Deloitte Access Economics

Economic analysis of exclusive distribution of PBS medicines

National Pharmaceutical Services Association

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Deloitte.

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Key findings

- Exclusive distribution potentially threatens a core pillar of Australia's National Medicines Policy (NMP), namely, timely and reliable access to PBS medicines for all Australians. Timely, universal access is compromised by:
    - lower service standards under exclusive distribution arrangements – in particular, absence of explicit, binding commitments to urgent supply arrangements, including 24-hour delivery, delivery to rural pharmacies and to pricing at or below the approved price to pharmacy;
    - absence of contingency in the supply chain, elevating the risk of non-supply of medicines to patients;
    - pricing and supply arrangements that lack incentives for timely delivery of medicines; and
    - elimination of competition in the distribution of affected PBS medicines.
- The introduction of exclusive distribution to 5,000 pharmacies in Australia undermines efficiency in the distribution of PBS medicines at both the wholesale and pharmacy level. Currently most of Australia's pharmacies maintain at least two active full-line wholesaler accounts to ensure that they have timely backup supply arrangements to meet the needs of their customers. This represents about 10,000 accounts serviced by three wholesalers delivering to an average of 3,000 pharmacies each day.
- The chief threat to the NMP is the potential for exclusive distribution to undermine the Community Service Obligation (CSO) – the mechanism which ensures that all Australians have timely access to the full range of PBS medicines regardless of where they live.
    - Withdrawal of major manufacturers will progressively erode the viability of the CSO, leaving CSO wholesalers with a pool of low-volume, low-margin medicines that are uneconomic to supply.
    - Withdrawal of the four largest manufactures from the CSO would result in a 37% increase in average unit costs and, despite the value of the CSO increasing in per-unit terms, approximately halve the CSO Distributors' current profit pool.
    - The option of abandoning the CSO will become increasingly attractive to traditional wholesalers as they seek to maintain viability, further compromising patient access to the full range of PBS medicines.
- More broadly, overseas experience illustrates how exclusive distribution can change the dynamics of the pharmaceutical distribution supply chain, shifting the focus from pharmacy to manufacturers; and hence from a system orientated toward patient need to one driven by commercial imperatives.
- The advent of exclusive distribution models in the UK produced similar adverse outcomes to those outlined above. In recent months, the UK Government has moved to reinstate regulated standards and competition in the market for pharmaceutical distribution.
- Policy intervention is required in Australia to sustain the CSO and uphold the objectives of Australia's NMP.

- one option is to refinance the CSO to compensate CSO Distributors for the impact of exclusive distribution on their profitability. However, this option is unlikely to be cost-effective for government.
- overseas experience suggests a more effective solution is to require that all PBS-listed medicines be made available to CSO Distributors, in addition to any direct distribution channels manufactures wish to retain. This approach re-introduces competition to wholesale distribution and upholds the intent of the NMP.

Introduction

In Australia, the use of medicines listed under the Pharmaceutical Benefits Scheme (PBS) is underpinned by the National Medicines Policy (NMP). The overarching objective of the NMP is to improve health outcomes for Australians by securing 'universal, timely and affordable' access to the 'quality use' of medicines.

Australians access over 180 million prescriptions of subsidised PBS/RPBS medicines through 5,000 community pharmacies each year.[1] Comprehensive and efficient distribution channels, which secure timely access to medicines irrespective of pharmacy location, are critical in upholding the NMP.

PBS medicines are distributed to pharmacies across Australia through a number of competing channels. The competitors for distribution of PBS medicines include both pharmaceutical manufacturers, who distribute their medicines through nominated distributors to pharmacy, and traditional wholesalers, who operate independently of manufacturers and supply the full range of PBS medicines.

A Community Service Obligation (CSO) was established in 2006 under the Fourth Community Pharmacy Agreement to ensure that:

- all approved pharmacists are able to obtain timely supply of the full range of PBS medicines, irrespective of the size or location of the pharmacy, the breadth of the PBS product range, the cost of the PBS medicines, or the cost of their distribution and supply to pharmacy; and
- all Australians have timely access to the PBS medicines they require regardless of the cost of delivering the medicine or where they live.[2]

In essence, the CSO enshrines a patient-oriented model of distribution, establishing safeguards to ensure that the objectives of the NMP are upheld. The CSO provides funding for wholesalers who commit to defined service standards ('CSO Distributors') governing the distribution of PBS medicines to any pharmacy in Australia, regardless of location or relative cost of supply.

Under the arrangements, CSO Distributors provide PBS medicines to any pharmacy at a specified service standard within 24-hours of request at or below the approved price to pharmacy. From 2009 to 2011, CSO Distributors supplied the full range of PBS medicines (more than 3,600 different brands) to all pharmacies. CSO Distributors compete against one another, and against manufacturers who distribute directly, to win the business of pharmacies.

From February 2011, the largest manufacturer of medicines on the PBS, Pfizer, moved to an exclusive distribution model for supply to retail pharmacies. Pfizer medicines are now distributed solely through its own distribution channel and are no longer available from

[1] IBIS Industry Report (2011) 'Pharmaceuticals wholesaling in Australia'

[2] Fifth Community Pharmacy Agreement Between the Commonwealth of Australia and the Pharmacy Guild of Australia

CSO Distributors. Consequently, CSO Distributors can no longer stock and supply the full range of PBS medicines.

As the remainder of this report details, the implications of this development extend to all participants in the supply-chain. CSO Distributors face declining viability as the pool of products available to them for distribution shrinks and becomes less profitable; pharmacists face diminished choice of supply; and – most significantly – patients no longer enjoy the security of supply that the CSO currently provides.

Exclusive distribution is not unique to Australia but has emerged in other jurisdictions as well, including the United Kingdom (UK), Germany and South Africa. In these instances, a variety of adverse consequences have been observed and, in some cases – e.g., the UK and Germany – governments have acted to restore acceptable standards of patient access.

The National Pharmaceutical Services Association (NPSA) has engaged Deloitte Access Economics to analyse the trend towards exclusive distribution of PBS medicines and to identify potential public policy responses to secure the integrity of the NMP.

1.1 Structure of this report

This report is structured as follows:

- **Access to medicines and the existing distribution model** — this section outlines the existing policy environment in which equal access to PBS medicines is funded and secured. It also describes the distribution model which existed prior to Pfizer's move to exclusive distribution in 2011.
- **Emerging trends in distribution and access to medicines** — this section reviews the exclusive distribution model for pharmaceutical distribution in Australia and draws implications with reference to international experience.
- **Potential policy response** — this section discusses possible policy responses to exclusive distribution with the goal of securing the objectives of the NMP.

2 Access to PBS medicines and the existing distribution model

2.1 The importance of access

The use of medicines in healthcare is widely recognised as a cost-effective method of preventing and treating disease. Pharmaceuticals often eliminate the need for other, more expensive interventions as illnesses that once required hospitalisation, nursing home care or surgery can often be treated more efficiently and effectively with medicines. Research published in the *American Economic Review* found that for every US$1.00 increase in spending on medicines there was a US$3.65 saving in outlays on hospital care.[3] A similar study found that a $1.00 increase in the use of medicines resulted in a $2.06 reduction in hospital spending, while the Centres for Disease Control in Atlanta found that increased adherence to diabetes medicines saved $7.00 for every additional dollar spent on medicines.[4]

An overarching objective of Australian public health policy is to secure equitable access for all Australians to high quality, affordable healthcare services, including access to doctors and medicines as required. The Pharmaceutical Benefits Scheme (PBS), in tandem with Medicare, is an expression of the Government's and the community's commitment to providing all Australian citizens with effective and affordable healthcare. Through the PBS, the Federal Government subsidises the cost of 888 molecules, marketed as 6,676 brands[5], making medicines more affordable for all Australians.

Equity of access to medicines is not defined by affordability alone; rather, it also encapsulates the dimensions of timeliness and reliability. Whereas subsidisation by the Federal Government addresses the matter of affordability, the strength and reach of supply chains from manufacturer to consumer determine the reliability and timeliness of access. Australian pharmaceutical wholesalers/distributors are an important interface between the 150 local and international pharmaceutical manufacturers and the nation's 5,000 community pharmacies.

2.2 Public policy context

Access to medicines in Australia is governed by Australia's National Medicines Policy (NMP). The NMP articulates the interrelated objectives that the community seeks to achieve when purchasing medicines. The policy document was released in 1999 with the aim of improving health outcomes for all Australians through their access to and use of medicines (Box 2.1).

[3] Lichtenberg, F. (1996) 'Do more (and better) drugs keep people out of hospitals? *American Economic Review*, 86, pp384-388
[4] Pharma (2010) 'Profile of the Pharmaceuticals Industry 2010'
[5] Department of Health and Ageing (2011) PBS List.

Box 2.1: The National Medicines Policy

Launched in December 1999, the NMP is a well established and endorsed policy framework, which is based on a set of partnerships among government, industry and the community. Australian governments, health educators, health practitioners and other healthcare providers and suppliers, the medicines industry, healthcare consumers and the media work together to promote the objectives of the policy.

The overall aim of the NMP is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved. The Policy has four central objectives:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

Source: Commonwealth of Australia (1999) "The National Medicines Policy', accessed online: http://www.health.gov.au/internet/main/publishing.nsf/content/nmp-objectives-policy.htm, last accessed 30 May 2011

The first pillar of the NMP is of most relevance to this report – that is, timely access to medicines that Australians need at a cost individuals and the community can afford. The NMP states that government, industry and the community should collectively seek to achieve pharmaceutical supply arrangements that 'optimise health outcomes' and represent 'efficient and effective distribution and supply networks', such that a 'fair distribution of costs and savings between the partners' is achieved.[6]

When medicines are listed on the PBS, an approved price is determined through negotiation between the Pharmaceutical Benefits Pricing Authority and manufacturers. The negotiations also set the wholesaling margin that CSO Distributors can charge on ethical pharmaceutical products. Wholesale margins are currently set at 7.0% of the approved price of PBS medicines as part of the Fifth Community Pharmacy agreement. The 7.0% margin acts as a cap on the cost of distribution, with CSO Distributors committing to price at or below this level. Only CSO Distributors are held to this pricing requirement. In addition to the funding provided via the 7.0% margin, government provides $184.9 million annually to fund a Community Service Obligation Funding Pool.[7]

2.3 Rationale for the Community Service Obligation

The Federal Government established the CSO Funding Pool in 2006 to mitigate tensions between public policy objectives and market incentives in the distribution of PBS medicines. Public policy specifies that all Australians have timely access to the full suite of PBS medicines irrespective of where they live. However, commercial incentives alone do not support the provision of the full range of pharmaceuticals on a universal basis. Government intervention is required to secure this public policy objective.

[6] Source: Commonwealth of Australia (1999) "The National Medicines Policy', accessed online: http://www.health.gov.au/internet/main/publishing.nsf/content/nmp-objectives-policy.htm, last accessed 30 May 2011

[7] Commonwealth of Australia and the Pharmacy Guild of Australia (2010) 'The Fifth Community Pharmacy Agreement'

As Table 2.1 shows, there are currently 6,600 medicines listed on the PBS. Around 3,600 of these are stocked by CSO Distributors, with others being largely generic substitutes and sourced from manufacturers when a request is placed by pharmacy. On average, pharmacies stock between 300 and 500 medicines in their dispensaries, relying on CSO Distributors for the supply of infrequently required medicines.

Table 2.1 Overview of PBS medicines

	Number of products
Total medicines on the PBS	6,600
Number of medicines stocked by CSO Distributors	3,600
Number of medicines stocked by pharmacies	300-500

Source: Department of Health and Ageing PBS Listing.

Note: Total includes Pfizer medicines. CSO Distributors hold 3,600 medicines in stock but will obtain from manufacturers any medicines available to CSO Distributors if requested by a pharmacy.

These PBS medicines vary across a spectrum of profitability and distribution frequency (noting the links between the two). Data provided by NPSA indicate that, in the absence of exclusive distribution, around 50% of PBS-listed medicines stocked by CSO Distributors are unprofitable to deliver. Indeed, the data suggest that 90% of drugs on the PBS: (i) collectively account for less than 10% of sales; and (ii) are ordered as single doses on average less than once per pharmacy per week (Table 2.2 below). In fact, the data indicate that nearly 60% of PBS medicines stocked by CSO Distributors are ordered less than once per pharmacy per month and 240 of these have not been ordered even once in the past 12 months.

Clearly, it is not in the commercial interest of private suppliers to deliver the full range of PBS medicines – certainly not within the guidelines prescribed by the CSO and reflected in the NMP. The incentives to supply medicines at the low-volume, low-margin end of the spectrum – particularly in rural and remote communities – are weak.

Table 2.2 Average frequency of distribution of PBS medicines

Frequency of order per pharmacy	Number of products	Proportion	Cumulative proportion
Less than once every three months	733	20.6%	20.6%
Between once every three months and once a month	1,353	38.0%	58.6%
Between once a month and once a week	1,085	30.4%	89.0%
1-2 times per week	206	5.8%	94.8%
Greater than twice per week	188	5.3%	100.0%
Total PBS medicines stocked by CSO Distributors	3,563	100%	

Source: NPSA

Note: Total refers to total products stocked by CSO Distributors.

These data are consistent with government-sourced data; however, government data do not include PBS medicine supplies under co-payment.

The misalignment of public policy objectives and commercial incentives provides a strong rationale for government involvement in the supply chain, exercised in this instance through regulation and funding via the CSO.

2.4 Operation of the CSO Funding Pool

The CSO Funding Pool is designed to underwrite the capacity of pharmaceutical wholesalers to supply the full range of PBS medicines to pharmacies across Australia, regardless of location and relative cost of supply. The goal of the CSO Funding Pool is to ensure that all Australians have ongoing and timely access to the full range of PBS medicines via their community pharmacy, and hence that the objectives of the NMP are upheld.[8]

The *CSO Service Standards and Compliance Requirements* define minimum services, standards and operating arrangements. They include a requirement to stock a minimum range of PBS medicines and to deliver them to any pharmacy in Australia within 24 hours of ordering from a regular cut-off time. Box 2.2 outlines the CSO Service Standards. The compliance of CSO Distributors with these standards is audited by an independent, government-appointed administration agency, which also investigates complaints lodged by pharmacists. Although no data are available, anecdotal reports indicate that there have been few negative reports regarding the performance of the current CSO Distributors.

Box 2.2: The Community Service Obligation – service standards

The Service Standards required of CSO Distributors are as follows:

- 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, unless otherwise requested;
- 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
- business continuity planning.

Source: Commonwealth of Australia and the Pharmacy Guild of Australia (2010) 'The Fifth Community Pharmacy Agreement'

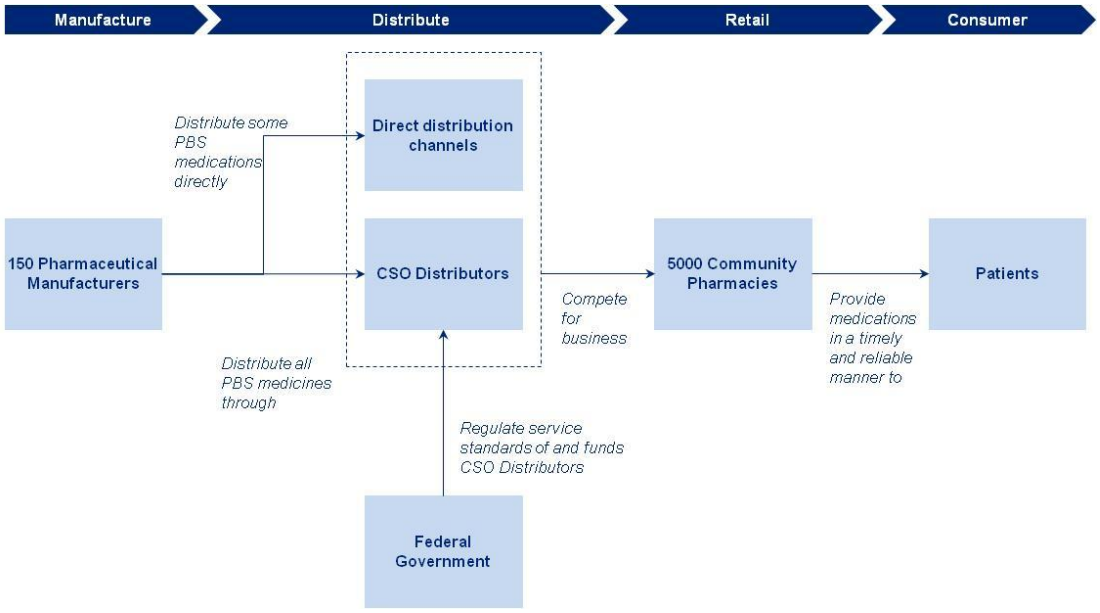
[8] Commonwealth of Australia and the Pharmacy Guild of Australia (2010) 'The Fifth Community Pharmacy Agreement'

2.5 The traditional distribution model for PBS medicines

Under the model of PBS distribution operating prior to the emergence of exclusive arrangements, a variety of stakeholders participated in the supply chain between manufacturer and consumer (see Figure 2.1 below). The distribution of PBS medicines occurred either via the CSO Distributors or through distributors appointed by manufacturers (commonly referred to as direct distributors).

The three national CSO Distributors – API, Sigma and Symbion – supplied all medicines to pharmacies within their jurisdiction and 70% of medicine supplies for hospitals, via a network of 43 warehouses and 3,000 staff.[9]

Figure 2.1 Supply chain for PBS medicines prior to the emergence of exclusive distribution



Many of Australia's major pharmaceutical manufacturers, including Pfizer, GlaxoSmithKline, Sanofi Aventis, Merck and Roche have historically engaged in direct (but not exclusive) distribution to community and hospital pharmacy settings. Direct supply arrangements have typically been orientated toward infrequent bulk deliveries rather than on-demand provision. For these medicines, distribution via the manufacturer operated alongside (that is, competed with) distribution via the CSO Distributors.

Irrespective of whether direct distribution occurred, pharmacists had the capacity to procure PBS medicines from a variety of sources and, despite some alliances, competition among CSO Distributors on the basis of trading terms was historically strong. In this respect, the traditional model and the service standards the CSO enshrines provide

[9] Data sourced from NPSA and current as at 17 March 2011.

pharmacies with choice, reliability and certainty. The value this offers pharmacists (and by extension patients), particularly in rural areas, is illustrated by the example given in Box 2.3 below – the experience of a remote Northern Territory pharmacy.

Box 2.3 Case study example – the value of the CSO in remote NT

"We appreciate the level of support we receive from our wholesaler and believe that without the CSO they would not be able to continue to provide this timely support. To supply a full range of PBS items from our dispensary, our pharmacy relies on the support of our full-line wholesaler. Although there is up to a two week wait for front shop and bulk supplies, we can provide PBS items not stocked within our dispensary within 24 hours of placing an order. These orders are air freighted into town. This timely service allows us to provide acute and chronic medications in a timely fashion to the residents of our town and to the indigenous health services that we look after."

Source: Personal communication from remote NT pharmacist

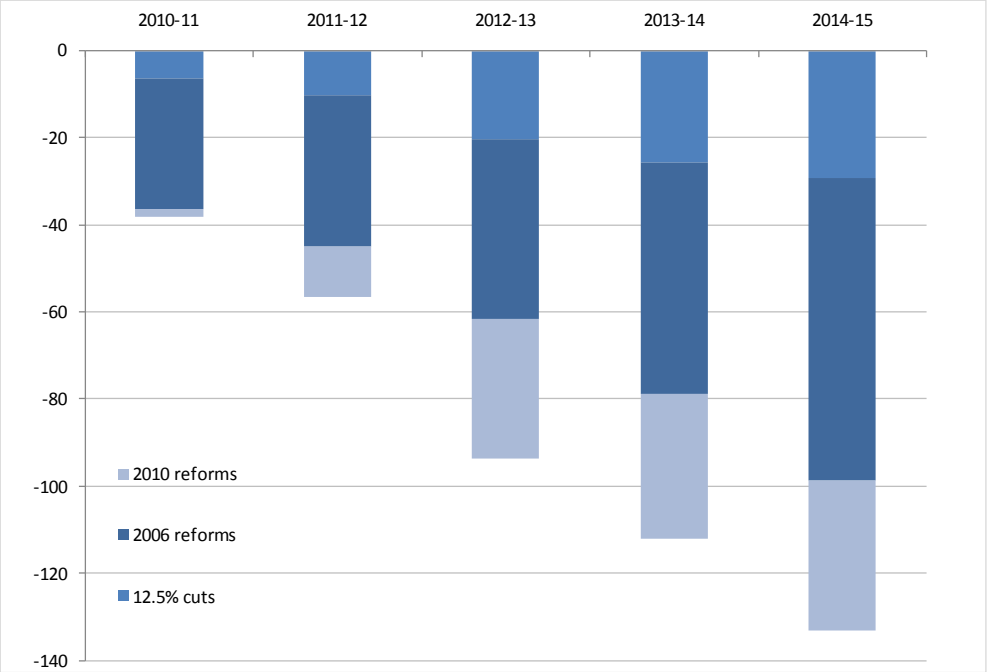
2.6 Pressures on the PBS supply chain

Over recent years pressures on the pharmaceutical wholesaling industry have intensified – most significantly as a result of the Government's endeavours to reduce outlays on the PBS. Successive reforms introduced since 2005 have extracted considerable savings from the PBS supply chain at a significant cost to – among others – pharmaceutical wholesalers.

Figure 2.2 illustrates an aggregation of impacts on wholesaler earnings across all 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.[10]

[10] Harper, Ian (2011) 'Impacts of PBS Reform', *Australian Journal of Pharmacy,* Vol 88

Figure 2.2 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

3 Emerging trends in PBS distribution

3.1 Exclusive distribution

In late 2007, faced with mounting cost pressure on its traditional pharmaceutical manufacturing business model, Pfizer (a global pharmaceutical manufacturer) introduced an alternative purchasing option named 'Pfizer Direct'. Pfizer Direct operates using DHL as its sole logistics service provider.

Initially the Pfizer Direct distribution model operated alongside existing wholesale distribution channels, as described in Section 2.6 above. CSO Distributors continued to supply the full range of Pfizer PBS medicines to pharmacy and Pfizer Direct priced its distribution services at competitive rates. In early 2011 Pfizer Direct instituted exclusive distribution arrangements with all community pharmacies, thereby bypassing CSO Distributors. The company stated at the time, that the move reflected increasing strain on its business model from PBS reform, as well as the looming expiry of a number of patents for Pfizer medicines, including *Lipitor* in 2012.[11]

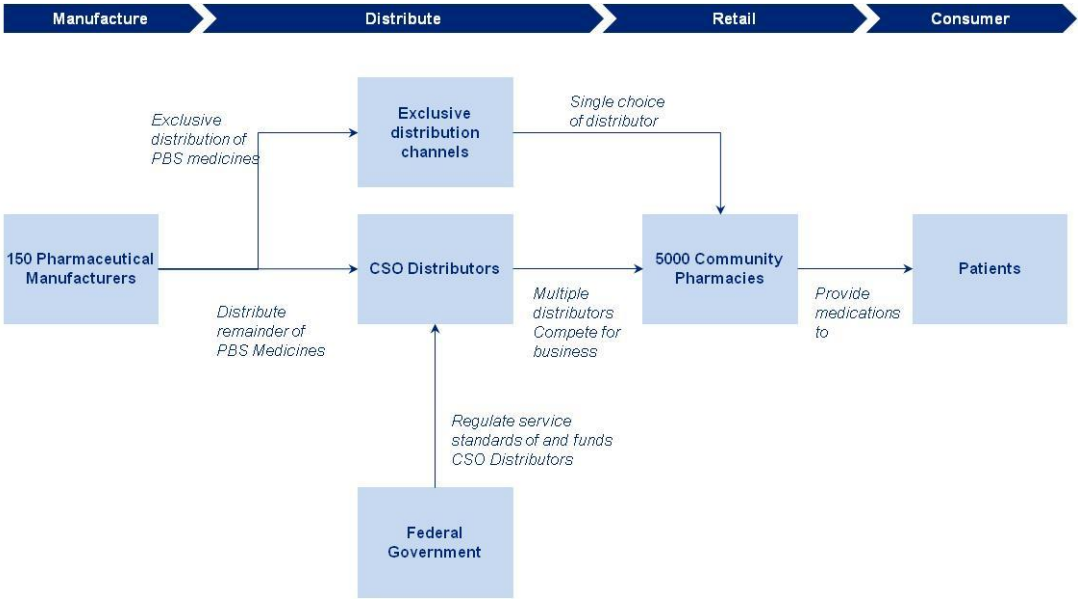
Exclusive distribution arrangements changed competitive conditions in the market for pharmaceutical distribution. In particular, competition for distribution of Pfizer PBS medicines has been eliminated. Pharmacists no longer have a choice of supplier for these medicines since they must purchase them from a sole supplier: Pfizer Direct (Figure 3.1). Furthermore, the CSO Administration Agency is no longer able to monitor timeliness and reliability of the supply of Pfizer-manufactured PBS medicines since Pfizer Direct operates outside the CSO.

Many pharmacists have expressed concern and reluctance over the move to exclusive distribution. The National President of the Pharmacy Guild recently confirmed in an article published in the *Australian Journal of Pharmacy* that 1,500 letters of complaint had been received from members in relation to this issue.[12]

[11] Pfizer Direct (2011) 'Frequently Asked Questions', accessed online http://www.pfizerdirect.com.au/Default.aspx, last accessed 31 May 2011

[12] Gupte, J (2011) 'Pfizer generates 1500 letters of complaint', *The Australian Journal of Pharmacy,* 92

Figure 3.1 Supply chain for PBS medicines under exclusive distribution



The source of concern among pharmacists derives at least partially from the fact that Pfizer Direct does not operate under the service commitment of the CSO. Rather, it operates in accordance with confidential service standards agreed with the Pharmacy Guild of Australia—an agreement which is both separate and distinct from the standards under which CSO Distributors operate.[13] Most notably, there is no commitment under this agreement to ensure that Pfizer-manufactured PBS medicines are supplied to all pharmacies within 24 hours of order irrespective of location or relative cost of supply.[14]

Since the Pfizer Direct model applies only to Pfizer medicines and does not comply with the CSO standards, neither Pfizer Direct nor DHL receive funding from the CSO Funding Pool. In order to recover and reduce their costs, therefore, a range of additional delivery charges are applied (see discussion in Section 3.2.1.3, below).

There is currently no legal obstacle to exclusive PBS distribution in Australia. While Pfizer has led this development in Australia, there is reason to expect that others will follow suit. This occurred in the United Kingdom (UK) when Pfizer moved to exclusive distribution in that country some years ago (see Box 3.1).

The move towards exclusive distribution and away from full-line wholesaling has been observed in countries outside of the UK as well. In France, major manufacturer Roche initiated such a model; however, the French Government intervened to prevent the move to uphold its Public Service Obligation. Similarly, in Germany, moves toward exclusive distribution were met with legislative amendments to enshrine supply of all medicines through wholesalers (see detailed discussion in Section 4). In South Africa, full-line wholesalers operated until 1993, at which point exclusive distribution models were introduced. The new model created incentives to reduce frequency of delivery and did not guarantee same-day service as had previously applied.

[13] The Pharmacy Guild of Australia has indicated that these service standards are not available for public scrutiny.

[14] Information sourced from Pfizer Direct website (www.pfizerdirect.com.au) and via personal communication with pharmacists.

Box 3.1 International experience – UK

Prior to 2007, nine full-line wholesalers operated in the UK supplying the full range of both branded and generic medicines. In 2007, Pfizer introduced a direct-to-pharmacy scheme, operating through a single pre-existing wholesaler, UniChem. Irrespective of previous wholesale agreements, all pharmacies were required to open an account with UniChem in order to access Pfizer medicines.

In the years that followed, other major manufacturers followed suit, introducing limited wholesaler schemes or direct-to-pharmacy schemes. Three major wholesalers now dominate the market for distribution in the UK, with smaller distributors unable to supply a significant proportion of medicines.

The changes were met with widespread concern among pharmacists, dispensing doctors and competing wholesalers, leading the Office of Fair Trade (UK) to launch an independent market study into the distribution of medicines in the UK. The study considered how proposed changes to exclusive distribution arrangements might affect competition, the National Health Service (NHS) and patients. The study concluded that exclusive distribution schemes had the potential to increase costs to the NHS, reduce service levels to pharmacies and potentially also to patients.

As predicted by the OFT study, supply shortages followed the increasing prevalence of exclusive distribution models. These are described in Box 4.1.

Source: Taylor, Lynne (2011) 'Pharmacies should receive drugs from suppliers within 24 hours', Accessed onlinehttp://www.pharmatimes.com/Article/11-02-08/Pharmacies_should_receive_drugs_from_suppliers_within_24_hours_says_govt.aspx; , last accessed 31 May 2011.; Office of Fare Trade (2007) 'Medicine distribution in the UK', accessed online: http://www.oft.gov.uk/OFTwork/markets-work/completed/medicines, last accessed 31 May 2011

3.2 Potential impacts

The trend to exclusive distribution of PBS medicines poses a major challenge to Australia's NMP, particularly in light of the nation's geo-demographics. While Australia has a small population and a vast area, the bulk of Australia's population could be serviced from a relatively simple East Coast-oriented supply chain. However, Australia's commitment to universal access to healthcare and medicines poses unique challenges to a medicine supply chain.

By way of illustration, Australia has one community pharmacy per 1,500 square kilometres. To put this into context, in Germany it is estimated that there is one pharmacy per 23 square kilometres and in the UK one pharmacy per six square kilometres.

The challenges posed to Australia's NMP are apparent when the changes instigated by Pfizer are analysed in isolation but heightened further when the potential for other major manufacturers to follow suit is considered. The impacts of exclusive distribution include those stemming directly from the model itself and those deriving from the knock-on impact on the CSO.

3.2.1 Direct impacts on the effective and efficient provision of PBS medicines

Several aspects of the exclusive distribution model have the potential to jeopardise timeliness of supply and accessibility of PBS medicines.

3.2.1.1 Sub-par service commitment

The conditions under which Pfizer has agreed to supply its medicines to pharmacies are confidential but fall short of those enshrined in the CSO standards, which currently govern the distribution of PBS medicines in Australia. Most significantly, there is no universal commitment to the supply of Pfizer medicines within 24 hours of ordering, at or below the approved price to pharmacy.[15] The absence of such requirements will probably affect rural and remote pharmacies most acutely, since it is here that commercial imperatives are most heavily skewed against timely supply. Forums such as *Auspharmalink* highlight examples where the capacity of pharmacists in rural and remote areas to offer timely supply to their community has been compromised under Pfizer Direct arrangements.[16] Indeed, many responses outline specific examples where critical patient needs were not met.

Under the Pfizer agreement, orders placed before 1pm are delivered at some time during the following day. In many instances deliveries therefore occur outside a 24-hour window (i.e. any time after 1pm constitutes more than 24 hours). In addition, pharmacists cannot give their patients an assurance regarding the time of delivery and so they commonly advise patients to collect their medicines the following day – especially in rural and remote areas where travel times are typically lengthy.

This is in contrast to wholesalers' current obligations under the CSO. In the above example an order placed before order cut-off on Monday would be met with a commitment to deliver within 24 hours – ensuring delivery during a limited window the following day. In especially remote areas, CSO Distributors will call on overnight air freight to ensure urgent patient need is met at no cost to the pharmacist. This certainty allows pharmacists to advise their patients with confidence the time at which their medicines will be ready for collection.

3.2.1.2 No contingency

Whereas the CSO distribution arrangements are underwritten by three wholesalers operating parallel distribution networks, exclusive distribution means the supply of significant volumes of PBS medicines hinges entirely on a single operator. Hence the contingencies that exist within the current framework are forgone – there is no longer a layer of insurance (or competition) in the distribution arrangements, and risks to timely supply of PBS medicines are elevated. In the event that an exclusive supplier is unable to make a delivery – for example, due to industrial action, flood or equipment failure – patients' access to PBS medicines is compromised. The value provided by this contingency is highlighted in the case study outlined in Box 3.2 below.

Box 3.2 Contingency under traditional supply arrangements

"Our main supplier is W1, but we also use W2 were necessary.^ All have warehouses in Sydney. At present we can order medicines from W1 with a 2.00 pm cut off which are delivered by 9.00 am the next day. W2 cut off for general stock is 1.00 pm and for ethicals it is 1.50 pm, both for delivery by about 10.00 am the next day.

[15] Information sourced from Pfizer Direct website (www.pfizerdirect.com.au) and via personal communication with pharmacists.

[16] www.pharmalink.com.au

If W1 does not have it in stock then I try W2; if they don't have it either, I will request a supply date from both suppliers so I know when to tell the customer the medicine will arrive. If I do have a problem with delivery, I can advise the CSO agency if the matter is one which they cover, or otherwise change wholesaler."

Source: North Coast NSW Pharmacy
^W1 and W2 denote different CSO Distributors.

The substantial nature of these risks – and the role of the CSO in mitigating them – was illustrated during the recent Queensland floods. API's warehouse in Ipswich was evacuated, Sigma's Rockhampton warehouse sustained water-damage and Sigma's Toowoomba warehouse was affected by the deluge. In response to this series of events the three distributors coordinated operations to address delivery and ensure that obligations were met.

The events following this natural disaster are in stark contrast to the events which followed snowstorms affecting pharmaceutical delivery in Scotland in 2010 (Box 3.3).

Box 3.3 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. These policy interventions are described in Box 3.3.

Taylor, Lynne (2010) 'UK Drug Shortages 'soaring', accessed online: http://www.pharmatimes.com/Article/10-09-07/UK_drug_shortages_%E2%80%9Csoaring%E2%80%9D.aspx; last accessed 31 May 2011.

3.2.1.3 Incentives skewed against timeliness

The pricing and supply arrangements initiated under the Pfizer model of exclusive distribution are not conducive to timely provision of medicines. From 1 April 2011, the Pfizer Direct service introduced delivery charges for pharmacies making more than five orders per month ($10 for additional orders up to ten per month and $30 for orders beyond this).[17] The incentives created by such a pricing structure clearly favour ordering less frequently and in larger lots.

While the Pfizer Direct pricing structure could generate cost savings by encouraging consolidated orders, it does so at the expense of timeliness. At present some 90% of PBS medicines are ordered as single doses on average less than once per month per pharmacy. Consolidation of orders will realise significant savings relative to continuing to order in small lots. But this will sacrifice timeliness as pharmacists seek to avoid the penalty of ordering more than once per week. In this regard Pfizer Direct's pricing structure runs counter to the standards imposed by the NMP, which ranks timeliness more highly than delivery cost efficiency, a value reflected in the subsidy paid under the CSO.

[17] Information on delivery charges supplied to NPSA by pharmacies.

At the same time Pfizer Direct's current pricing structure introduces the risk that, for a given medicine, the delivery costs incurred by pharmacists could exceed their revenue from dispensing the medicine. To cite just two examples, the table below shows that, where between six and ten orders per month are placed by a pharmacy, the profit margin on Lipitor and Caduet is marginal. In the event that more than ten orders per month are placed, the pharmacy makes a significant net loss on the medicine. In supplying Lipitor, for which the price to pharmacy is around $32, the pharmacist would incur a loss of nearly $20 per unit if an urgent order was placed for a single unit.

Table 3.1: Impact of delivery charges on pharmacy net profit

	Lipitor 10mg 30	Caduet 10/10
Price to Wholesaler ($)	29.56	44.09
Wholesale Margin ($)	2.22	3.32
Price to Pharmacy ($)	31.78	47.41
Pharmacy Margin ($)	4.50	4.74
Dispense Fee ($)	6.42	6.42
Price to Consumer($)	42.70	58.57
Pharmacy Gross Profit	**10.92**	**11.16**
Scenario 1: Pfizer delivery Charge (Up to 5 orders/month)	-	-
Pharmacy Net Profit ($)	**10.92**	**11.16**
Scenario 2: Pfizer delivery Charge (6-10 orders/month) ($)	10.00	10.00
Pharmacy Net Profit ($)	**0.92**	**1.16**
Scenario 3: Pfizer delivery Charge (any orders > 10/month)	30.00	30.00
Pharmacy Net Profit ($)	**-19.08**	**-18.84**

Source: Deloitte Access Economics calculations

This is not to suggest that pharmacists will put their patients' access at risk – they have a responsibility to service the needs of their patients. However, it will generate financial pressures on pharmacy and introduces a disincentive to timely access. PBS medicines supplied to pharmacy under the CSO, on the other hand, are subject to a price cap. The price to pharmacy cannot exceed the approved price under the terms of the CSO. Incentives to delay ordering are therefore eliminated, as is the policy intent of the CSO.

3.2.1.4 Competition

Concern should always be expressed when buyers face a restricted choice of suppliers. The advent of exclusive distribution means that, for the affected medicines, supply is only available through a single channel. Accordingly, there is less scope for negotiation on price and service standards (pharmacists must source a Pfizer medicine whenever it is prescribed by a doctor) than in the traditional supply environment where three CSO distributors compete on price and service quality.

Exclusive distribution need not enhance the monopoly power of the manufacturer, especially when generic substitutes for the manufacturer's patent medicine are about to become widely available. Nevertheless, substantial lessening of competition in a substantial market is a threshold test for the presence of market power under Australian law. At the very least, exclusive distribution raises the question of whether it strengthens the market power of manufacturers to the point of compromising efficiency in the market for pharmaceutical distribution.

3.2.1.5 Efficiency

As noted above, the NMP also requires that 'efficient' distribution and supply networks exist for medicines.

The costs of distributing medicines are predominantly fixed (that is, they do not vary by volume). Distributors must maintain a network of warehouses, service those warehouses with labour and equipment, and conduct frequent distribution runs over a given distribution network. Where new distributors, such as DHL, are introduced into the existing supply chain, new infrastructure is required to support distribution, raising fixed costs across the industry. Consequently, with a constant volume of PBS medicines distributed across a higher cost base, average unit costs of service delivery are increased, and the efficiency of distribution reduced.

Indeed, the General Director of Pfizer's Established Products Business Unit stated that the new distribution arrangements will be more expensive than previous arrangements – indeed, the cost would be 'considerably more', both as a result of initial set-up and subsequent running costs.[18]

Efficiency in distribution may also be undermined by the increased administrative burden created at the pharmacy level. Australia's 5,000 pharmacies currently maintain at least two active full-line wholesaler accounts to ensure that they have timely backup supply arrangements in place to meet the needs of their customers. This represents about 10,000 accounts serviced by three wholesalers delivering to an average of 3,000 pharmacies each day. Should exclusive distribution become widespread, the number of accounts held by pharmacies, and the associated administrative and handling costs per pharmacy, could increase significantly.

3.2.2 Implications for the viability of the CSO

As noted above, the CSO is premised on reconciling tensions between commercial imperatives and public policy objectives. The CSO serves to underwrite the timely, universal provision of the full range of PBS medicines, irrespective of the commercial viability of doing so. This means that pharmacists are not financially disadvantaged when they put the needs of their patients first.

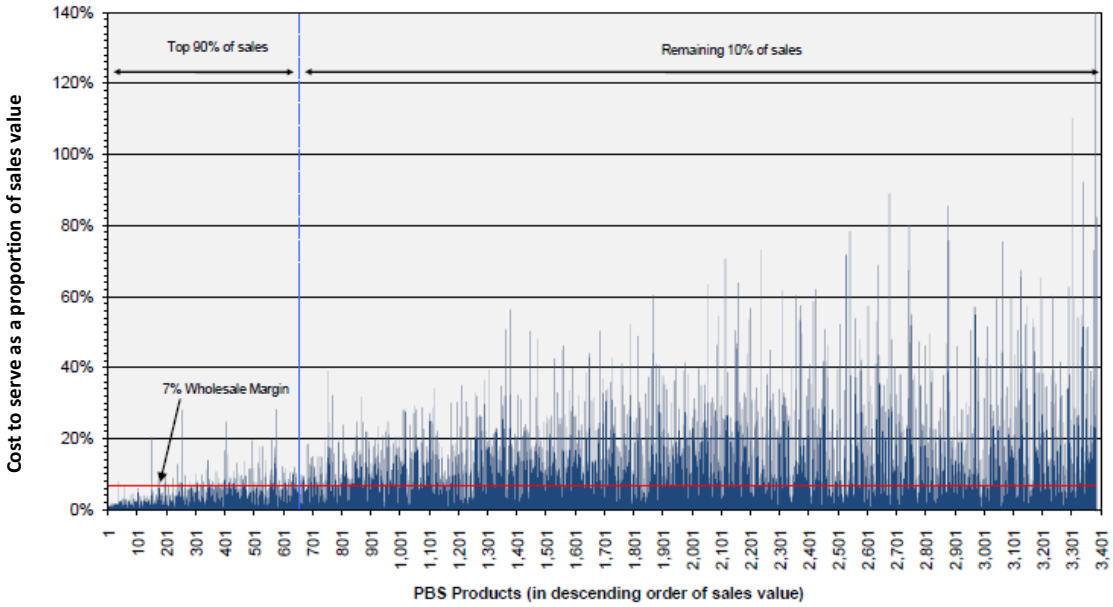
PBS medicines can be characterised along a spectrum of distribution frequency and profitability. Figure 3.2 illustrates this spectrum, showing the cost relative to sale value – that is, the relative profitability – of each PBS medicine distributed over a 12 month period, based on analysis conducted by the NPSA. The analysis does not include medicines not sold

[18] Holyer. N (2011) "The whole sale" *Supply Chain Review,* February 2011.

in the 12 month period or medicines not stocked. Medicines are ranked according to sales value and the 7% wholesale margin is illustrated by the horizontal red line in the figure.

As evident from the figure, a significant proportion of PBS medicines is not viable to distribute on a stand-alone basis. That is, their cost to range and distribute relative to sales value exceeds the 7% margin allowed under the PBS. While the CSO funding pool provides CSO Distributors with additional funds to mitigate these commercial pressures, significant internal cross-subsidisation remains in the distribution of PBS medicines.

Figure 3.2 Relative profitability of individual PBS medicines



Source: NPSA

The withdrawal of major manufacturers from the CSO distribution model erodes wholesalers' capacity to undertake this cross-subsidisation. The source of this erosion is twofold. First, the withdrawal of major manufacturers reduces the volume of medicines passing through the CSO distribution model which, in light of the cost characteristics described in Section 3.2 above, increases the average per-unit cost of distributing the remaining medicines.

Second, and notwithstanding the fact that distribution costs vary markedly based on factors such as the location of the pharmacy, size of the order, etc., many of the most profitable medicines to supply are produced by the major manufacturers. This reflects the fact that these medicines generally attract higher per-unit margin revenue (by virtue of their higher price and hence the 7% margin being greater in dollar terms) and that they are more efficient to handle (primarily due to the higher average order size). The withdrawal of these medicines therefore reduces the average profitability of the medicines in the CSO distribution pool.

The fact that medicines which are profitable to distribute under the current model are disproportionately represented among those produced by major manufacturers is illustrated by the data presented in Table 3.1 below:

- taken in aggregate, around half (51%) of PBS medicines are profitable to distribute (i.e. the dollar margin exceeds 7% of the approved price to pharmacy);
- when pharmaceuticals manufactured by Pfizer are isolated, an estimated 60% are profitable to distribute; and
- when pharmaceuticals manufactured by the four largest manufacturers are considered, an estimated 58% are profitable to distribute.

Consequently, if more manufacturers shift to exclusive distribution, thereby by-passing CSO Distributors, the pool of remaining CSO medicines becomes increasingly less profitable to distribute. Indeed, as the scenarios below explore, withdrawal of the top four manufactures from the CSO erodes an estimated 50% of the current CSO Distributor profit pool.

Table 3.2 Profitability impact analysis

	No. of medicines	Profitable medicines*	Proportion of medicines profitable	Proportion of remaining profitable medicines – by unit	Remaining CSO Distributor profit pool^
Stocked PBS	3,565	1,818	51%	51%	100%
Pfizer	205	123	60%	45%	78%
Top 4 manufacturers	545	316	58%	40%	50%

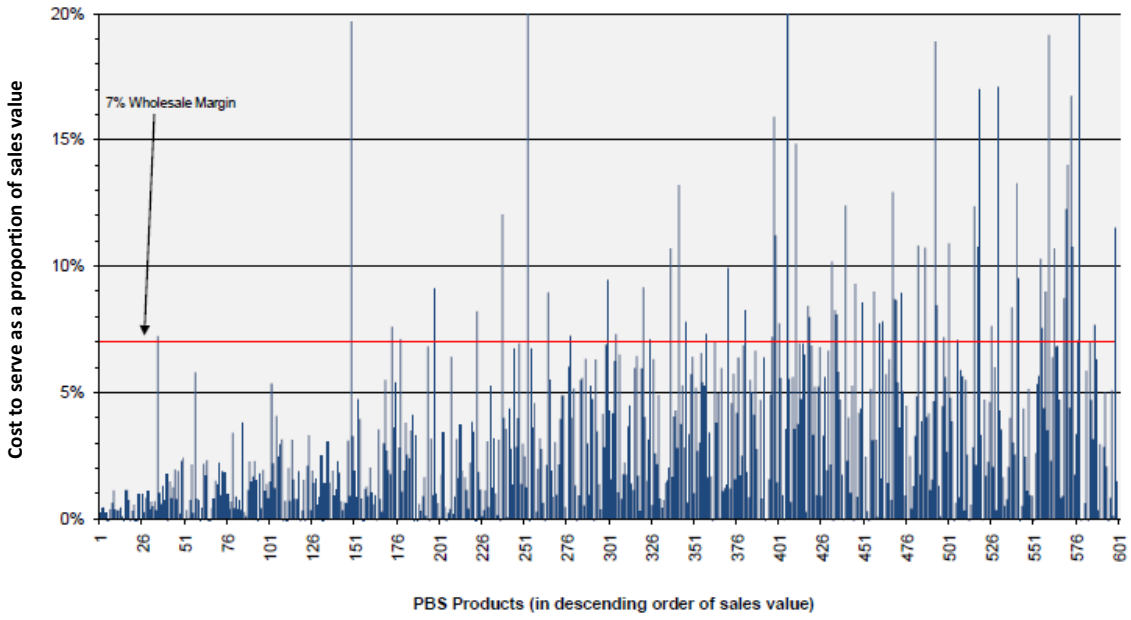
Source: NPSA. The sensitive nature of these data means they cannot be published by Deloitte Access Economics. However, Deloitte Access Economics has reviewed the underlying data, assumptions and calculations.
*Profitability defined relative to the 7% wholesale margin. ^Denotes the estimated proportion of current CSO Distributor net profit which remains under each scenario.

3.2.2.2 Impact of exclusive distribution by Pfizer

The withdrawal of Pfizer medicines from the PBS supply chain has significant repercussions for the viability of the CSO. Whereas around half of the medicines in the pool are profitable when all PBS-listed medicines are included, the withdrawal of Pfizer medicines reduces this figure to 45% (refer to Table 3.1). Figures 3.3 and 3.4, below illustrate this impact, showing the top 600 products by sales value (equivalent to around 90% of total PBS sales), including and excluding products manufactured by Pfizer.

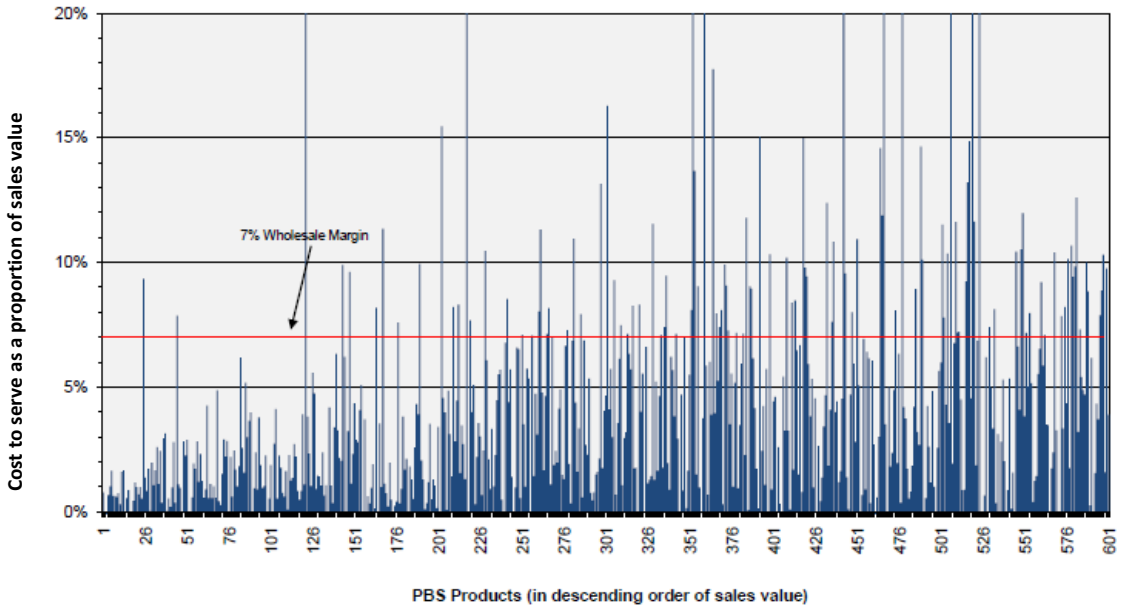
While Figures 3.3 and 3.4 do not depict CSO revenue, the decline in profitability occurs despite the CSO funding pool being invariant with the number of medicines available to CSO Distributors—that is, despite CSO revenue per product increasing as the pool of products diminishes. The magnitude of the economies of scale in distribution are such that this increase in unit revenue is insufficient to compensate wholesalers for the associated increase in unit cost.

Figure 3.3 Top 600 PBS medicines *including* products manufactured by Pfizer



Source: NPSA

Figure 3.4 Top 600 PBS medicines *excluding* products manufactured by Pfizer



Source: NPSA

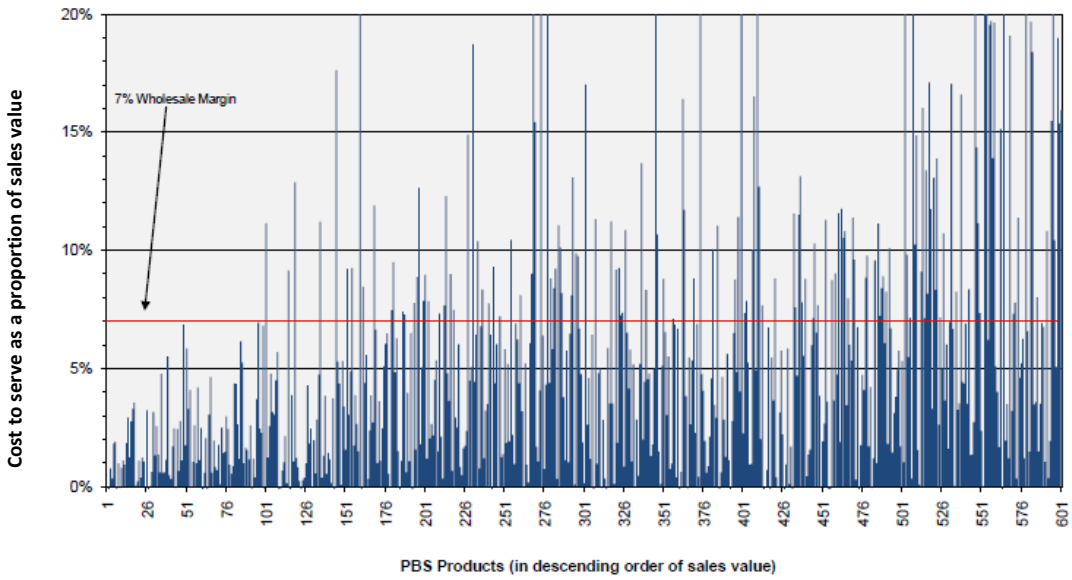
3.2.2.3 Impact of higher levels of exclusive distribution

While the charts above illustrate the impact of Pfizer's shift to exclusive distribution, as the preceding discussion in this report highlights – and as UK experience indicates –other major manufactures may follow suit.

Figure 3.5 illustrates the profitability of the top 600 medicines which would remain for distribution by CSO Distributors if the top four manufacturers (Pfizer, Astra Zeneca, Sanofi Aventis and GlaxoSmithKline) were all to adopt an exclusive distribution model.

Under this scenario, the proportion of products which are profitable to distribute falls a further five percentage points to 40%, further compromising the profitability of PBS wholesaling.

Figure 3.5 Top 600 PBS medicines excluding medicines manufactured by Pfizer, AstraZeneca, Sanofi Aventis and GlaxoSmithKline



Source: NPSA

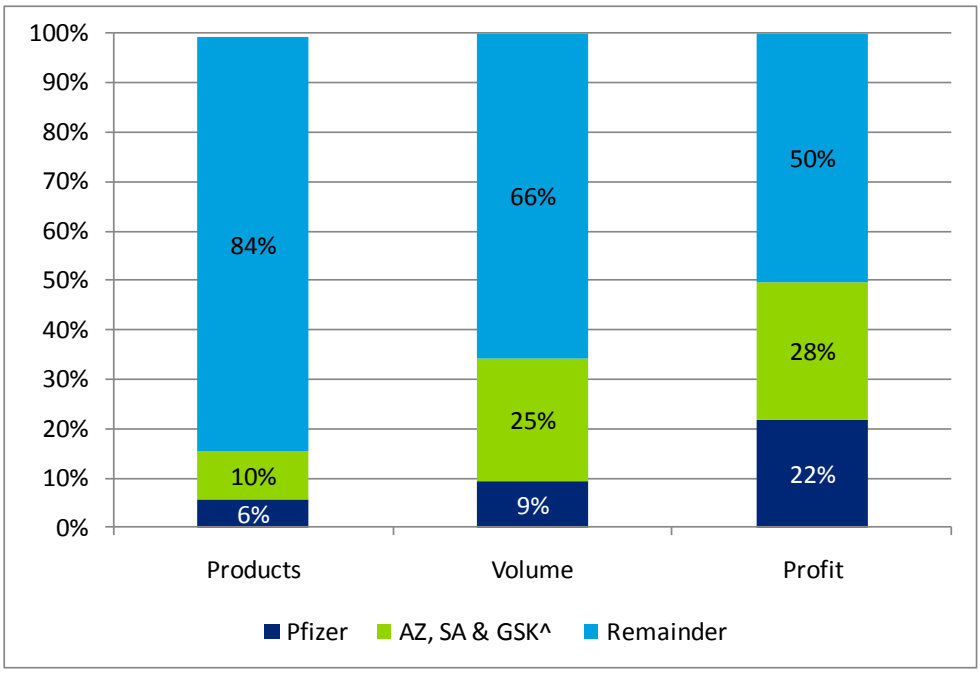
Absent policy change, there is a chance that CSO Distributors may find their situation commercially untenable, and hence withdraw from the CSO, leaving a PBS supply chain which is no longer capable of meeting the needs of patients.

3.2.2.4 Summary of impacts

Figure 3.6 below summaries the potential impacts of exclusive distribution on the PBS supply chain, depicting the effects of Pfizer's withdrawal, together with the hypothetical impact of the next three largest manufacturers also opting for exclusive distribution.

While the four largest manufactures collectively account for 16% of products, these products represent around one third of total volume of PBS medicines sold and – most significantly – half of the CSO Distributor profit pool. Exclusive distribution by the top four manufacturers would result in a 37% increase in average per-unit costs and, despite the CSO increasing in per-unit terms, a 50% reduction in the CSO Distributor profit pool.

Figure 3.6 Summary of financial impacts of exclusive distribution



Source: NPSA. The sensitive nature of these data means they cannot be or published by Deloitte Access Economics. However, Deloitte Access Economics has reviewed the underlying data, assumptions and calculations.

^ AZ: AstraZeneca; SA: Sanofi Aventis; GSK: GlaxoSmithKline

3.3 Possible broader supply-chain implications – evidence from overseas

Considering the longer term implications, the change in distribution arrangements has implications for all stakeholders in the PBS supply chain. While it is difficult to foresee stakeholder responses, overseas examples illustrate the nature of the potential longer term risks.

In response to increasing levels of exclusive distribution in the UK, full-line distributors – which are comparable to CSO Distributors in Australia – responded to the changing market conditions by aligning themselves with major manufacturers. In the event that other major manufacturers followed Pfizer's lead in Australia, it is likely that CSO Distributors would respond in a similar fashion. Indeed, the preceding analysing demonstrates the financial pressures they would experience. Faced with these pressures, it is likely CSO Distributors would pursue avenues to increase utilisation of their fixed infrastructure – that is, they would seek exclusive distribution business.

The alignment of manufacturers and distributors in the UK resulted in a reduction in the number of distributors in operation as some were unable to secure adequate market share. In Australia, where there are only three CSO Distributors, any reduction in suppliers could significantly compromise the pharmacies' supply channel choice, reducing the resilience of the supply chain. At the same time, the market power held by major manufacturers would allow them to secure favourable deals with distributors – again, this has been witnessed in the UK. Not only would smaller manufacturers lack the leverage to secure such deals, there

are also risks that distributors may seek to cross-subsidise their deals with large manufacturers by levying higher charges on smaller manufacturers.

In recent years, pharmacists in the UK have indicated growing frustration regarding frequent supply shortages and the inability to procure medicines in a timely manner. Similarly, pharmacists in South Africa now hold more stock, taking on greater risks and costs to guard against supply shortages under emerging exclusive distribution models. It is not difficult to see how these impacts could materialise in Australia, particularly if distribution was to become concentrated among a small number of suppliers and the competition and contingency provided by the CSO Distributors was reduced or eliminated.

These overseas trends have in turn affected patient access to medicines. The model in these countries moved from a primarily patient-centric model, where supply was driven by patient demand, to a manufacturer-centric model, with patient access determined by the commercial decisions of manufacturers and their aligned distributors.

In recent months the UK Government has moved to reinstate minimum standards and competition in the market for pharmaceutical distribution. Similarly, the German government has moved to regulate exclusive distribution models through the introduction of legislation stating that pharmaceutical companies must guarantee a demand-oriented and continuous supply to the full-range wholesalers of medicinal products. In France, the government intervened early to cancel an exclusive distribution arrangement proposed by Roche Pharmaceuticals in the interest of maintaining its Public Service Obligation.

3.4 Summary of impacts on supply chain participants

Box 3.3 below summarises potential impacts of the exclusive distribution model on the pharmaceutical supply chain.

Box 3.3 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 manufactures 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 not ranged in pharmacy no longer have a path to patients.

4 Potential policy responses

Exclusive distribution has the potential to compromise the CSO and hence, jeopardise timely, affordable access to PBS medicines. If other major manufactures follow Pfizer's lead, the CSO in its current form may cease to be viable, leaving the timely distribution of a significant proportion of PBS medicines in doubt. The policy challenge for government is to re-establish – in the most cost-effective manner – an environment conducive to upholding its own National Medicines Policy.

The optimal way to achieve this objective would be to mandate, as a condition of listing on the PBS, that manufacturers make their medicines available to CSO Distributors at the regulated ex-manufacturer price. This would allow manufacturers to establish their own supply chain arrangements to meet their commercial objectives without compromising the current arrangements for timely supply of medicines and redundancy in the supply chain. Other options such as re-financing the CSO or establishing service delivery guidelines for exclusive distribution would not mitigate the risks in an adequate or cost-effective fashion.

4.1 The policy options

A simple way to secure the viability of the CSO would be to inject additional funding into the CSO funding pool. Funding that compensates CSO Distributors for the reduced profitability stemming from exclusive distribution would support their capacity to deliver the range of medicines available. However, not only does such a response fail to address all of the risks posed by exclusive distribution (e.g., those related to exclusive supply and service standards for directly distributed medicines) but it is also unlikely to represent the most cost-effective solution. Indeed, it would be a costly response which would provide little assurance that the risks posed by exclusive distribution do not materialise.

Two options which warrant further consideration are:

- establishing service delivery guidelines for exclusive distribution; and
- mandating that all PBS medicines be made available to CSO Distributors.

4.1.1 Regulating service standards for exclusive distribution

There is currently no policy framework governing the exclusive distribution of PBS medicines. Pfizer's exclusive distribution accords with a voluntary set of service standards it has agreed with the Pharmacy Guild and which are unavailable for public scrutiny.

One option to support the NMP would be to regulate service standards for exclusive distribution, such that the conditions under which medicines are distributed through this channel accord with the standards imposed by the CSO. This approach would ensure timeliness of access by mandating supply within 24 hours and would – depending on its specification – support affordability by capping the price of PBS medicines to pharmacy (as the CSO currently does). Such a response would be similar to that initiated by the UK government in recent months (Box 4.1).

Box 4.1 International experience – Policy intervention following supply shortages in the UK

Responding to complaints of short and unreliable supply of medicines to patients, the UK Department of Health enforced supply chain obligations in late 2010, outlining key legal and ethical obligations for manufacturers, wholesalers, NHS Trusts, registered pharmacies and dispensing doctors in relation to the supply and trade of medicines. 'Best practice guidelines' were subsequently introduced by the Department in early 2011 in response to ongoing problems with the timely supply of medicines. The guidelines specified that all parties should aim to provide pharmacies with medicines within 24 hours of order. The guidelines also noted that supply would be kept under review and further action taken as necessary.

Taylor, Lynne (2010) 'UK Drug Shortages 'soaring', accessed online: http://www.pharmatimes.com/Article/10-09-07/UK_drug_shortages_%E2%80%9Csoaring%E2%80%9D.aspx; last accessed 31 May 2011.

However, this solution would not resolve the potentially adverse consequences of minimal or zero competition in the supply of a large number of PBS medicines. The incentives for competition based on price and/or service quality are weakened and the risks of relying on a single avenue of distribution for certain medicines would remain.

Furthermore, such a solution would not resolve how the tail of unprofitable medicines is distributed. In other words, it is not clear how those medicines which are uneconomic to distribute would be supplied if increasing numbers of manufacturers moved to exclusive distribution arrangements.

At the same time, the costs of administration and governance would increase with larger numbers of distributors, as would the level of oversight, monitoring and reporting required to police service standards.

4.1.2 Mandated supply to CSO Distributors

A more comprehensive policy option would be to mandate, as a condition of listing on the PBS, that manufacturers make their medicines available to CSO Distributors at the regulated ex-manufacturer price. Such a response would be similar to that initiated in Germany in response to the advent of exclusive distribution in that country (Box 4.2).

Box 4.2 International experience – Policy intervention to secure supply to full-line wholesalers in Germany

Changes introduced to Germany's *Medical Products Act* specify that pharmaceutical companies must guarantee, within the framework of their responsibility, "a demand-oriented and continuous supply to the full–range wholesalers of medicinal products." Full-range wholesalers are defined as businesses that maintain a "complete, manufacturer-independent assortment of pharmacy-only medicinal products" which "is constituted in such a way that the demand from patients from the pharmacies with which the wholesaler does business can be met within an appropriate space of time on weekdays." The medicinal products to be kept in stock must correspond, in such a case, to at least the average demand for a period of two weeks.

Translation of *Medicinal Products Act, Section 52(b)* (Germany)

A mechanism of this nature would reinforce the four pillars of the NMP by ensuring that all medicines are available under the conditions stipulated in the CSO (since the CSO Distributors are compelled to comply with these conditions for any and all PBS medicines made available to them), thus restoring timely, universal and affordable access to PBS medicines.

At the same time, such an approach would re-instate the competition and resilience secured by multiple channels of supply. Manufacturers would be free to undertake direct distribution (as they are today) provided that their products were also made available to CSO Distributors.

Ensuring that the full range of medicines was available to CSO Distributors would secure the CSO against erosion by commercial pressure and undergird the service standards laid down in the NMP.

Statement of responsibility

This Report was prepared for the National Pharmaceutical Services Association (NPSA) solely for the purposes of assisting NPSA to consider the economic impacts of emerging trends in the distribution of PBS Medicines.

In preparing this Report we have relied on the accuracy and completeness of the information provided to us by NPSA and from publicly available sources. We have not audited or otherwise verified the accuracy or completeness of the information. We have not contemplated the requirements or circumstances of anyone other than NPSA.

The information contained in this Report is general in nature and is not intended to be applied to anyone's particular circumstances. This Report may not be sufficient or appropriate for your purposes. It may not address or reflect matters in which you may be interested or which may be material to you. Events may have occurred since we prepared this Report which may impact on it and its conclusions.

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