

The Pharmacy Guild of Australia

Submission to the Regulation Taskforce

Reducing the Regulatory Burden on Business

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**The
PHARMACY
GUILD of
AUSTRALIA**

Contact

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Introduction

The Pharmacy Guild of Australia was established in 1928 and registered under the then Conciliation and Arbitration Act (now Workplace Relations Act) as a national employers' organisation. The Guild's mission is to service the needs of its members, who are the pharmacist proprietors of some 4,500 independent community pharmacies, which are small retail businesses spread throughout Australia. Almost 90% of all pharmacist proprietors are Guild members.

Community pharmacy makes a significant contribution to the Australian economy with an annual turnover of \$8 billion and \$200 million in tax revenue, employing some 15,000 salaried pharmacists and 30,000 pharmacy assistants. Through the Pharmacy Assistant Training Scheme, the Pharmacy Guild provides a significant career path for young Australians, particularly young Australian women.

The Guild aims to maintain community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicine management and related services.

Background

Pharmacists who are the proprietors of community pharmacies play a dual role in that they are health professionals at the same time as being small business retailers. This dual role means that they have to cope with a dual set of regulations.

The Pharmacy Guild and the community pharmacists it represents are not against regulations. In fact, we are strong supporters of the continuation of regulations which maintain the current system of pharmacist-owned community pharmacies which is based on a health-care rather than a retail model. Such a system provides the Australian community with an assurance that it is served by qualified and competent professional pharmacist practitioners who will protect their health interests.

Regulations Governing the Practice and Operation of Pharmacy

These regulations, which cover the way community pharmacy operates in terms of its ownership, standards of professional practice and the strict rules governing the scheduling of medicines and the dispensing and supply of these medicines to ensure their quality use by consumers, are contained in the State and Territory Pharmacy Acts and the Drugs, Poisons and Controlled Substances Acts.

These are also Commonwealth regulations which relate to the Commonwealth-funded Pharmaceutical Benefits Scheme (PBS) which is administered by community pharmacy. These regulations cover the location of PBS-approved pharmacies and pricing of PBS-subsidised drugs to ensure that consumers have equal access to these life-saving drugs no matter where in Australia they live and are contained in the National Health Act and its attached regulations.

The Guild strongly supports the retention of all of these regulations which provide community pharmacy with the certainty of a regulatory framework within which to operate and ensure that the public expectation of access of product and pharmacy service is met.

Government-Required Regulations

It is then necessary to look at the two other areas of regulations, outside of the above, which are imposed on pharmacy because of Government requirements. These fall into two categories: those which are health-related and are specific to pharmacy; and those which are general and which apply to the whole business sector.

With regard to the first category, the Guild recognises that these regulations are either essential for health and safety reasons or are required by Government to ensure there is not fraudulent use or misuse concerning the use by consumers of tax-payer funded Government programs such as the Pharmaceutical Benefits Scheme (PBS). With regard to the second category, we also understand the necessity of many of the general business-imposed regulations.

However, the imposition of regulations both on the health-care side, coming from Medicare Australia (formerly the Health Insurance Commission) and the Therapeutic Goods Administration (TGA) and on the business/tax side, creates costs for pharmacies and the Guild believes that the extent of these costs is often not fully appreciated by the various Government agencies involved.

Therefore it is important to recognise that while many of the existing regulations are essential and must be in place, they do impose a financial burden on a business, particularly a small business like a community pharmacy, and this needs to be acknowledged and addressed.

Another issue for consideration is the way in which a regulation is implemented and whether changes could be introduced to improve this process which might address the compliance issues with which a pharmacy is faced in meeting the Government's requirements.

To critically evaluate the various regulations which affect pharmacy, there are therefore three issues to consider:

- whether the regulation is absolutely necessary or whether it could be removed;
- where it is necessary, whether changes could be made to improve its implementation and thereby decrease compliance costs for the business;
- what the costs are to the business of dealing with the regulation and how these costs might be recognised and addressed to provide compensation to the business.

Health Related Regulations

The compliance burden on pharmacy is not simply driven by regulation; it is often a direct result of the administration of Government programs such as the Pharmaceutical Benefits Scheme. As stated earlier in this submission, these regulations, by and large, are required by Government to ensure there is not fraudulent use or misuse by consumers of tax-payer-funded Government programs such as the PBS, or because they are essential for health and safety reasons.

Medicare Australia and the PBS

For the most part the PBS regulations relevant to community pharmacists are administered by Medicare Australia. During the Third Community Pharmacy Agreement, the Guild and the Commonwealth (Department of Health and Ageing and the then Health Insurance Commission) undertook a review of PBS Regulations. The objective of the Review was ‘to ensure the regulations and their associated administrative arrangement are appropriate to current pharmacy and medical practice’.

In the Guild’s view there have been few tangible outcomes from this process. On the positive side, one or two regulations have been amended to streamline pharmacists’ administration of the Scheme. One example is a change that now allows a patient’s agent to sign the safety net application forms when the dollar threshold for concessionary or free status is reached. Previously only the patient’s signature was acceptable which in some circumstances was not practical, eg in nursing homes. On the negative side, the already extensive list of rejection codes (the multifarious reasons Medicare Australia has to refuse payment to pharmacists for claimable prescriptions) was *increased* in number following the review, despite a number of ‘reason codes’ being removed from the list, usually for redundancy reasons. The list of reasons for rejecting payment for prescriptions dispensed now extends well beyond 100. Moreover, a second list of ‘reasons codes’ has now been developed by Medicare Australia for those pharmacists who make their claims electronically via PBS Online.

Reconciliation Report

An added frustration for pharmacists is the complexity of the monthly ‘Reconciliation Report’ issued by Medicare Australia each month to approved pharmacists. This 36 page Report sets out the details of the prescriptions claimed, paid and rejected by Medicare by that pharmacist in the past month. However, as there is no separate list of prescriptions rejected, the pharmacist has to search through the list page by page to identify the rejected prescriptions so as to examine the feasibility of correcting the ‘error’ made in the claiming process, and resubmitting the rejected prescriptions for payment. A simple redesign of the Reconciliation Report would quickly overcome this source of difficulty and frustration for pharmacists.

An initiative announced in the May 2005 Federal Budget, and due to take effect on 1 January 2006, will undoubtedly cause much difficulty and angst in community pharmacies as well as considerable hardship for patients. The measure changes the regulations that apply to the '20 Day Rule'. This rule, first introduced some years ago, was intended to prevent hoarding and wastage of medicines by requiring a 20 day gap between separate dispensing of the same PBS medicine. The pharmacist has been able, until now, to exercise his/her professional judgement, and allow patients to have their repeat supplies within the 20 day period. This can be necessary where, for example, the doctor requires the medicine to be taken more frequently than normal, where the patient loses the prescription, or where the patient is travelling and has left their medicine behind.

From 1 January 2006, with the passage of the National Health Amendment (Budget Measures – Pharmaceutical Benefits Safety Net) Bill 2005, many patients seeking to have repeat supplies of PBS medicines within 20 days of a previous dispensing will either not have the item counted for their safety net or will be forced to pay at the higher level. That is, an additional \$24 for CN (concession) card holders and an additional \$4.60 for SN (safety net) card holders.

CN card holders are individuals or families who have a chronic health condition and spend more than \$874.90 and become eligible to receive medicines at the concessional rate. A SN card holder is an individual or family who has chronic health conditions and has had more than 52 prescriptions in a calendar year who then receive their medications for free.

These people are often the disadvantaged in our community.

- Implementation of the 20 day rule in nursing homes will be difficult, particularly with respect to maintenance of supply and packing more than one month supply in a dose administration aid.
- In rural and remote locations lack of regular access to pharmacies will mean people in rural areas may have to pay the full price or full general co-payment for medications as they often only go to town once a month.

The impracticality and unfairness of this measure is illustrated by the following examples:

1. A low income family that has reached their safety net limit and received a CN card and has an asthmatic child. The child may lose their asthma medication at school and could be on Ventolin, Seretide and Atrovent.

To replace the medication within the 20 days, the family would then be forced to pay \$85.80 instead of \$13.80 – additional cost of \$72. This is a massive impact on a family budget. In some families you can have more than one child, or the entire family, with asthma, which could make this expense even great.

2. A diabetic patient on Metformin, Ramapril and Atorvastatin who misplaced their medicines by leaving them in a holiday house or loses their luggage or misplaces their medicines for any other reason would again be faced with an additional \$72 payment if they required their medicines within 20 days.

3. Another Government health priority area is mental health and there are many in our society who, again if they lose or misplace their medicines for any reason, are required to pay additional amounts if they want their medicines within the 20 day period. An example could be a person suffering from schizophrenia on Zyprexa who would be required to pay an additional \$4.60 for this medicine. While this may seem a small amount, for the disadvantaged in our society this can be a considerable impost.

The Guild believes this measure is inherently unworkable and impractical for pharmacists, and unfair and potentially a health risk for patients who may require their repeat supplies of essential medicines within the 20 day period and cannot afford the additional cost that this measure imposes.

This is an example of where Government has decided to implement a new regulation without taking the time to consult and seek input from major stakeholders so that any negative impacts or unintended consequences of the change could be assessed and taken into account before making a final decision on whether or how the change might be implemented.

The PBS in Residential Aged Care Facilities

The regulations that govern the PBS were never designed to operate in the context of residential aged care facilities. Consequently, community pharmacies that service these facilities face innumerable problems in delivering the best possible care to the residents while trying to work within the restrictions of the regulations.

One of the most significant problems is dealing with a prescription for less than one month's supply of a medication. It is quite common for a doctor to write a prescription for either sleeping tablets or pain medication in a dosage that means the prescription will last less than a month. However, the facility will often require the pharmacy to provide one or even two month's supply of a medicine in a dose administration aid such as a Websterpak. To supply the facility with the medication for the patient, the pharmacist is forced to "bend the rules" and supply the medication on an "owing script" basis.

It is the community pharmacy which bears the administrative burden of following up with the doctor to obtain a written prescription so that the resident can receive medicines at the subsidised PBS price and so that there is continuity of the resident's medicine therapy. While it could be argued that the writing of the script is the doctor's responsibility, in practice it is the pharmacist who ensures that the system is maintained and the resident's dose administration aid continued to be filled.

A solution that the Guild has advocated for some time is for the medication chart kept in the facility to be considered a "prescription" in this context. This would immeasurably reduce the administrative burden on the nurses in the facility, the doctor and the pharmacist while also ensuring that the patient receives the medication they require in a timely manner.

This is a practical simple solution to a problem which currently causes enormous frustration and time wastage by those people – nurse, doctors and pharmacists – involved in the administrative process of supplying medicines to nursing homes. However, so far no steps have been taken by Government to address this issue.

Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration is involved with the regulation of medicines and devices to ensure that they are safe, of therapeutic value to consumers and are not advertised in a way which is misleading.

While the Guild recognises that these regulations are of course necessary, there is nevertheless a compliance burden on community pharmacy in ensuring that they observe them correctly.

Recall of Medicines

In the interests of public safety the regulations requires the sponsors of medicines to recall defective products. This may include cases such as suspected contamination associated with blackmail or hoax. The level of recall depends on the type of defect. Recalls to a consumer level may require community pharmacies to:

- determine which patients received the defective stock;
- mail out advice to individual patients;
- check stock holdings and quarantine defective stock;
- re-order replacement stock;
- receive medicines from the public;
- provide advice and discuss the issue with the public;
- replace or dispense the medicine at no charge to the patient or issue a refund;
- hold and/or return the defective stock for destruction; and
- claim the cost of refunds from the sponsor.

The Pan Pharmaceutical products recall is an example of the burden placed on community pharmacy. The regulator had very little information about which products were affected by the recall. Pharmacies were left to sort it out at a retail level.

There is a need to recognise the cost associated with this administrative burden and the time taken by community pharmacy to implement the requirements of medicine recalls in the interests of public health and safety. In the case of a recall, pharmacists are the ones who must deal face-to-face with the consumer and explain why a product is not available and try to organise an equivalent product to be provided. These exchanges understandably take a great deal of time and patience as it is the pharmacy that is often blamed by the consumer for the lack of availability of a product.

Scheduling Regulations

The regulation controls for medicines are designed as a risk-management system with medicines of higher risk requiring a prescription and those of low risk able to be supplied without a prescription. Controls are in place with respect to labelling, storage (access) and requirement for professional involvement.

The system generally works very well. However, the recent problem associated with criminals attempting to access pseudoephedrine medicines so that they can “manufacture” methamphetamine (speed) is an example of how the community pharmacy small business sometimes has to respond over and above the requirements of the regulations.

There has been no recognition of the additional costs associated with the extra checking of the bona fide nature of a pseudoephedrine request; for example, checking a photo identification, recording details of suspicious requests and advising police of suspicious requests.

The Pharmacy Guild of Australia has supported members with information and materials to assist them with these tasks and in an effort to ensure that the products are not removed from the market and therefore become unavailable to genuine consumers. To date, three projects at a value of \$1.14 million have been funded, almost entirely by the Guild, but this does not assist with the time and training costs associated with compliance with voluntary and regulatory guidelines.

It would assist community pharmacy to support Government policies more effectively if assistance in this area were provided by Government.

Advertising Regulations

There are regulations related to the advertising of health-care products. The regulations are important as they protect the public from unscrupulous operators who may mislead the public by making exaggerated and misleading claims about product effectiveness and safety.

The Therapeutic Goods Advertising Code, the Price Information Code and the Registering Authorities provide a framework to regulate the advertising of medicines and devices and the provision of price information for non-advertisable medicines. These requirements are additional to the requirements of the Trade Practices Act.

The Guild is supportive of these essential regulations as they are in the public interest and support Australia’s National Medicine Policy and Quality Use of Medicines.

However, the regulatory system around advertising is quite confusing and the majority of pharmacists and the public are not aware of how the advertising complaints system works. States and Territories have different health complaints mechanisms in place which although they may be integrated with local Registering Authority complaints processes, do not appear to be integrated with the national system for advertising complaints.

The system could be streamlined and there is a need for greater clarity and awareness of pharmacy’s obligations with respect to these regulations.

Business Regulations

Community pharmacies are, with few exceptions, small businesses and complying with endless Government regulations is certainly a major cost factor for pharmacist proprietors who must take this into account in assessing cost structures in their businesses and in employing additional staff. These regulations range from taxation and workplace relations through to superannuation, occupational health and safety, local government, planning and tenancy laws.

Taxation

Meeting taxation obligations, and specifically ensuring that all associated paperwork is prepared and lodged within the required time constraints, is probably the biggest area of regulatory burden for pharmacies, along with other small businesses.

GST

The introduction of the GST and the lodgement of Business Activity Statements (BAS) has massively increased this burden on business.

In the case of pharmacy, this has been exacerbated by the model which has been applied to collect GST on scheduled products sold in pharmacy which are all GST-free to the public and which comprise approximately 85% of all products distributed through pharmacies. The problem for pharmacy is that these products only become GST-free at the point of retail sale rather than being tax-free all the way through the supply chain. This means that the pharmacy has to pay the GST on these goods and then claim the tax back as an input credit, which in many cases is a quite substantial sum, from the Tax Office.

Therefore, unlike other small businesses, pharmacies are always in a negative cash-flow situation and this in turn creates a need to lodge **monthly** Business Activity Statements in order to retrieve the money paid out as soon as possible.

At any given time, the ATO owes pharmacies about \$45 million which could be described as a revolving credit of \$45 million at pharmacists' expense. On top of this is the **administrative** burden imposed by the GST and the need to lodge a monthly BAS. Community pharmacists cannot take advantage of the reduced administrative workload offered by quarterly returns, available to other small businesses which are in the reverse situation of needing to remit the tax to the ATO.

An independent study conducted in August 2001 by Sirianni International Pty Ltd confirmed our concerns about the significant administrative cost imposed on pharmacies when it estimated that an average of 18 hours per week is devoted to GST compliance. This may have decreased slightly since then as a result of point of sale systems being introduced into pharmacies, but the burden is still significant because of the fact that the returns need to be completed each month.

At the time when the GST was introduced, Treasury insisted on the need to have purity of the GST model. However, this purity argument vanished when ‘fresh food’ was deemed by Treasury to be GST-free right through the supply chain; ie, ex-farm rather than at the point of retail sale.

The current model in pharmacy is as inefficient as it is without purpose and it is time that it was revised, particularly when the system is causing extra work for both pharmacy and the ATO. The regulatory burden imposed by the current model in pharmacy means that resources are directed away from more productive functions of pharmacy such as looking after the health of the community.

The Guild can see no down-side for the Government in changing the arrangements for the handling of GST-free products in pharmacies so that community pharmacy is not disadvantaged in this way. In fact, it seems to the Guild that there would be some advantage to Government as a result of the savings in administrative costs to the Australian Taxation Office if the 4,500 pharmacies who are currently lodging their BAS twelve times per year were able to reduce this to four times per year.

Recommendation

- That the Taskforce recommend to the Government that this model be changed so that pharmacy products which are GST-free to consumers, be GST-free prior to entering community pharmacies, rather than have the pharmacies collect the GST and remit it to the ATO. This would mean the tax would be collected and remitted earlier in the supply chain, either by the manufacturers or the wholesalers.

Proposed Implementation of Recommendation

The Guild has been advised that to change the collection point to earlier in the supply chain would require a change in the legislation and there has so far been a reluctance by Government to do this.

One option which perhaps could be considered, although it has not been examined in any detail at this stage, is that wholesalers, or manufacturers where they supply direct to pharmacy, be nominated as the **tax** agents of community pharmacies, in regard to the collection of GST on products which are GST-free to consumers.

As tax agents, the wholesalers/manufacturers would withhold the GST component for these products when invoicing pharmacies and would pass that amount to the ATO. The pharmacies would no longer be responsible for making the GST payment to the ATO as the wholesalers/manufacturers would do it on their behalf and then claim it back.

It is understood that the model would be similar to that which applies in the building industry under the Prescribed Payments System whereby builders withhold tax on behalf of their subcontractors.

The outcome of this proposal would meet the Guild’s objective but we understand would not require any legislative changes.

Conclusion

In concluding, it should be stated that the Pharmacy Guild supports the position taken by the Australian Chamber of Commerce and Industry when it states, in its media release of Wednesday 9 November, that “The most effective way to relieve the impact of regulation does not necessarily involve a radical overhaul of the current system. Instead what is needed is far greater vigilance on the part of government to enforce the checks and balances that are currently part of the regulatory structure.”

We therefore support the ACCI recommendations contained in its submission and detailed in its media release as follows.

- 1) The Prime Minister will table in Parliament an annual regulatory budget that provides a cost and benefit analysis of all business-related regulations. Measuring the cost of regulation is the first step in controlling its growth;
- 2) All regulatory budgets delivered by the Prime Minister must be placed on a centralised website. This will help to inform the public of the amount of regulation being created and the amount of regulation it is required to comply with;
- 3) The Office of Regulatory Review will be moved from the Productivity Commission to the Department of the Prime Minister and Cabinet. The new body, to be known as the Prime Minister’s Regulatory Reform Unit (PMRRU), will be headed by a Chief Executive chosen from the business community;
- 4) A modelling unit located in the Productivity Commission will be created to develop a standardised costing tool to be applied to all new regulatory proposals. Line departments will be required to apply this costing tool to objectively measure the compliance costs of their regulatory bids; and
- 5) Regulation that does not pass the Regulatory Impact Statement (RIS) process as determined by the PMRRU will not be allowed to proceed.