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Senate Standing Committees on Community Affairs
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5 August 2011

Special arrangements for supply of Pharmaceutical Benefits Scheme (PBS) medicines to Remote Area Aboriginal Health Services

Submission from the NPSA (National Pharmaceutical Services Association) representing Full Line Pharmaceutical Wholesalers

The National Pharmaceutical Services Association (NPSA) represents Australia's national and state based full line wholesalers. They deliver all medicines to all pharmacies and they ensure that pharmacies can provide the full range of PBS medicines to consumers across Australia when their doctor prescribes them.

Nearly 5000 pharmacies across Australia, including rural and remote pharmacies, depend on full line wholesalers for full line supply of medicines.

The CSO, which was agreed between the Government and the Pharmacy Guild of Australia in November 2005, is funded by the Government to:

- Ensure that all community pharmacies are able to obtain **timely supply** of the full range of PBS medicines; and
- Ensure all Australians have **timely access** to the PBS medicines they require.

Wholesalers are eligible to access the CSO Funding Pool if they demonstrate they meet specified service standards, including distribution and supply of the full range of PBS medicines **generally within 24 hours**. The CSO Funding Pool remunerates pharmaceutical wholesalers for the additional cost they incur in providing the full range of PBS medicines, as compared to those wholesalers, manufacturers and suppliers who distribute and supply a lesser range of PBS products.

Submission Summary

- This submission addresses the following Terms of Reference for the Senate Community Affairs Committee ***Inquiry into the special arrangements for supply of Pharmaceutical Benefits Scheme (PBS) medicines to Remote Area Aboriginal Health Services:***

The effectiveness of the special arrangements established in 1999 under section 100 of the National Health Act 1953, for the supply of Pharmaceutical Benefits Scheme (PBS) medicines to remote area Aboriginal Health Services, with particular reference to:

- (h) access to PBS generally in remote communities; and
- (i) any other related matters.

- The NPSA's chief concerns relate to the continuing capacity of pharmacies in remote areas to easily access the full range of PBS medicines within 24 hours and, indeed, the continuing viability of some remote community pharmacies and the services which depend upon them.
- Nearly 5000 pharmacies across Australia, including rural and remote pharmacies, depend on full line wholesalers for full line supply of medicines.
- Their capacity to do this is highly dependent on:
 - the CSO arrangement which underpins the wholesalers' ability to meet the time and location arrangements and to supply all PBS medicines at or below the approved price to all pharmacies within 24 hours.
- The continued efficient distribution of PBS medicine in Australia is now under threat as a result of:
 - the impact of a series of PBS pricing reforms which have significantly cut the wholesale margin funding available for PBS supply, and
 - the emergence of exclusive distribution arrangements (which are not bound by the conditions of the CSO) created by the largest supplier of PBS medicines. This arrangement not only prevents wholesalers from meeting their Community Service Obligations to stock and distribute all PBS medicines, but undermines the viability of the wholesalers' operations and therefore the viability of the CSO. If other large suppliers of PBS medicines enter into similar monopoly supply arrangements – as was the case in the UK, – then the high cost CSO services will become significantly more expensive to provide.

- Without the CSO, the Government will not be able to uphold one of the four central objectives of National Medicines Policy: i.e., “timely access to the medicines that Australians need, at a cost individuals and the community can afford.”
- This will affect all pharmacies regardless of their location, but especially remote pharmacies and other health organisations within remote regions which rely on the timely and affordable delivery of medicines through pharmacies.

Recommendations:

The NPSA asks the Committee to:

- Note that the CSO arrangements are vital to timely delivery of PBS medicines to remote areas;
- Note the fragility of the current CSO PBS medicines distribution arrangements;
- Note the significance of these arrangements to remote pharmacies and the health services which are dependent on them; and
- Support the call of the NPSA wholesalers, pharmacists and patients for an amendment to the National Health Act 1953 to prohibit exclusive supply of PBS medicines by manufacturers to community pharmacies.

1. Rationale for and terms of the Community Service Obligation (CSO) on wholesale distributors

- 1.1** In 2006 the Australian Government established a Community Service Obligation (CSO) funding pool to ensure that every Australian would have timely access to the full suite of PBS medicines, irrespective of where they live.
- 1.2** This intervention was and is necessary because market forces would otherwise erode these objectives and put timely supply of medicines at risk.
- 1.3** PBS medicines vary across a spectrum of profitability and distribution frequency (noting the links between the two). Data provided by NPSA members indicate that, under current distribution arrangements, around 50% of PBS-listed medicines are unprofitable to deliver. Furthermore, the data suggest that 80% of the drugs on the PBS collectively account for less than 10% of sales; and are ordered as single doses on average less than once per month. The incentives to supply medicines at the low-volume, low-margin end of the spectrum – particularly in rural and remote communities – are weak.
- 1.4** It was in order to resolve this tension between securing timely access to medicines for all Australians and market forces that the Government agreed to provide funding to ensure that the distributors of medicines could and should meet the following standards of service:
- supply any community pharmacy within their national or State-based CSO jurisdiction;
 - supply any brand of any PBS medicine (as defined under the CSO) on request;
 - maintain specified stocks of PBS medicines;
 - supply PBS medicines at or below the approved price to pharmacy;
 - supply PBS medicines generally within 24 hours of order being lodged;
 - make available a daily delivery service to community pharmacies within their CSO jurisdiction as part of the standard service delivery infrastructure;
 - supply rural and remote pharmacies; and
 - supply low volume PBS medicines.
- 1.5** In Australia, there are three national CSO Distributors with warehouses geographically distributed across Australia. They commit under Deeds of Agreement with the Federal Government, with few exceptions, to be able to supply all pharmacies in a State or across Australia with any PBS medicine within 24 hours. They represent a significant investment in the infrastructure which underpins Australia's community pharmacy network. Together they create a robust system of back-up supply and redundancy for times of patient crisis and when Australians need to cope with natural disaster, such as during the recent

Queensland floods. This is a key feature of the CSO model that cannot be relied upon under exclusive distribution arrangements.

1.6 This arrangement has worked very well for pharmacies and their patients. It has ensured that all pharmacies, regardless of their location, receive the medicines their clients require within 24 hours. The fact the wholesalers are required to stock a full range of medicines provides system redundancy for when the stocks of another are low.

1.7 Pharmacists order Section 85 drugs to supply to Aboriginal Health Services. These are usually supplied to remote pharmacies under the S100 Aboriginal Health Services Remote Access Program for on-supply and attract the standard wholesale fee. Supply to these communities is underpinned by the CSO arrangements that ensure timely supply of the full range of Section 85 medicines to all pharmacies in Australia.

2. The importance of the CSO to remote communities

2.1 The services full-line wholesalers offer under the CSO obviously benefit all pharmacies, but they are particularly important to pharmacies serving remote communities. Not only do they ensure the timely arrival of all available PBS medicines – an important concern when patients may have to travel considerable distances to access their medicines and when there is no alternate provider within the region – but they also offer a standard, uncomplicated, stand-alone process for procuring supplies. This is very important to pharmacies relying on locum pharmacists and temporary pharmacy assistants who simply don't have the time to familiarise themselves with unfamiliar and diverse ordering systems in addition to local peculiarities and patterns of medication demand. As one Alice Springs pharmacist interviewed in the course of developing this submission put it: "Without the CSO and our full-line wholesaler we would be in a mess".

2.2 The value of the CSO arrangements to remote communities is demonstrated by as the case studies below.

Box 1 – Remote case study

Example 1: Northern Territory Very Remote Pharmacy:

- Gove Pharmacy is located in Nhulunbuy, East Arnhemland. The town has a population of 4000 and a significant population of Indigenous people living in remote communities scattered around the region. The pharmacy is 700 km away from the nearest approved pharmacy on a road that is only accessible during the dry season.
- To supply a full range of PBS items from the dispensary, this pharmacy relies on the support of their full-line wholesaler. Although there is up to a 2 week wait for front shop and bulk supplies - PBS items not stocked within the dispensary can be delivered within 24 hours of placing an order. These orders are air freighted into Gove. This service enables the provision of acute and chronic medications in a timely fashion to the residents of the town and to the Indigenous health services that the pharmacy looks after.

Box 2: Remote case study

Example 2: NSW Remote Pharmacy:

- Located in Bourke, 360km from the nearest regional centre, and services a population of approx. 4500 spread over 50,000 kilometres.
- Provides a daily backup supply of medicines to the local hospital local health Aboriginal Health Service, 'Primary Care' (Mental Health, Drug & Alcohol, Diabetes Education, Community Nursing, etc.), Opiate Dependence and Aged Care programs.
- Carries about 900 PBS lines and does an average of 140 prescriptions per day.
- Virtually 100% of dispensary medicines are delivered daily via overnight road transport from a wholesaler warehouse at Orange.
- Forty percent of prescription drug supplies are unpredictable as a result of:
 - high levels of acute and poorly-controlled chronic illness in what is a very socio-economically disadvantaged population;
 - constantly changing prescribing patterns due to the heavy local reliance on locum doctors who change frequently and the fact that 100% of specialist medical services are delivered by 'fly-in-fly-out' doctors who also change frequently;
 - variable daily script volumes due to variability of available medical workforce;
 - travelling patients;
 - changing antibiotic resistance.
- It is very expensive for wholesalers to maintain a reliable supply chain to this pharmacy.
- The viability of this business depends on subsidised delivery and a reliable daily service which can be made available through CSO arrangements.
- The capacity of local health services to deliver treatment is largely dependent on the pharmacy.

2.3 The value of the CSO arrangement was also well illustrated during the Queensland natural disasters which tested the ability of Australia's medicine supply chain to supply medicines to patients. Fortunately multiple supply options for pharmacies throughout the impacted area were available via the three national CSO distributors. They worked together to meet the needs of the impacted communities and they had staff looking at ways to reach pharmacies that could not be accessed by any CSO distributor. This was a very real example of how the system operates.

2.4 It should also be understood that wholesalers provide a great range of services to pharmacy beyond just delivery. As one sector commentator has noted:

"The fact is that wholesalers are the life blood of pharmacy. They don't just distribute products, they manage brands, advertising, systems support, payroll, merchandise services, funding guarantees, property negotiations, refits, staff training and general business strategy and advice." Stephen Greenwood, *Australian Journal of Pharmacy*, February 2011.

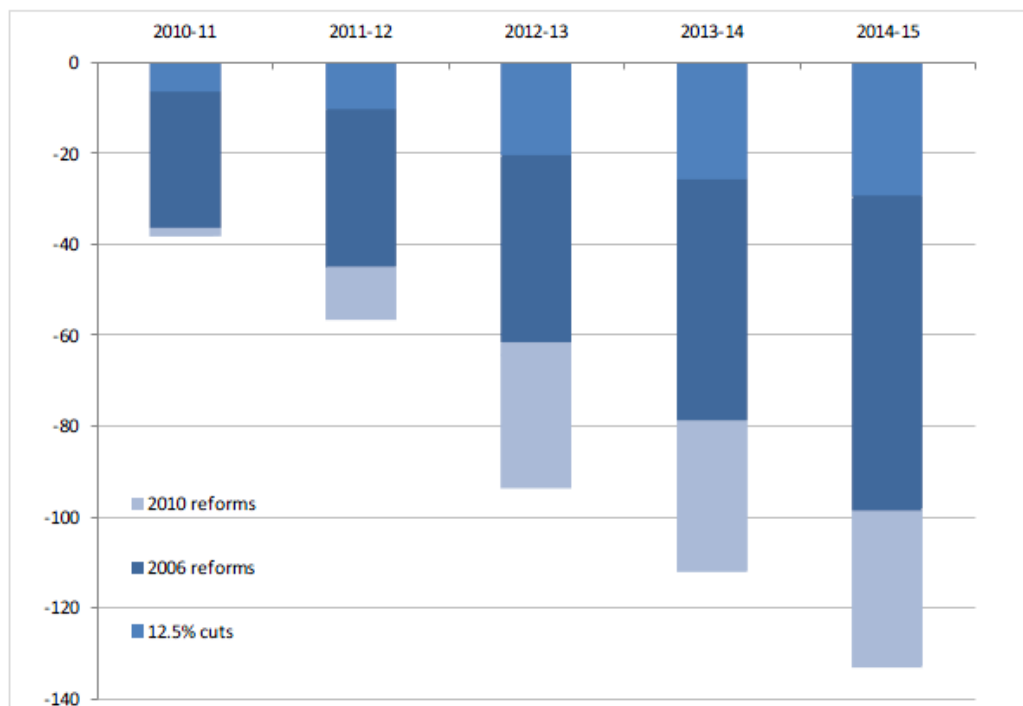
3. Why is the CSO under threat?

3.1 The viability of the CSO arrangement has come under threat from two sources.

3.2 Cumulative Impact of PBS Reform

- Under the Community Pharmacy Agreement, 3% of the wholesale margin was removed from pharmaceutical wholesalers and a portion of that savings was put into the Community Service Obligation fund (CSO). Wholesalers had to sign up to the CSO fund in order to access a share of the fund and participation was based on the basic principle that medicines had to be available within 24 hours anywhere in Australia. The wholesale margin was set at 7%.
- In 2006, the Government introduced PBS Reform - which introduced price reductions and price disclosure so that the price the Government pays for PBS medicines more closely reflects the actual price at which medicines are being sold by pharmacies. The National Health Amendment (PBS) Bill 2010 introduced further PBS price reductions agreed in a Memorandum of Understanding between the Australian Government and Medicines Australia (MA) announced in the 2010 Federal Budget. NPSA was not a party to these negotiations.
- With the wholesale margin remaining constant at 7%, when the price of a PBS medicine is reduced, the dollar value of the wholesaler mark-up is automatically reduced.
- The figure below illustrates an aggregation of the impacts on wholesaler earnings across these PBS reforms since 2005. Deloitte Access Economics estimates that the combined annual revenue loss to wholesalers, resulting from PBS reform, will be \$38 million in 2010-11 rising to \$133 million in 2014-15. This is equivalent to 1.5 percentage points of the 7% wholesale margin or around three-quarters of the current EBIT margin of the CSO Distributors.

Projected cumulative impact on wholesaler earnings from PBS reforms[^]



Source: Deloitte Access Economics based on analysis undertaken by Victoria University, Illuminate Health Consulting and PricewaterhouseCoopers

[^]Gross impacts: offsetting effects of the additional PBS reform-related CSO funding are not captured

- In its submission to this Inquiry the Pharmaceutical Society of Australia (PSA) expressed concerns about the continuing viability of wholesaler depots serving remote communities:

“With the reduction of pharmaceutical wholesale margins, rural pharmacies are worried that wholesalers will close a number of their regional depots, resulting in delayed delivery times for medicines and pharmacies being forced to increase stockholdings of medicines and thus become less financially viable as businesses”.

- This is an entirely valid concern.

3.3 The emergence of exclusive supply arrangements by manufacturers

- In January 2011 the biggest supplier of PBS medicines in Australia decided to by-pass the CSO distributors and deliver direct to pharmacies; awarding **exclusive distribution rights** to a mainstream global logistics company that does not commit to the CSO service standards.
- Since the implementation of exclusive distribution arrangements in Australia, more than 1,500 pharmacists are reported to have expressed their concern and patients have experienced unacceptable delays in the delivery of their essential medicines.
- The attachment to this submission (*under separate cover and to be held in confidence*) provides a collection of emails from pharmacies from across Australia detailing the nature of the problems they have had with the exclusive direct distribution model – many of which relate to the failure to deliver essential medicines within an acceptable timeframe.
- A particular problem reported by remote pharmacies is the complexity of different ordering procedures which have resulted from the exclusive direct distribution model. Anticipating supply requirements can be a complex business, particularly when pharmacy staff need to take into account different timing and processing protocols and different payment arrangements for particular brands. Remote area pharmacies tend to have high staff turnover and rely on temporary staff placements. The task of constantly retraining and accustomising staff to dealing with separate ordering arrangements has been difficult enough with the entry of one new distinct supplier. The prospect of dealing with multiple suppliers is truly daunting.
- The PBS medicines now subject to exclusive distribution arrangements, many of which cannot be brand substituted, are for conditions including epilepsy, Parkinson's disease, schizophrenia, depression, diabetes, heart disease and rheumatoid arthritis.
- Pharmacists now only have one option for supply of these medicines. They have no ability to go to another distributor when a medicine is required more urgently or when it is not available at all. Pharmacists can no longer complain to the independent CSO Administration Agency when they cannot supply patients with essential life-saving medicines.

Box 3: International experience – Medicine shortages in the UK

In the years following the emergence of exclusive distribution in the UK, concerns regarding delays in access to medicines and shortages of supply became increasingly frequent. Complaints of supply shortages and difficulties in supplying medicines to patients under the NHS escalated through 2010, with 80% of UK pharmacies reporting that it had become more difficult than before to obtain and stock branded medicines. In late 2010, snowstorms in Scotland led to a crisis of supply, with 92% of surveyed pharmacists stating they had been prevented from dispensing prescription medication over the period because of supply difficulties.

By late 2010 complaints were so frequent and severe that public policy interventions took place aimed at tightening regulation of supply.

Deloitte Access Economics, *Economic analysis of exclusive distribution of PBS medicines*, 2011

- Case studies from the UK, Germany, Spain and France illustrate the worldwide concerns with exclusive supply arrangements for medicines, even in countries with a high saturation of pharmacies.
- In Australia, where there is one pharmacy per 1,500 square km, the Government established CSO arrangements in order to secure medicine supply to all pharmacies. In contrast, in the UK where patients have experienced long delays under exclusive distribution arrangements, there is one community pharmacy every 23 square km and, in Germany, where the ratio is one pharmacy for every 6 square km and pharmaceutical wholesalers must comply with a Public Service Obligation, exclusive distribution arrangements have been prohibited.
- Other pharmaceutical manufacturers in Australia are likely to opt for the direct distribution model which offers advantages with respect to the marketing of their off-patent medicines. The outcomes for the different parties are identified in Box 4 below.

Box 4: Summary of exclusive distribution impacts

Patients: Patients face less assurance regarding timely supply, especially in regional and remote areas of Australia, as a result of service standards which are below the CSO benchmark, the risks generated by reduced contingency in the supply chain, and uncertainty regarding supply of low-volume medicines and medicines from smaller manufactures.

Pharmacists: As overseas examples and early anecdotes from the Pfizer Direct experience suggest, pharmacists face a more complex, more costly and less certain procurement environment. Complexity and cost increase as the number of suppliers in the system – and hence the number of individual supply arrangements – grows and pharmacists increase stock holdings. At the same time, service delivery charges present a cost to pharmacy that cannot readily be recovered (since the price to patient of PBS medicines is capped).

CSO Distributors: Exclusive distribution will increase the unit cost of distribution for CSO wholesalers. While initially such cost increases may be absorbed, should exclusive distribution become increasingly widespread, the viability of CSO wholesalers will be compromised. In the event that the CSO becomes untenable, and the current distributors shift to a purely commercially-orientated strategy, the distribution of medicines is likely to become increasingly concentrated.

Manufacturers: While direct distribution provides a path to pharmacy for major manufactures, smaller manufacturers may experience greater difficulty in securing such arrangements on reasonable terms and they will likely face higher supply chain complexity, risk and cost.

Government: Government faces the risks that: the CSO becomes commercially untenable; the supply chain becomes more responsive to manufacturer needs than patient needs; supply chain costs increase; rural and remote patients experience problems with timely access to essential medicines; and a pool of medicines ranged in pharmacy no longer have a path to patients.

NPSA Recommends

- The NPSA asks the Committee to:
 - Note that the CSO arrangements are vital to timely delivery of PBS medicines to remote areas;
 - Note the fragility of the current CSO PBS medicines distribution arrangements;
 - Note the significance of these arrangements to remote pharmacies and the health services which are dependent on them; and
 - Support the call of the NPSA wholesalers, pharmacists and patients for an amendment to the National Health Act 1953 to prohibit exclusive supply of PBS medicines by manufacturers to community pharmacies.

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