NPSA
National Pharmaceutical Services Association

COMMUNITY SERVICE OBLIGATION
ensuring timely access to medicines for all

Submission

Review of Pharmacy Remuneration and Regulation

NPSA

Donna Staunton
Chief Executive Officer
M: 0439 441 720
E. CEO@npsa.org.au

29 September 2016

The National Pharmaceutical Services Association represents Australia's full-line pharmaceutical wholesalers. Full-line wholesalers provide timely supply of PBS medicines to all pharmacies in Australia – regardless of location – under the Community Service Obligation.

SUBMISSION TO THE REVIEW OF PHARMACY REMUNERATION AND REGULATION

INTRODUCTION

NPSA is pleased to make this formal submission to the Review.

In this submission we present arguments supported by detailed economic modelling as to why medicines wholesaling in Australia has worked so well up to this point in time, what is at risk if the status quo is maintained, and how wholesaling under the Pharmaceutical Benefits Scheme (PBS) can be improved.

In general, the NPSA continues to support:

- The policy framework centred on the National Medicines Policy (NMP);
- The network of over 5,500 community pharmacies, which provide dispensing, other medicines-related services and general health care support to Australians regardless of where they live; and
- A compact between Government, industry and consumers through the Australian Community Pharmacy Agreement (CPA) or comparable arrangements that provides stability and predictability to Government and Industry.

As we have noted previously, it is important to recognise that the medicines supply system that has evolved in Australia is one that is heavily interdependent. Changes once made can have unintended consequences that are difficult to reverse.

Contents of this submission

The NPSA submission package has three parts:

1. Part One – This document which includes an Executive Summary, Appendix and Answers to a number of questions raised by the Review Panel in its Discussion Paper (not otherwise covered by the L.E.K. Report);
2. Part Two - The principal submission prepared in consultation with NPSA by respected management consultants, L.E.K. Consulting;
3. Part Three - A report prepared by Medici Capital that provides an expert position on the value of the working capital arrangements of the wholesalers to pharmacies.

We would be willing to expand further on our responses or to address additional specific questions, if it would assist the Review Panel in its deliberations.

EXECUTIVE SUMMARY

Full line wholesalers play a vital role in the delivery of the National Medicines Policy (NMP)

The NMP framework was established by the Australian Government to capture the principles of a system that had evolved over a period of 60 years. This system ensures equitable access to cost effective and quality medicines for all Australians; is the envy of many countries and indeed, has elements that are now copied in a number of countries.

> Wholesalers play a vital role in the delivery of the NMP, supplying approximately 6,200 PBS items (stock keeping units) to over 5,500 community pharmacies and through them to millions of consumers throughout Australia, generally within 24 hours. This vital service enables the dispensing of 295 million scripts annually by Australian community pharmacists. This model consolidates and brings efficiencies to what would otherwise be an extremely inefficient and fragmented supply chain between over one hundred manufacturers and thousands of pharmacists. The effectiveness of the NMP depends on a clear and stable set of regulations and remuneration certainty throughout the PBS supply chain.

The Commonwealth Government as a monopsony buyer effectively sets the prices for PBS-listed medicines and the terms on which they are dispensed and sold. This means from the outset this sector is a highly regulated and distorted market.

While there is room for improvement in current funding arrangements, adopting a purely free market approach would result in poorer service levels and higher costs for consumers in rural and remote areas and availability of many medicines, even in metropolitan areas, would become challenging.

Currently over 10 wholesalers and distributors compete for community pharmacy business, utilising a range of different business models.

There are three main types of distribution models that operate today:

1. Four full-line wholesalers (three national and one state-based supplying Victoria and South Australia) compete to deliver the full range of PBS products to all community pharmacies in Australia generally within 24 hours;

2. Several short-line wholesalers provide a limited range of PBS products and services predominantly in metropolitan areas; and

3. Some pharmaceutical manufacturers deliver all or part of their products direct to pharmacy utilising third party logistics (3PL) providers.

Wholesale and distributor remuneration for PBS products is provided through two key funding mechanisms:

- A regulated mark-up percentage of 7.52 per cent applied to the PBS price; and
- A share of a Community Service Obligation (CSO) Funding Pool that incorporates a wholesaler's share of the volume of medicines dispensed.

> The CSO Pool was introduced in 2006 in response to the increasing presence of short-line wholesalers, which were progressively putting at risk the economics of full-line wholesaling activities (and therefore timely and efficient access). This was the same policy that had been introduced and then withdrawn by the Federal Government in 2001. It was designed to compensate wholesalers for CSO activities i.e. the delivery of many uneconomic PBS products to any pharmacy in Australia generally within 24 hours, including low volume and difficult to handle products (i.e. cold chain, cytotoxic or drugs of dependence).

The CSO Funding Pool is open to all companies that meet the community service standards and compliance requirements. Prior to the introduction of the Pool, many of the now CSO-linked activities had become unprofitable for wholesalers. This was in part, due to short-line wholesalers "cherry picking" the more profitable, high volume product lines and metropolitan delivery areas.

> The CSO Funding Pool has become an even more essential remuneration component over time; particularly as successive PBS remuneration structures and savings measures have been implemented.

We note that the comment has been made several times that the CSO is 'lazy' policy. We would respectfully disagree. Perhaps it is blunt policy in the sense that it is difficult to target regions or products. There is however, no doubt that it makes wholesalers extremely responsive to pharmacists in their service levels, in pharmacists' requirements and in a continuous focus on operational efficiencies.

In this respect it provides important benefits for consumers, pharmacists and Government through efficient achievement of NMP goals. Conversely, to simply let the CSO decline in value until one wholesaling operation fails we would suggest would be irresponsible on Government's part. Further, if the CSO did in fact contain rent in the form of an excessive level of remuneration, one would expect to see new entrants into the system. The fact that this has not happened would suggest that this is not the case. In fact, one distributor (a long-time critic of the system) entered the market as a full-line wholesaler, obtained a share of the CSO Funding Pool, and then subsequently withdrew, unable to meet the CSO requirements.

The changing regulatory environment has jeopardised the long-term sustainability of full-line pharmaceutical wholesaling.

Market evolution since 2005 has included a range of regulatory reforms. A suite of PBS reforms over the last decade, in particular, the introduction of price disclosure, have reduced the cost of medicines and provided significant savings to government and to end consumers. It is estimated that the savings will be in the order of a staggering $25b over ten years from 2010. However, these reforms have also hurt the viability of full-line wholesalers in two ways:

- Falling unit prices of PBS medicines have also reduced the per-unit margin available to wholesalers, who are remunerated based on a fixed percentage mark-up on the PBS price. Since 2011, the proportion of PBS products dispensed with an ex-manufacturing price under $15 has increased from 55% to 77%. By 2020, it is forecast that over 84% of PBS medicines dispensed will be priced under $15 due to price disclosure impacts; and

- At the same time, the wholesaling business has become more complex. Since 2011 the number of individual product items (i.e. Stock Keeping Units or "SKUs") listed on the PBS and distributed by full-line wholesalers has increased by over 40%. This is largely the result of an increase in the number of competitors for off-patent medicines which has in turn, delivered savings to government through price disclosure.

Overtime, PBS related full line wholesale tasks have become loss making activities once discounts to pharmacy have been included. Currently, the full line wholesalers can only generate an acceptable return on invested capital through cross-subsidisation of PBS lines by other non-PBS sales, for example, Over-the-Counter (OTC) products.

While the reforms allow increased choice that benefit consumers, they also impose greater complexity and increased costs on wholesalers required to invest additional working capital in holding inventory of a greater variety of medicines. This has occurred at a time when the average dollar amount earned per product by wholesalers is falling.

Wholesalers have responded to these changes by aggressively pursuing a range of efficiency and productivity gains in their businesses. As indicated in the L.E.K Report, over the period FY13 to FY16 unit costs have been reduced by approximately 16% on average across the three national full-line wholesalers through investments in automation and business restructuring. This has required significant investment.

In the past, wholesalers offered discounts and rebates to pharmacies to win market share and to benefit from scale economies. The ability to offer these discounts has fallen significantly and discounting will become unviable as the mark-up continues to decline.

The current Review is a very timely consideration of the regulations and remuneration that enable achievement of NMP outcomes. Indeed, it is the first wide review of policy and regulation in this space since the Wilkinson Review of 15 years ago.

Under the current funding arrangements, the existing PBS wholesaling model is unsustainable and without some incremental modification of the funding model, achieving NMP outcomes will increasingly be dependent on factors that are external to regulated wholesaler funding such as:

- Cross-subsidising distribution of PBS items via mark-up on non-PBS items; and

- Wholesalers charging service fees to pharmacies for the delivery of 'high volume' products in 24 hours and/or reducing terms of trade.

Responses that increase fees and costs to pharmacies will impose cost on all pharmacies, but have a greater impact on the smaller independent pharmacists, many of which operate in rural and remote areas. This has the effect of increasing risk in the pharmacy industry by a flow on impact to the recoverability of

pharmacist debt. This will jeopardise the financial viability of pharmacies and in turn, the consumers who rely on these pharmacies.

> Full-line wholesalers provide significant working capital (trade debtors) to pharmacies, estimated at c$1.69bn or almost $310,000 per community pharmacy as at 30 June 2016 (see the report by Medici Capital). If this level of funding were not provided to community pharmacy, then pharmacy owners would need to seek additional funding from other lending institutions or sources of capital. Given the current state of capital markets, including bank funding, and the current lending ratios of banks to pharmacy, it is unlikely that this level of additional funding would be readily available. Given the interdependency between the two sources of funding (bank and wholesaler) a withdrawal of wholesaler funding will have a significant impact on the pharmacy lending appetite of banks. It is also important to note that we are currently operating in an abnormally low interest rate environment and any increase in interest rates will place further stress on the market. Thus, there is a strong possibility of market failure if the funding from NPSA members were to be withdrawn.

A sustainable funding model

A sustainable funding model must consider both the funding quantum, and the funding mechanisms.

Our conclusion is that the current wholesale funding model (mark-up plus the CSO funding pool) works well, but needs to be updated and adjusted to both reflect current realities and anticipate future evolution in the Australian community pharmacy and medicines markets.

Funding quantum

> Sustainable long-term investment in the sector depends on a funding model that provides confidence to participants that running an efficient business will allow them to invest with confidence and also earn a sufficient return on capital. This is particularly important for wholesalers, because assets such as warehouses and logistics systems, and IT for inventory management and warehouse management systems are 10-20+ year lifecycle investments that require a substantial commitment, constant forward planning and renewal.
>
> Achieving returns at or above the cost of capital is important to ensure ongoing investment in the sector, including investment in innovation to bring about efficiency gains. The economic analysis conducted by L.E.K suggests that remuneration for wholesalers contained within the Government's forecasts for the 6th CPA (6CPA) is sufficient to deliver the minimum return on capital expectations (WACC of 11%) for wholesalers, assuming the money budgeted is actually spent. Here lies the nub of the problem. It is noted that exactly the same issue applied to community pharmacy and was addressed in the 6th CPA last year.

A resolution of the wholesaler problem does not require new funding by Government.

Our analysis is that the level of funding required over the next five years for the wholesale and distribution sector to meet a return on capital in the range of 11% - 15% is in the order of $3.0 – $3.1 billion, of which the lower end of the range is in line with the funding levels budgeted under 6CPA.

Funding to the wholesalers has taken into account two sources of PBS revenue:

- government funding under the 6CPA which is currently budgeted at $2.775bn; and
- consumer contributions for below co-payment drugs dispensed which is estimated to total $0.2bn over the term of the 6CPA.

The L.E.K. economic analysis demonstrates that there is adequate funding for wholesalers contained in the budgeted expenditure within the 6CPA, however the NPSA's forecasts of projected PBS expenditure and wholesaler remuneration fall below the government's budgeted numbers, resulting in a forecast funding gap of $0.4bn to $0.5bn. It is our experience that government has consistently and significantly underestimated expenditure in this area for more than a decade. Without a change in the funding mechanism, this will result in a substantial shortfall to wholesalers, jeopardising their long-term sustainability.

Funding mechanism – wholesaler mark-up

Prices are tightly regulated by policy and legislation throughout the pharmaceutical value chain.

This is important to ensure consumers receive the benefit of PBS prices negotiated by government with pharmaceutical manufacturers. It also reflects taxpayers' large financial underpinning of the cost of manufacturing, distributing and dispensing PBS medicines.

Currently, the per-item wholesaler price to pharmacists is regulated via a maximum mark-up on the manufacturer price.

The wholesaler mark-up is the primary revenue source from distribution of PBS products. Under successive CPAs it has been structured as a fixed percentage of the PBS ex-manufacturer's price, and that remains the case under 6CPA.

The recent and expected future trend in PBS prices has been a bifurcation towards both very low and very high prices. Over 75 per cent of PBS products dispensed are now priced ex-manufacturer below $15 and therefore well within the current general patient co-payment for PBS items. At the other end of the scale, an increasing number of products dispensed have PBS prices in the thousands of dollars, such as Hepatitis C medications. These high cost products have capped wholesaler mark-ups at a PBS price of $930.06, which equates to a $69.94 mark-up fee to wholesalers. These products have also significantly increased financial risk associated with stock loss.

As prices have moved towards these two extremes, the fixed percentage mark-up structure has resulted in an unsustainable drop in the average margin per unit for full-line wholesalers and this decline in margin will continue which will render the current PBS wholesaling model unsustainable. It is clear mark-ups are failing to keep pace with cost and return-on-investment realities.

A moderate change in the mark-up structure, coupled with a continued CSO Funding Pool, therefore is justifiable to provide greater stability and sustainable levels of remuneration into the future.

The introduction of a floor price of $8.00 - $9.25 as proposed in the L.E.K Report, similar to the AHI structure now in place for pharmacists, would enable more appropriate remuneration for the wholesaling of these medicines. The NPSA forecasts that a mark-up floor price of $8.00 - $9.25 (wholesale mark-up of $0.60 - $0.70 per unit at 7.52%) is required for a sustainable industry with a minimum return on capital. This would equate to $3.0 - $3.1bn (Government and patient contribution combined) paid over the life of the Agreement. The lower end of the proposed margin floor price of $8.00 would provide wholesaler and distributor funding equivalent to 6CPA Government budgeted levels.

The current mark-up ceiling price of $930.06 (which provides a $69.94 per unit mark-up to wholesalers) is no longer appropriate. An alternate structure for funding of high range drugs that recognises the significant stock holding costs and risks though the supply chain is required. NPSA will provide further details on alternative structures in an addendum to this submission that we will table with the Review Panel.

Funding mechanism – CSO Funding Pool

A fundamental aspect of the NMP is equitable access to medicines for all Australians, regardless of where they live. This "community service obligation" is currently achieved by providing fair and sufficient compensation for wholesalers to make the full range of PBS medicines available to any pharmacy.

The NPSA April 2016 paper makes a policy and economic case for why the CSO Funding Pool works. We attach the relevant section of that paper as an Appendix to this overview document.

You will see that rather than being "lazy policy", the CSO Funding Pool helps offset the effects of market distortion that disadvantage full-line wholesalers as critical agents in delivering the NMP objectives.

The CSO Funding Pool is an appropriate mechanism in the economically irrational market in which full-line wholesalers are expected to operate, created by Government's aggressively applied PBS monopsony, and requirements to achieve the NMP access goals for all Australians.

Full-line wholesalers are the linchpins of the whole PBS system, for if full-line wholesaling breaks down, there is a risk that the whole medical prescribing and pharmaceutical service delivery system breaks down with them. It is critical national infrastructure that needs to be sustained, while still promoting competition and efficiency in the market.

However economically imperfect, the CSO Funding Pool has been effective in addressing an urgent and unsustainable situation that arose due to government policy change and cherry-picking of the small percentage of profitable lines by some distributors a decade ago. It has also underpinned very substantial savings to government over the past decade in the area of pharmaceutical wholesaling. So, far from being a cost, it is in fact a part of a very substantial government fiscal savings.

As such, it has been doing an important job for both the Commonwealth Government and the Australian public. It compensates for a myriad of market failures that distort the market and how pharmaceutical goods and services are priced and paid for. It supports the partnership between Government and pharmaceutical manufacturers, wholesalers and dispensers.

In short, the CSO Funding Pool does the fundamental policy job expected of it, at a reasonable and affordable cost to taxpayers in the context of the PBS and health expenditure as a whole. It has proved critical to delivering Government's objectives under the NMP, while ensuring that there is still internal contestability in the medicines wholesaling sector.

If there was not a CSO (or if it were discontinued in the foreseeable future), and/or if the erosion of wholesale revenue from declining pharmaceutical prices is not addressed, two things may happen:

- A rationalisation of the full-line wholesaling industry – an outcome that has been previously rejected on multiple occasions by the Australian Competition and Consumer Commission as being anti-competitive and not in the consumer's interest; and/or

- A major "downwards" redefinition of what reasonably can be expected by retail pharmacists and consumers as full-line service without additional payment, in terms of range of stock maintained and the timeliness and frequency of deliveries to pharmacies.

Compared to alternatives, the current CSO Funding Pool mechanism is a critical component that ensures the needs of the NMP are met.

There are numerous other ways to deliver a community service obligation, including:

- Tendering (national, state, regional, remote markets);
- Fixed fee per item funding;
- Fees paid directly to pharmacists in rural and remote areas; and
- Manufacturers taking responsibility for distribution of medicines.

Each of these models has benefits and downsides. Under several of the alternative models, the direct cost to government of achieving NMP could be reduced (at least in the short term). However, in each model this benefit would be off-set by negative impacts on consumers either in the form of reduced access to medicines; higher costs both to consumers in the short term and Government in the longer term; and a loss of redundancy in the system. This latter point is highly significant. The current pharmaceutical wholesale supply chain is formally designed by Government as part of Australia's critical national infrastructure. No doubt, as some suggest, a monopoly situation might be cheaper. It is also with not the slightest doubt, that had a situation existed in 2011 when API's Bundarra Distribution Centre in Queensland experienced a significant flood event, then the consequences for the public would have been catastrophic.

Under a tendering approach, there is the risk that Government would be faced with higher costs in the longer term as the competitiveness of subsequent tender rounds is eroded due to incumbency advantages such as an installed base of delivery infrastructure. This could see incumbents establish monopoly positions that deter competitors in subsequent tender rounds from investing and tendering. There are significant barriers to entry in this industry. One cannot simply assume a myriad of competitors will appear in a market once they have previously exited.

We also understand that the Review Panel is keen to explore the option of manufacturers taking responsibility for distribution of their medicines. This has a myriad of issues associated with it including the concentration of market power with the larger manufacturers, the relative unattractiveness of providing services to smaller manufacturers; a system that will be practically difficult for pharmacists given multiple delivery points.

The achievement of satisfactory NMP outcomes acceptable to the community will also be challenging under those models that require small pharmacy businesses or manufacturers to negotiate directly or bear additional costs.

When compared to these alternatives, the current CSO Funding Pool represents a more efficient and effective approach to meet the needs of the NMP. It provides confidence to wholesalers that funding will be available to offset the higher cost of services relating to low volume medicines, 24-hour delivery and responsive services that benefit all pharmacists and consumers. The "share of pool" funding mechanism also provides a powerful incentive for healthy competition between full line wholesalers on the basis of responsive service to pharmacists and cost efficient operations.

The CSO Funding Pool is not currently adjusted to take into account growth in volumes or cost inflation. The NSPA is proposing the indexation of the CSO Funding Pool be reinstated to ensure funding keeps pace with inflation and growth in volumes.

The NPSA would not oppose an alternative to the CSO Funding Pool that delivered both NMP outcomes and industry viability more efficiently. However, having given serious consideration to the options, our conclusion is that none of the alternatives raised in the Review's Discussion Paper would achieve this on the ground in terms of meeting the NMP goals, cost, efficiency or consumer satisfaction.

SUMMARY

In summary, the NPSA submission provides detailed economic modelling to justify $2.775bn billion in government wholesale and CSO funding.

Such a model would include:

1. Retention of the wholesale margin of 7.52%;
2. The introduction of a product mark-up floor price of $8.00 - $9.25 (wholesale mark-up of $0.60 - $0.70 per unit);
3. Retention of the CSO Funding Pool at its current level; and
4. Indexation of the CSO reinstated.

We believe this could be achieved within the funding envelope of the 6CPA.

CONCLUSION

NPSA members are highly committed to their businesses, and to being full partners with Government, manufacturers and pharmacists to keep the PBS the world-leading scheme that it is, for the benefit of all Australian consumers.

The NPSA is very keen to work with Government and our other partners to make the PBS, and its supply chain, as efficient, sustainable and affordable as it can be while at all times ensuring that the objectives of the NMP are met.

We would be delighted to discuss this submission package with the Review Panel or provide any additional information that the Panel might require.

National Pharmaceutical Services Association
September 2016

APPENDIX 1

THE ECONOMICS OF THE COMMUNITY SERVICE OBLIGATION

Introduction

In a truly free market, the CSO would not be necessary. Competition between wholesalers and distributors alone would be sufficient to drive timely and affordable access to all PNS items anywhere in Australia.

The problem however, is that pharmaceutical wholesaling is not a distortion-free market. Instead, it is severely affected by a range of factors distorting the operating environment so much that pure price, service and quality-driven competition is impossible, and the full range of PBS items cannot be delivered in a timely and affordable manner without significant external intervention in the market.

Market failures preventing a pure competitive market in this sector, and justifying interventions like the CSO to overcome distortions, include:

- The PBS is the gateway to Australians' access to prescription medicines and being controlled by Government through its subsidy, effectively sets Government up as a monopsony purchaser and price-setter of PBS-listed pharmaceuticals and distribution services[1].

- Government effectively determines the overall terms of that monopsony in conjunction with the Pharmacy Guild of Australia via the Australian Community Pharmacy Agreements, not by the providers of wholesale service and distribution networks.

- There are strong elements of market failure based on other externality factors including wider public policy, politics and regulation, not simply those expressed through the four pillars of the National Medicines Policy and PBS rules.

- The realities of Australia's geography, distances and population distribution, which makes delivering medicines to regional, rural and remote pharmacies uneconomic for most medicines if wholesaler mark-up is the only source of wholesaler PBS-derived revenue; and

- Cherry picking by non full-line distributors and self-distributing pharmaceutical manufacturers undermines the already marginal viability of the broader market.

When these factors are rolled together, it means that the obstacles to satisfying the high expectations of the National Medicines Policy are impossible to meet in conventional market terms.

[1] This includes the medicines dispensed that do not attract a direct subsidy payment because their total dispensed cost is within the General or Concessional co-payments. Government still makes the rules for all listed PBS medicines.

A volume-based subsidy through the CSO keeps full-line wholesalers "in the game" by making the storing and delivering low-volume and high-delivery cost medicines, and the infrastructure, labour and operating costs needed to meet National Medicines Policy expectations, commercially-sustainable.

PBS monopsony

The PBS overwhelmingly is the vehicle by which Australians get access to prescription medicines. PBS subsidies and related payments underwrite the entire pharmaceutical supply chain, from manufacture to patient. In 2015-16, Budget estimates for PBS outlays – the Commonwealth's subsidy – were just on $10 billion[2]. While this is a large amount of money, it is actually declining in real terms and as a percentage of GDP. The published figures underestimate the decline, as they do not take into account over $1 billion of rebates paid to Government by pharmaceutical manufacturers that are not separately identified and taken into account elsewhere in the Budget.

That subsidy outlay is in addition to patient co-payments for medicines priced above the general and concessional thresholds (or paid in full because the relevant patient and family safety nets have been reached), and full payment by patients for those medicines priced below the thresholds.

The absolute predominance of the PBS, the whole supply chain's dependence on its subsidies, and the centrality of PBS listing to the public's access to around 6,200 medicines, effectively make Government the overwhelming monopsony purchaser of pharmaceuticals and pharmaceutical services. It determines the policy that sets the terms of the PBS's overall policy underpinnings and it determines and operates pharmaceutical listing and price setting.

Government's PBS monopsony is just as much a factor of market failure as any provider monopoly. Because of the nature of the subsidy, and how it overwhelmingly dominates the medicines market, its pervasiveness arguably is far greater than most monopolies.

In effect, Government is the principal buyer at all points of the supply chain. Private prescriptions, while important as a revenue stream, are too limited and specialised a market to justify the needed investment in the supply chain.

Above all, Government's budgetary and political priorities in constantly seeking to reduce the rate of real growth in PBS outlays, imposes severe and unavoidable financial and commercial pressures on all parties in the Australian pharmaceutical industry. In our experience, many policy and decision-makers have limited understanding of the commercial realities of running a pharmaceutical wholesaling business, which is understandable given their focus is on the PBS and making it work as efficiently as possible for taxpayers.

The normal scheme of things in a free and open market, where suppliers of goods and services determine availability and price based on the cost of providing the good or service; the demand for them; and the ability to derive a reasonable profit and return in investment, simply do not apply in a pharmaceutical supply and distribution chain effectively governed by the PBS and its policy and regulatory frameworks. This is surely a market failure in economic terms.

[2]2015-16 Health Portfolio Budget Statements, Outcome 2

Even when the price of medicines does not invoke any actual Government subsidy – that is, when the price of the medicine to consumers is below the general or concessional co-payment thresholds, the PBS's regulatory reach still gives Government the final word over the terms and conditions of pharmaceutical supply, distribution and dispensing. It is indeed a highly regulated environment.

Its monopsony is embodied in the Commonwealth's leadership and financial dominance over the National Medicines Policy and its four key pillars, namely:

- Timely access to the medicines 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.

These national policy pillars are also reflected in the CSO Deeds that full-line wholesalers accept.

These four pillars, in the context of Australian geography and population distribution are, however, major contributors to market failure in the pharmaceutical wholesale and distribution sector. Complying with them carries costs that would not apply in a pure market, all things being equal.

ANSWERS TO SOME OF THE QUESTIONS RAISED BY THE REVIEW PANEL - NOT OTHERWISE COVERED BY THE L.E.K. REPORT

Question 4 - Should Government funding take into account the business model of the pharmacy when determining remuneration, recognising that some businesses receive significant revenue from retail activities?

The NPSA does not believe the business model of any one pharmacy or pharmacy operator should be taken into account in determining remuneration.

There is no one pharmacy model that suits each community or indeed, every pharmacist. This is not a "one size fits all" sector.

Essentially, the PBS/CPA remuneration model applies to only one element of a pharmacy business, even though it invariably is by far the biggest component of a pharmacy's customer service and turnover.

That is not to say that pharmacy business models are, or should be, static. Indeed, over the last two decades they have evolved as retail pharmacy has responded to commercial and regulatory changes, especially the regular and successive changes to regulations, by Government, as it seeks to rein in cost growth in relation to administering the PBS.

Each pharmacy, regardless of scale, location, customer desires or branding, has fixed and variable costs that continue to change and grow as a percentage of PBS-derived revenue. Pharmacies need to remain profitable to provide the sorts of customer-centred advice as well as dispensing that are expected by Government as payer. As PBS/CPA dispensing revenue rules are tightened, pharmacies as businesses, and partners including wholesalers and banner groups, have been adapting to change in terms of maximising efficiency and profitability.

To factor in non-core aspects of pharmacy business models inadvertently would punish drives to increase business efficiency and profitability in a way that could compromise pharmacies' core dispensing business. In our view, it is better to let different pharmacy business models flourish that maximises affordable access to PBS medicines generally, but particularly in regional and other localities where sustaining a profitable pharmacy business is more difficult than in well-served metropolitan markets.

As a final comment, should Government wish to restrict community pharmacy to a dispensary style operation with pharmacy only medicines, then significant additional funding would be required.

Question 7 - Should the CPA be limited to dispensing and professional programs provided by community pharmacy only? If so, how can contestability and effectiveness be ensured in professional programs? If no, why not?

It is a Community Pharmacy Agreement and, as such, it should remain exclusively about the dispensing of PBS medicines and the provision of localised pharmacy- and pharmacist- delivered, and patient-focused, services.

In relation to effectiveness, we note that it is a prerequisite of the 6CPA programs that they are first evaluated for cost-effectiveness by an independent assessment process before being approved for inclusion and funding. We also support ongoing monitoring and re-evaluation of CPA programs and services in the best interests of taxpayers and PBS consumers.

A benefit of the present arrangement is that programs have consistent execution. Multiple contested providers would pose a risk to this consistency, a risk that would require mitigation.

Question 8 - Is it appropriate that the Government continues to negotiate formal remuneration agreements with the Guild on behalf of, or to the exclusion of, other parties involved in the production, distribution and dispensing of medicines? If so, why? If not, why not, and which other parties should be involved? Is there currently an appropriate partnership with these other parties, including consumers?

The NPSA view is that, as an exclusive bipartite agreement between the Government and the Guild, the CPA does not reflect that key deliverables under the CPA, including medicines wholesaling and distribution, is provided by third parties such as NPSA members. Those parties are materially affected by the CPA, and are accountable under it for delivery of their key responsibilities, but have no direct voice in decisions affecting their viability and future.

While Government 'contracts' with community pharmacy to dispense PBS prescriptions in support of the National Medicines Policy, the Guild cannot be expected to speak on behalf of, or be accountable to Government for the performance of, these third parties. That is not to say, however, that the Guild should not remain the most important party in any post-6CPA Agreement, as PBS dispensing remuneration always will be the key deliverable of the CPA.

Question 10 - Is the current system of dispensing of medicines in Australia that focuses predominantly on community pharmacies operating as small businesses, the best way to achieve the objectives of the NMP? Should there be alternative approaches for the dispensing of PBS medicines beyond a community pharmacy, such as through hospitals or different pharmacy arrangements? If so, what could these alternative approaches look like?

The NMP aims to provide better health outcomes through the accessibility, affordability and wise use of affordable medicines.

In our view, the current distribution of community pharmacies across Australia, being more accessible than banks, supermarkets and medical centres, underpins the NMP and as such, should not be subjected to

change. On the whole, it works well. Pharmacy location is driven by population, demographics and competition. Pharmacy locations have evolved over time to match community demand for services. We do not advocate more locations, as this would undermine viability.

The fact that community pharmacy has developed primarily as small business is due to the fact that there is no commercial model to support pure PBS dispensing in a retail setting. While regulation affecting the operations of community pharmacy may change community pharmacy as the basis PBS delivery unit has no need to do so. In effect, it is important that regulation keeps pace with innovation in the community pharmacy sector.

Market dynamics already play a big part in differentiating different community pharmacy models and promoting innovation (big box discounter, high street and professional service orientated, medical centre co-located etc.). Further expansion of the Government-remunerated role of pharmacy services in or around the CPA (vaccinations, adherence, minor ailment schemes, primary care etc.) will provide incentive for further differentiation.

Question 26 - Should there be limitations on some of the retail products that community pharmacies are allowed to sell? For instance, is it confusing for patients if non-evidence based therapies are sold alongside sold prescription medicines?

There are already a number of products that are not allowed to be sold in community pharmacies including tobacco/cigarettes, alcoholic beverages, and food (including coffee) prepared on the premises. These would seem self-evident. Beyond this, we are of the view that the issue is highly problematic.

With respect to complementary medicines, we note that these are lawful retail products listed as approved for sale by the Therapeutic Goods Administration.

The chief consideration for these products is that they are safe for human consumption, irrespective of therapeutic or other efficacy claims made for them. Nevertheless, while the evidence required for listing on the therapeutic register is not as great as that required for TGA product registration, many of these products are therapeutically active and can often interact with other medicines (whether prescription, over the counter or complementary). As such, they are most appropriately sold under the supervision of a pharmacist.

We also note that in addition to therapeutic goods regulations, products sold in pharmacies re also subject to Commonwealth and State/Territory competition, consumer and sale of goods laws. That means that pharmacies, like any other retail businesses, must not make claims to the properties, safety and efficacy of medicines, complementary medicines or any other sold item that are not factual and evidence-backed.

Question 28 - More generally, is there a need for new business models in pharmacy? If so, what would such a business model look like and how would it lead to better health outcomes?

As previously mentioned in relation to Question 4, the market will determine what business models survive or perish. More to the point, regulation should not future-proof the system from new innovative and disruptive ways of delivering professional services – both dispensing and wider service – as part of community pharmacy-based practice.

Health hubs are an example of this. Pharmacies that offer a range of health services via other health professionals is a model that has been trialled, but to date has not been viable. Models will evolve over time that demonstrate valuable consumer and patient outcomes, but in the end, it is the market that will determine where and when this occurs.

Question 40 - What pharmacy services should be fully or partially Government funded and what is left to market or jurisdiction demands?

Public subsidy of pharmacy services always should be on the basis of safety, efficacy and evidence.

Therefore, all pharmacy services that have been independently evaluated for cost- effectiveness and can lead to better health outcomes for patients should be considered for Government subsidy in respect of eligible patients, less a reasonable co-payment (in terms of the patient's means and capacity to pay) to send an appropriate price signal and manage demand.

Examples of such services include, but are not limited to:

- Medication packing services (sachets or 7x4 blister packs), medication adherence interventions and other clinical inventions
- Risk screening and assessment services (for example blood pressure monitoring, inhaler technique etc.)
- Vaccination services; and
- Minor ailment services.

Many of these services would not be expensive to fund yet free up valuable cost, staff and time resources in otherwise high-demand settings such as GP surgeries and public hospitals.

Funding could be provided by either allocating approved pharmacists an MBS provider number (with access to agreed item numbers at appropriate funding similar to nurse practitioners) or via the current claiming method.

Questions 42 – 53 - Ownership and location rules

The NPSA notes that while pharmacy location rules are in the scope of this Review, community pharmacy ownership is a State and Territory Government responsibility.

Nevertheless, NPSA generally supports both the current ownership and location rules as having served the Australian community's best interests well. There is much competition and innovation in Australia's pharmacy industry and these rules have not held the industry back.

We believe that it is open to serious question as to whether or not a totally different model of pharmacy (whereby pharmacists were simply employees of a larger corporate structure) would provide the same level of service and professionalism to the community, as does the current model.

We see no reason that the rules should be changed substantially and indeed, we see substantial risk in doing so.

Question 49 - It has been suggested to the Review that pharmacies should be allowed to enter new locations subject to payment of an appropriate fee to Government to prevent excessive entry to the pharmacy market. Any pharmacy then having been competitively impacted by a new entrant, or who would prefer to exit the market, would be able to receive compensation for surrender of its own approval number. Would such an approach by desirable or undesirable?

The existing pharmacy location rules serve both the community and Government well. While the above suggestion might benefit certain operators, it is difficult to see how it would benefit the sector or consumers generally.

In the NPSA's view, there is no reason for change, other than to address unintended consequences of the current rules where they arise.

The existing distribution of community pharmacies is better than that of supermarkets, banks and medical centres. New licences are catered for by the shopping centre; medical centre and greenfield site rules.

That said, if any substantial changes were introduced to location rules, then fair compensation for disadvantaged entities and individuals would need to be considered as part of a transition.

We would like to make two final points.

1. Pharmacy licenses are an asset that can be sold or traded. As such, new entrants already have a mechanism for market entry.
2. As the mechanism is proposed in the question, it is our view that an unintended consequence of its introduction would be substantial predatory behaviour by certain entrants.

Question 53 - Recognising that restrictions on co-location of pharmacies and supermarkets exist under state and territory legislation, would the removal of this restriction from the pharmacy location rules be desirable or undesirable?

NPSA is opposed to supermarket chains owning pharmacies.

Community Pharmacy locations have evolved over the years, driven by patient and consumer demand and are well distributed. There is no blanket or overarching benefit to colocation with grocery.

There is already a far better distribution of community pharmacies than supermarkets, with many of these pharmacies already located next door or in very close proximity to supermarkets.

We believe the current distribution of community pharmacies does the job consumers and Government expect in terms of convenient and affordable access to dispensed PBS medicines, and we do not see a demonstrated need to change existing restrictions in that regard.

Having said that, NPSA members will continue to supply medicines to community pharmacies wherever they may lawfully be located now or in the future.