the industrial relations system discourages pharmacies from employing staff, which in turn can have an impact on both opening hours and levels of service, subsequently impacting patients.

  The current paid parental leave employer paymaster role has created an unnecessary burden on community pharmacy small businesses. Community pharmacy, as with many health care professions, attracts high numbers of women as both owners and employees. The high prevalence of women in our workforce, coupled with the employer paymaster role under the current PPL scheme, has resulted in an administrative and financial burden on the industry. The financial costs have been incurred primarily through administering payments, maintaining records, meeting compliance and reporting requirements and undergoing the appropriate system upgrades.

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- **Small Business Definitions**

  The lack of a standardised definition between Government regulators and departments has resulted in small businesses having to increase their understanding to ensure that they maintain their regulatory compliance obligations(areas such as taxation, industrial relations and consumer law are examples). As identified by the Australian Small Business and Family Enterprise Ombudsman (ASBFEO), there are an estimated 71 separate registers for which a small business could be obligated to maintain their registration.

  'Small Business' is defined differently by regulators in Australia depending on the laws they administer. For example, the Australian Taxation Office (ATO) defines a small business as one that has annual revenue turnover (excluding GST) of less than $2 million. The Fair Work Act 2009 defines a small business as one that has less than 15 employees. In addition, the Australian Securities and Investment Commission (ASIC) defines a small business with a turnover less than $25 million, fewer than 50 employees and consolidated gross assets less than $12.5 million, whilst the Australian Bureau of Statistics (ABS) has developed several reports based upon different definitions of small business.

- **Payroll Tax**

  The Guild would also like to highlight the issue for some of our members regarding payroll tax.

  Some community pharmacy owners may own pharmacies in different States and Territories and therefore have cross border compliance obligations that vary between their businesses. The variable rates of payroll tax (from 2.5% in South Australia to 6.85% in ACT) and the varying thresholds at which payroll tax applies are frustrating.

  Additionally, it needs to be recognised that payroll tax can be a disincentive which discourages businesses from employing additional staff. This is particularly the case if a small business is approaching a payroll tax threshold and this additional on-cost can be the deciding factor in whether to increase staffing levels or not. Unlike most businesses, the ability of pharmacies to defray these additional employment costs by absorbing them into the prices they charge for their products and services is severely limited as noted previously. As stated, this is because up to 70% of pharmacy remuneration is derived from the dispensing of government subsidised prescriptions. The Federal Government sets reimbursement prices for these medicines as well as the remuneration that pharmacies receive for dispensing them. It also sets the maximum co-payments that can be charged to patients.

- **Goods and Services Tax (GST)**

  The operation of the GST and the necessity to lodge Business Activity Statements (BAS) causes a red tape burden on community pharmacies as well as cash flow challenges. The way the GST system works means that medicines and other 'GST-free' items sold through community pharmacies only become GST-free at the point of sale. This means that pharmacies first pay GST to a supplier and claim back from the ATO via a BAS which is usually lodged monthly. For medicines, the higher its cost, the higher amount of GST that has to be paid to the supplier, and the greater the impact on cash flow. The ability for a pharmacy to claim and receive reimbursement for the GST component before the supplier's invoice is due to be paid directly affects the pharmacy's cash flow with other subsequent flow on effects (e.g. overdrafts). Additionally, the need for pharmacies to manage the bespoke GST arrangements that apply to medicines result in a significant increase in paperwork for no apparent benefit to their patients.

- **Medicine Recalls**

  A medicine is recalled from supply to the Australian market when there is an 'established deficiency in quality, efficacy or safety'. A recall might be initiated as a result of reports referred from a variety of sources including the manufacturer and the Therapeutic Goods Administration (TGA).

  The current process followed is largely defined by the Uniform Recall Procedure for Therapeutic Goods (URPTG), established by the TGA. This procedure describes the stages of recall, including notification, crisis management, information requirements, an assessment of strategy, class and level of recall, communications, responsibilities of sponsors and recall coordinators and follow-up actions.

  The recently updated URPTG explicitly outlines the roles and expectations of Health Professionals (including community pharmacists) in regards to safeguard patients during a recall. The document advises that health professionals need to follow a range of instructions including quarantining affected stock and notifying affected patients where applicable

The issues for community pharmacy in relation to medicine recalls include:

- the adequacy of information exchange with product sponsors and suppliers
- costs and logistics associated with recall processes
- timeliness of reimbursement of their expenses
- lack of payment for their role in providing community information and advice

There is also additional complexity when the recall involves a prescription medicine, such as what occurred earlier this year in relation to the recall of the product Valium ®. In this instance, the Guild contacted each State and Territory Health Department to seek clarification regarding a pharmacist offering the patient an equivalent generic product without the presentation of a prescription under the following scenarios:

- A. When the Valium product being returned was originally dispensed at that pharmacy; and
- B. When the Valium product being returned was not dispensed at the pharmacy

The responses from each of the Health Departments advised that the permitted course of action varied between the scenarios and across jurisdictions. The Guild encourages the development of standards for medicine recalls that reflect a defined role for pharmacies and provide a series of actions at the community pharmacy level that are predictable and able to be monitored. A uniform process to be followed for medicine recalls would maximise efficiency/simplicity, and ensure recall-related tasks were commensurate with any remuneration provided. Most importantly, it would ensure that patients benefit from a consistent approach across both individual recalls and pharmacies.

The Guild also believes that pharmacists should reasonably expect to be paid for the time and effort when they are asked to manage the process on behalf of the manufacturer. A system of payment to community pharmacies should be in place for participation in medicines recalls, such as:

- payment of an agreed fee by sponsors, based upon volumes of recalled products; or
- a single annual up-front payment financed by sponsors for participation in recalls by community pharmacies.

The payment would cover additional costs incurred such as:

- time associated with locating, packaging and returning recalled stock
- space allocated to store recalled stock
- time and the actual cost of examining the dispensing database to identify affected patients, phoning them and/or writing a letter to inform them the stock should be returned
- time and expertise in counselling patients about what to do next
- time taken to contact doctors to inform them that their patient may require replacement medication.

Recommendation: Improved communication and coordination between relevant stakeholders (e.g. TGA, medicine sponsor companies, state/territory health departments) and a standardised formal process for remunerating community pharmacies.

PBS Online

Pharmacists approved under Section 90 of the *National Health Act 1953* (hereafter referred to as community pharmacies) are entitled to dispense pharmaceutical benefits subsidised under the Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS).

As well as assisting the Government with prompt data collection, *PBS Online* has unquestionably improved the administrative efficiency of PBS and RPBS claiming and payments. Because PBS Online is the primary means for transmitting data between pharmacies and the Department of Human Services – Medicare (DHS) for the payment of PBS and RPBS claims, virtually 100% of community pharmacies are connected to PBS Online.

PBS Online is capable of confirming:

- the concessional eligibility of a patient
- 'Authority Prescription' eligibility
- conflict with the PBS Safety Net early supply rule[1]
- prescriber eligibility for a PBS prescription
- patient eligibility for urgent PBS Continued Dispensing supply by a pharmacist

However, despite the advantages provided by PBS Online, a number of administrative problems still remain with the administration of the PBS, increasing the red tape burden for community pharmacies. These problems are summarised below:

- **Retention of PBS and RPBS Records**

  In mid-2015, DHS introduced streamlined claiming for the PBS and RPBS. As part of the change, pharmacies were instructed that they were no longer to send in the hardcopy of their PBS/RPBS prescriptions but were to retain copies at the pharmacy for a minimum of two years. Subject to State and Territory laws, this could be as either a paper copy or electronic copy.

  While there was an improvement for pharmacies in the timeliness of payment of high-cost PBS/RPBS medicines and there was no longer postage costs associated with submitting claims, the change resulted in a cost shift from Government to community pharmacies. An analysis by the Guild in early 2015 estimated the average community pharmacy would be storing an extra 40 prescription storage boxes (37cm x 23cm x 15cm) by the end of two years. Based on pharmacy rental at the time of $700 per square metre, the cost to a pharmacy was estimated to range from $500 to $1000. At a midpoint of $750, this equals $4.1 million per year across all pharmacies for base rental cost only. It would be higher for an opportunity cost basis, and there would also be additional costs in the form of secure destruction on a rolling basis after the two year retention period.

  We note that this problem will be addressed once electronic prescriptions become the norm and there is no need for hard-copy prescriptions.

  Recommendation: The Commonwealth to work with States and Territories and relevant stakeholders to progress the implementation of electronic prescriptions in a way that maintains consumer choice.

- **Payment of concessional PBS prescriptions during PBS Online outages**

  Community pharmacies rely on the real-time feedback from DHS through PBS Online to confirm a claim for payment for a PBS prescription has been accepted. When PBS Online is not working, either from scheduled maintenance outages or unplanned outages due to system failure (whether at DHS, the pharmacy or the telecommunications provider), pharmacies do not receive this notification. Section 42 of the *National Health (Pharmaceutical Benefits) Regulations 2017* requires a pharmacist to collect and submit concessional details as part of a PBS claim. The person's status is confirmed by DHS and the pharmacy is provided with a claim acceptance. If a person's concessional status changes, they are informed by the Department of Social Services. Irrespective of the change in status, the person may still possess a concessional card which appears to be valid and current. If this is presented to a pharmacy and a prescription is dispensed as a concessional entitlement when there is no connection to DHS via PBS Online, the PBS claim will ultimately be rejected.

  A pharmacist can call the IME Helpline operated by DHS to confirm a person's entitlement, however this function interrupts the pharmacy's workflow and is impractical and onerous, particularly if the outage occurs at a busy time for the pharmacy and the pharmacist is expected to check the status for all concessional prescriptions being dispensed. Alternative options provided to pharmacists are to dispense concessional prescriptions as a general pharmaceutical benefit and issue a receipt to the patient to reclaim from Medicare or request the person returns to the pharmacy when PBS Online is reconnected.

  Both options are impractical and unfair for the majority of concessional patients who use their cards appropriately. The risks involved in delivering a public service has been completely transferred to the community pharmacy. In these circumstances and noting that the incidence of occurrence reported by DHS is very small, the PBS claim by the pharmacy should be paid and reclaimed from any patient fraudulently presenting a concessional card.

[1] http://www.pbs.gov.au/info/general/pbs-safety-net-pharmacist

Recommendation: All pharmacy PBS claims for concessional prescriptions to be honoured when a community pharmacy is not connected to PBS Online due to PBS Online outage and for which a seemingly valid concessional card has been presented with reclaims for fraudulent use made against the patient.

- **Standardised access to PBS medicines at the approved price**

The price a community pharmacist is paid for dispensing a PBS prescription consists of the relevant professional fees and Administration, Handling and Infrastructure (AHI) fee agreed between the Government and the Guild as part of the Community Pharmacy Agreements, and the approved Price to Pharmacist (PTP) reflecting the amount that a pharmacy pays for a PBS medicine. The PTP consists of the Approved Ex-Manufacturer Price (AEMP) agreed between the Government and product sponsor at the time of listing on the PBS and relevant mark-ups for the distribution by wholesalers. However, there is no guarantee that a pharmacy can purchase a PBS medicine at the PTP. As part of their deeds for receiving funding under the Community Service Obligation (CSO)[2], wholesalers agree to supply Section 85 PBS medicines at no more than the PTP, but the CSO deeds do not apply to pharmaceutical benefits exclusively listed under Section 100 of the National Health Act or exclusively under the RPBS. It is not uncommon for the Guild to be contacted by a member who has purchased a Section 100 PBS medicine or RPBS product to fill a prescription and found that they have paid more for the product than the price on which their remuneration is based. The Guild has several examples of members having dispensed these prescriptions at a loss, sometimes significantly. While the Department of Veterans' Affairs (DVA) has arrangements in place for pharmacists to reclaim any difference, this is onerous for the pharmacist. For Section 100 medicines, the options are to contact the product sponsor to see if an arrangement can be made or to make a claim through the Government's Act of Grace process[3], both of which are onerous for the pharmacy and neither guarantee success.

In addition, when a product is listed on the PBS, unlike the requirements that a CSO wholesaler must meet, there are few standards applying to product sponsors. Apart from PBS medicines being distributed through CSO wholesalers, there is little to ensure any of the following:

- that any Section 90 Approved Pharmacist can access any quantity of a PBS medicine
- that the cost to the pharmacy is no more than the approved PTP on which the PBS remuneration is based
- that the pharmacy can access the medicine within a guaranteed time period (ideally 24 hours)

With Direct Supply arrangements (e.g. Pfizer), community pharmacists rely on the company implementing standards equivalent or superior to that of the CSO wholesalers. The Guild is aware that Pfizer has implemented such arrangements and the Guild is regularly contacted by Pfizer to discuss any problems that may emerge. By contrast, there are some other Direct Supply arrangements which do not meet the same standards and which causes problems for pharmacists to access the PBS medicines for dispensing.

Recommendation: Irrespective of the whether direct supply or through wholesalers, the distribution of all pharmaceutical benefits listed on the PBS and RPBS should meet minimum standards equivalent to that for the CSO.

- **Inability to pass on surcharges**

Under PBS legislation, apart from the discretion to apply a delivery cost (e.g. postage) or a fee for dispensing a PBS prescription after the pharmacy has closed, an approved community pharmacist cannot charge a person more than the applicable patient co-payment (in 2017 this is a maximum of $38.80 for a general patient and $6.30 for a concessional patient exclusive of any applicable premiums). Unlike other businesses, a pharmacist cannot pass any additional costs on to their customers for pharmaceutical benefits. By contrast, the government agreed standards[4] to which pharmaceutical wholesalers operate under the CSO allow wholesalers to charge an additional fee for orders of high volume PBS medicines which do not meet the standard's Minimum Order Quantity or if delivery is required faster than the Guaranteed Supply Period (72 hours). Despite being discretionary, the amount that can be charged is uncapped being 'an additional amount deemed appropriate by the

[2] http://www.health.gov.au/internet/main/publishing.nsf/Content/community-service-obligation-funding-pool
[3] https://www.finance.gov.au/resource-management/discretionary-financial-assistance/act-of-grace-mechanism/
[4] Community Service Obligation Operational Guidelines; May 2017;
http://www.health.gov.au/internet/main/publishing.nsf/Content/community-service-obligation-funding-pool

[wholesaler] at their discretion for the increased service requirement'. While this arrangement was introduced ostensibly to improve the efficiency for ordering high volume medicines, it penalises a pharmacy when it is seeking to be responsive to unanticipated urgent PBS medicines e.g. when a patient is travelling or returns from a specialist and presents to a pharmacy with a prescription for a 'High Volume' medicine the pharmacy has never had need to stock. If the pharmacy needs a quantity less than the Minimum Order Quantity or delivery within 24 hours, it may have to pay an additional fee applied by the wholesaler. While the Guild is not aware of this fee being applied, it remains an option for wholesalers as their margins continue to be diminished. If such surcharging becomes commonplace, patients are likely to suffer as a result of slower access to these medicines.

As there are no similar standards to the CSO for which PBS product sponsors with Direct Supply arrangements must meet, these sponsors also have the ability to apply additional service fees at their discretion.

Recommendation: Irrespective of distribution arrangements, any additional service fees for the distribution of pharmaceutical benefits to community pharmacies should be capped at a reasonable level and community pharmacies should have the capability to discretionally pass on such costs.

- **Overnight Stock Devaluation**

  When PBS price reductions come into effect through price disclosure and other regulatory arrangements, manufacturers, wholesalers and pharmacies immediately experience a significant loss due to a reduction in the value of their inventory. Wholesalers have an incentive to keep stock levels to a minimum as more medicines come off patent and are affected by government price drops and pharmacists will also keep limited stock to avoid losing money on stock revaluations.

  While the Department of Health provides advance notification of impending price reductions to assist the supply chain to plan for and manage their stock holdings at the time these price reductions are implemented, this does not address the fact that under the 6CPA, community pharmacies are expected to hold sufficient PBS stock to meet community demand. With high cost medicines in particular, overnight price reductions can be to the value of hundreds of dollars and with many medicines, it is critical that the patient's therapy is uninterrupted. Examples of significant overnight price reductions are:

  - April 2017 – Enbrel (etanercept) $609; Orencia (abatacept) $916; Humira (adalimumab) $103
  - October 2018 – imatinib (all brands) $281, quetiapine (all brands/strengths) up to $30/pack

  Pharmacies have a duty of care to carry minimum stock levels which can significantly de-value overnight and this is particularly problematic when reductions occur on weekends or public holidays which delays the pharmacy from re-plenishing. As an example, the price changes for 1 October 2017 came into effect on the Sunday of a long weekend for many pharmacies. As a result, pharmacies were having minimal order replenishment from Friday 29th September until Wednesday 4th October. The fulfilment of pharmacy orders also requires the wholesaler to have stock to meet demand. Reductions in wholesaler inventory at the time of price reductions can also delay pharmacy replenishment.

  While manufacturers, wholesalers and community pharmacists may have informal arrangements to pass on reductions earlier to manage the impact on the day of effect, this is not standardised and varies between manufacturers, wholesalers and pharmacies with the larger corporate banner groups having the greater negotiating power. In the interests of patient care, the Guild believes the Federal Government must work with the whole PBS supply chain to better manage price reductions to guarantee continuity of supply and reduce the overnight impact of inventory devaluation.

  Recommendation: The Commonwealth to work with community pharmacies and relevant stakeholders to implement a staged application of price reductions to ensure continuity of supply for patients and minimise overnight stock losses for the medicine supply chain.

- **PBS Medicine Shortages**

  The Guild is increasingly hearing from its members about shortages of medicines and in particular, long-term shortages of PBS medicines. A study[5] by the University of Sydney noted that pharmacies in the community are experiencing shortages that are affecting their workload, affecting patient satisfaction, and pharmacists are struggling with the shortages.

[5] https://ajp.com.au/news/medicines-shortages-huge-impact-study/

When a PBS medicine is in short supply, pharmacists act to manage the situation as best as possible for their patients. This usually involves working with wholesalers and/or manufacturers to check on the availability of alternative brands, checking with other pharmacies for local availability, communicating with prescribers about product availability including alternative options, and organising patients for review by their prescriber when needed. For PBS medicines, it is particularly problematic when the base priced PBS item is unable to meet demand and pharmacists can only supply items with a brand premium which comes at a cost to patients and for which the pharmacy staff must often bear the brunt of patient dissatisfaction.

Accepting that it is improbable to completely prevent any medicine shortage, there needs to be arrangements in place that streamline the processes to manage the shortage and mitigate the impact on patients when they occur. This will require the cooperation of industry, pharmaceutical distributors, pharmacists, hospitals, prescribers, regulators and funders.

The Guild believes the management of medicine shortages can best be achieved by the Department of Health working with relevant stakeholders to develop and implement a strategy to proactively prevent and manage shortages, including:

- more rigorous and ongoing assessment of supply capabilities for newly listed products or brands
- a risk assessment of currently listed products to identify potential situations of greatest patient risk should a shortage occur
- flexibility in pricing to enable price increases if needed
- a more stringent approach with manufacturers repeatedly having long-term shortages
- removal of the Brand Price Premium for PBS listed items if base-priced generic alternatives are out of stock or unable to meet demand for extended periods.
- provision of more complete and timely communication about shortages to health care professionals to enable more effective patient support

Recommendation: The Commonwealth Department of Health to work with stakeholders to develop and implement a strategy to proactively prevent and manage shortages.

On behalf of the Guild and ultimately community pharmacies, we appreciate the opportunity to provide feedback related to Red Tape in our industry.

Regards,

David Quilty
Executive Director
Pharmacy Guild of Australia