SUBMISSION BY
THE PHARMACY GUILD OF AUSTRALIA
TO THE PRODUCTIVITY COMMISSION

ANNUAL REVIEW OF REGULATORY BURDENS ON BUSINESS –
MANUFACTURING AND DISTRIBUTIVE TRADES

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1. THE PHARMACY GUILD OF AUSTRALIA

1.1 The Guild is a national employers' organisation registered under the *Workplace Relations Act 1996*, which functions as a single legal entity rather than a federation. It was first established in 1928 and currently has Branches in every State and Territory.

1.2 The Guild's members are the pharmacist proprietors of some 4,500 community pharmacies, which are small retail businesses operating throughout Australia. Almost 80% of all pharmacist proprietors are Guild members.

1.3 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 32,000 pharmacy assistants.

1.4 Through the Pharmacy Assistant Training Scheme, the Pharmacy Guild provides a significant career path for young Australians, particularly young Australian women.

1.5 The Guild's mission is to service the needs of proprietors of independent community pharmacies.

1.6 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. A range of services are provided to members including:

(a) to negotiate an ongoing Agreement between the Government and the Guild to facilitate suitable conditions for approved pharmacies to dispense under the Pharmaceutical Benefits Scheme (PBS), including an appropriate level of remuneration;

(b) to maintain close liaison and negotiation with governments, manufacturers, wholesalers and other organisations involved in the health care delivery system;

(c) to implement strategies to enhance the professional role of pharmacists and to assist community pharmacists practising in rural and regional areas of Australia to ensure that the current network of community pharmacies in Australia is maintained; and

(d) to provide economic and management information to community pharmacists to assist them in making their pharmacies more efficient.

2. OPERATION OF HEALTH RELATED REGULATIONS

2.1 The list of issues contained in the *Issues Paper* for this reference relating to pharmacy[1] draw heavily on subjects discussed in the Regulation Taskforce's *Rethinking Regulation* report[2], to which the Pharmacy Guild made submission (the earlier submission).

2.2 In the earlier submission, the Guild made a number of observations that were discussed in the *Rethinking Regulation* report.[3]

2.3 This current submission constitutes an update on the issues raised in the paper.

2.4 They are:

THE SAFETY NET 20 DAY RULE

2.5 As the Guild said in its earlier submission:

> 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 judgment, 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 traveling and has left their medicine behind.
>
> 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 greater.

[1] Productivity Commission *Annual Review of Regulatory Burdens on Business Manufacturing Sector and Distributive Trades – Issues Paper* February 2008

[2] *Rethinking Regulation – Report of the Taskforce on Reducing Regulatory Burdens on Business* – January 2006, in particular recommendations 4.13-4.16 pp. 28-29

[3] Pharmacy Guild of Australia *Submission to the Regulation Taskforce Reducing the Regulatory Burden on Business* November 2005

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.

2.6 The Guild again reasserts its observations made in its 2005 submission.

2.7 As COAG has said:

> Regulation should be designed to have minimal impact on competition. Although it may be necessary, for example, to regulate some aspects of commercial practice, regulation should avoid imposing barriers to entry, exit or innovation. To meet the requirements of National Competition Policy, regulation should not restrict competition unless it can be demonstrated that:
>
> - the benefits to the community from a restriction on competition outweigh the costs; and
> - that the objectives of regulation can only be achieved by restricting competition[4].

2.8 Whatever savings are made by the Government from the implementation of the 20 day rule, they are significantly and negatively affected by the potential for misadventure and hardship, such as those cited in the Guild's previous submission.

Recommendation:

That The Pharmacy Guild of Australia and the Federal Government work in cooperation to ensure that the savings gained from preventing the hoarding of medicines, outweigh the cost to individual consumers who may suffer hardship as a result of the rule.

THE PBS IN RESIDENTIAL AGED CARE FACILITIES

2.9 The Guild said in its earlier submission:

> 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 facilitates 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

[4] Council of Australian Government *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies* p.5

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 continues 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 and 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.

2.10 As part of the Fourth Community Pharmacy Agreement, the Guild and the Commonwealth agreed to undertake a review of the existing PBS supply arrangements in the context of aged care residential facilities and private hospitals. The objectives of this review are to:

- Identify and address areas within PBS supply to aged care residential facilities and private hospitals which may achieve better productivity and efficiency, whilst maintaining Quality Use of Medicines, and reflecting the role of community pharmacy; and

- Consider and provide options, which may include, but are not limited to:

    - Changes to the National Health Act 1953 and relevant legislation aimed at improving the efficiency and effectiveness of PBS supply (including through community pharmacy) to aged care residential facilities and private hospitals; and
    - identification of new models of PBS supply to aged care residential facilities and private hospitals.

2.11 The Review will be overseen by Guild and Department of Health and Ageing representatives but will be facilitated by an independent consultant. This consultant has been selected but not yet formally appointed. It is anticipated that the Review will be completed by June 2008.

Recommendation:

That the review of the existing PBS supply arrangements in the context of aged care residential facilities and private hospitals proceed as planned. However, with regard to the above issue, rather than waiting for the outcome of the review, the Government separately and immediately address this issue as proposed.

ADVERTISING

2.12 In its earlier submission, the Guild said:

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.

2.13 The Guild has been working with the Therapeutic Goods Administration, through comments on proposed regulatory instruments such as the *Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule 2006*

Recommendation:

That the Guild continue working in cooperation with the Therapeutic Goods Administration on regulatory instruments in order to simplify the regulations governing the advertising of medicines, and render them more uniform, as well as to simplify the complaints system associated with this.

TRANS-TASMAN REGULATORY SCHEME FOR PHARMACEUTICALS

2.14 On 16 August 2007 the New Zealand Government announced it did not have a parliamentary majority necessary to create the joint authority.

2.15 The governments of the two countries are still working on how to progress the project.

2.16 The *Rethinking Regulation* report contained these recommendations:

> 4.17 The Australian Government should ensure that the regulatory framework and supporting legislation for the Australia New Zealand Therapeutic Products Authority are developed and implemented in accordance with the principles agreed by COAG for good regulatory practice, particularly in relation to industry consultation.
>
> 4.18 The Australian Government should improve existing domestic regulatory arrangements for therapeutic products and medical devices, particularly by rationalising amendments to the Therapeutic Goods Act, together with the supporting orders, codes, standards and determinations and guidelines issued by the Therapeutic Goods Administration, and removing requirements specific to Australia unless they can be fully justified.

2.17 The Guild hopes that the two governments follow these recommendations if and when the ANZTPA concept is revived.

Recommendation:

That the Government be urged to follow the recommendations of the Rethinking Regulation report if and when the ANZTPA concept is revived.

3. OPERATION OF TAXATION RELATED REGULATIONS

GOODS AND SERVICES TAX

3.1 The Guild said in its earlier submission:

> The introduction of the GST and the lodgement of Business Activity Statements (BAS) has massively increased this burden on business.
>
> **Current model for GST-free scheduled products creates unnecessary regulatory burden for pharmacy**
> 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.
>
> 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.
>
> **Proposal to change model to reduce regulatory burden**
> 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.

3.2 The cost and inconvenience to pharmacists remain. The Guild reiterates its recommendation, and asks that GST legislation be revised accordingly.

Recommendation:

As previously recommended, that the Government examines ways of collecting the GST on scheduled products – which are GST-free to consumers – before it reaches the retail stage. This would dramatically decrease the administrative burden both on pharmacies, and also on the Tax Office.

4. RECOMMENDATIONS

THE SAFETY NET 20 DAY RULE

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