Review of Pharmacy Remuneration and Regulation
#192_BHLF-58KW-N52Y-W

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28 July 2017

Professor Stephen King
Chairman
Review of Pharmacy Regulation and Remuneration
Pharmacy Review (MDP 900)
Department of Health
GPO Box 9848
Canberra ACT 2601

Dear Professor King

NPSA RESPONSE TO THE INTERIM REPORT OF THE REVIEW

On behalf of the National Pharmaceutical Services Association (NPSA) we welcome the opportunity to comment on the Review's Interim Report.

We acknowledge and respect the challenging task your Review Panel has been given and we have appreciated the opportunity not only to make submissions to the Review, but also to engage with the Review Panel and Secretariat in frank and robust discussions about the nature of pharmaceutical wholesaling, its relationship to community pharmacy and manufacturers and the challenges facing our industry.

Our response will predominately focus on Chapter 6 of the Interim Report.

EXECUTIVE SUMMARY

NPSA contends the Community Service Obligation (CSO) meets the expectations of both the National Medicines Policy (NMP) and Government to ensure PBS medicines are delivered in very short time to all pharmacies across Australia, enabling patients' timely and equitable access to those medicines at an affordable cost. The CSO has operated successfully for 12 years and any option to dismantle it risks a return to the market failure that was the reason for its introduction in the first place.

As demonstrated in the NPSA's submissions, where the CSO falls short is not as a mechanism per se, but in the quantum of compensation it affords full-line wholesalers that accept the NMP-linked supply and distribution obligations it imposes. To date, the Review has not made the case to the contrary. In fact, the Review has acknowledged "CSO Distributers *(sic)* are not earning economic rents"[1].

The Interim Report outlines three options relating to The Distribution of Medicines to Community Pharmacy namely: Alternative 6-1: a manufacturer distribution model; Alternative 6-2: the current CSO arrangements with uniform implementation of standards; and Alternative 6-3: a separate review of the CSO.

NPSA does not support Alternatives 1 and 3. Alternative 2 is acceptable to the NPSA, provided that future sustainable funding requirements for wholesalers are addressed.

NPSA is concerned that a Manufacturer Distribution Model represents a significant shift from the status quo with no obvious benefit and significant implementation risk. This option includes a number of material drawbacks and associated risks. These include greater regulatory burden for government; greater administrative burden for pharmacy; increased risks to medicines availability due to diminished system redundancy, and greater complexity for all parties along the supply chain. We note that Medicines Australia supports this view.[2]

With regard to 6-2, we note that the wholesale and distribution network in Australia historically has worked so well that the expectation that a medicine can be ordered by, dispatched to, and received by a community pharmacy within 24 hours is now largely taken for granted. The specification of 24-hour delivery (without the ability for wholesalers to charge a fee) does not address sustainable funding requirements.

NPSA's submission to the Review demonstrates that projected PBS funding under the current 6CPA arrangements is not adequate. This has led to wholesalers expanding their activities to supplement PBS delivery with OTC and front of shop products. This cross-substitution is not sustainable in the long term. NPSA believes Option 6-2 could be acceptable if future sustainable requirements for wholesalers are addressed. As previously outlined in the NPSA submission, this should include the introduction of a floor price which represents a workable alternative that can be funded within existing Government budget guidelines.

In relation to 6-3, NPSA would need more information about the nature of any proposed review of the CSO before it can substantially comment on this proposed Alternative. Should this recommendation find its way into the Final Report, NPSA would seek to inform the Terms of Reference of any such review.

NPSA welcomes Option 7.2. as we do not believe that the Guild can be expected to speak on behalf of, or be accountable to Government for the performance of third parties, such as wholesalers.

We encourage the Panel to ensure its findings and recommendations reasonably reflect the inter-related and interdependent relationships *throughout* the pharmaceutical supply chain, and the economic and commercial implications of those relationships, specifically as they relate to ensuring the requirements of the NMP are met. Recommendations should be practical, implementable and road-tested with industry wherever possible before they are finalised. It is vital for our industry, and for the whole pharmaceutical supply chain, that whatever is given to government for decision is comprehensive, realistic and affordable.

NPSA remains ready to assist the Review as it finalises its Report.

[1] Interim Report, page 125

[2] See Medicines Australia Media Release dated 23 June, 2017

OUR COMMENTS ON THE CONTENTS OF THE INTERIM REPORT

Our concerns essentially can be categorised as "general" and "specific".

At the **general** level, appreciating that the Terms of Reference and the Review Discussion Paper had a strong emphasis on community pharmacy, we believe the Interim Report does not sufficiently recognise the complex interdependent relationship between pharmaceutical manufacturers, wholesalers and community pharmacy. We also believe that the Interim Report does not sufficiently recognise that the market for services (including wholesaler services) is severely distorted by competing policies. On the one hand are the aspirational and equality of access goals of the NMP and on the other is deliberate intervention by governments in the community pharmacy market, especially as they relate to pharmacy location rules, pharmacy ownership, and restrictions placed on commercial transactions with pharmacy operators.

At the **specific** level, we have major concerns about the Review's assumptions about our industry, and its specific conclusions and recommendations in Chapter 6 about the future support and remuneration for pharmaceutical wholesale and distribution services. This concern especially relates to the Alternatives regarding the Direct Manufacturer Distribution model and the Community Service Obligation (CSO) pool.

We address each of the proposed Alternatives in detail in the following pages but say at the outset, we do not support Alternatives 1 and 3 and Alternative 2 is only acceptable to NPSA members **if** the future funding requirements for pharmaceutical distribution are addressed appropriately.

GENERAL CONCERNS

Insufficient consideration of the complex and interdependent relationship between pharmaceutical manufacturers, wholesalers and community pharmacy

In the Interim Report, the Review's emphasis is firmly on the needs and priorities of community pharmacy.

The Review makes this crystal clear at the outset in setting out its Strategic Vision and Intent:

> *The Panel has determined its strategic vision and considered options for constructive pharmacy reform by anticipating the future requirements of community pharmacy in Australia…As an agent of the Australian Government, community pharmacy can only be effective if it is appropriately remunerated and provided with appropriate incentives.*[3]

That strategic commitment to the primacy of community pharmacy interests characterizes the entire Interim Report (as it indeed runs through government policy on the PBS and the pharmaceutical sector). It is very much an assessment focused on the retail end of the pharmaceutical supply chain, as the part with which consumers engage, and where the politics of access to medicines and the PBS are most acutely felt by governments.

The NPSA accepts the political reality of the pharmaceutical supply chain, and the fact that the benefits wholesalers provide to consumers is all but invisible to them as end users.

Similarly, we acknowledge that an efficient and prosperous community pharmacy sector benefits all parties in the industry and is crucial for sustainability of the PBS and maximising the quality and range of medicines and medicines-related services to patients and consumers.

However, to focus the Interim Report predominantly on supporting the needs of community pharmacy, means that it does not sufficiently consider the complex and interdependent web of relationships between manufacturers, wholesalers and community pharmacies.

[3] Interim Report, page 3

In this light, we hope that before its Final Report is completed the Panel would revisit the Interim Report as a whole to ensure its findings and recommendations reasonably reflect the inter-related and interdependent relationships **throughout** the pharmaceutical supply chain, and the economic and commercial implications of those relationships.

If that is not possible given time constraints, we propose to work with Government in the lead up to the next Guild Government Agreement to ensure appropriate and sustainable remuneration is achieved for wholesalers well into the future.

Insufficient recognition of externalities caused by government intervention

The Interim Report refers to the NMP as a principal frame of reference. The NMP has had bipartisan acceptance for nearly twenty years, and in that time, has guided and set government policy regarding the PBS and the supply and access to medicines. NPSA supports the principles of the NMP unequivocally and has framed its response to the Interim Report on that basis.

In relation to the Review's approach to the NMP, the Interim Report says this:

> *The concept of 'access' as it relates to medicines and pharmacy services is multidimensional. While the physical location of a pharmacy is important, as is a consumer's travel distance, there are multiple factors that impact on accessibility. Whereas the National Medicines Policy (NMP) does not define the concept of 'accessibility', it does refer to timely access, affordability, care that is responsive to people's needs, quality use, and cost-effectiveness for the community.*[4]

That is a correct statement but, as the NPSA pointed out in its original submission to the Review, the NMP has high and socially-desirable aspirations in relation to access and timeliness, particularly in regional and remote Australia that are hard and not cost-effective to deliver. That applies particularly to wholesalers' obligations under the CSO.[5]

We also welcome Option 7.2 as we do not believe that the Guild can be expected to speak on behalf of, or be accountable to Government for the performance of third parties, such as wholesalers.

SPECIFIC CONCERNS ABOUT CHAPTER 6 OF THE INTERIM REPORT

The Interim Report insufficiently addresses Term of Reference #3

Term of Reference 3 relates to wholesalers and pharmaceutical wholesale and distribution specifically "The appropriate level and structure of remuneration for wholesalers and pharmacies for wholesaling, logistics and distribution of medicines from manufacturer to community pharmacy".

Essentially, that Term of Reference asked the Review Panel to consider the regulation requirements; costs and cost drivers; the adequacy of funding to promote investment in supply chain infrastructure; and the relationships between manufacturer, wholesaler, distributor, delivery partner, pharmacy and government and how these impact on consumer and community need.

Consistent with the Review's overall focus on the needs and a priorities of community pharmacy as its paramount consideration, the NPSA's view is that the Review's consideration of Term of Reference 3 has fallen short of what it expected.

[4] Interim Report, page 17
[5] NPSA submission to the Review, Appendix 1

Compared to other Chapters of the Interim Report, Chapter 6 on wholesaling issues is surprisingly brief. Chapter 6 lacks depth and rigour of inquiries into wholesaling and does not show an appreciation of business operations or the interdependent commercial relationships between wholesalers' and community pharmacies and their proprietors. We do not believe the specific points of Terms of Reference 3 have been worked through systematically.

We are particularly concerned the Interim Report Review overlooks the nature of long term infrastructure investments that wholesalers are required to make to provide efficient and timely supply. Ongoing investment in physical infrastructure and supporting systems with 10-15 year lifecycles requires a stable and predictable remuneration environment and reasonable expectation that invested capital will achieve acceptable returns.

The Review also suggests that:

> *(M)any CSO Distributors are moving into other areas of the pharmaceutical supply chain, such as more vertically integrated models of pharmacy franchising and banner groups as well as supply and distribution of non-PBS product lines. This diversification is proving profitable as evidenced by the positive financial performance of these publicly listed companies*.[6]

For avoidance of doubt, the move by CSO wholesalers to diversity income streams simply reflects the inadequate returns that are currently received from the distribution of PBS products which are the core of distribution activities.

Even though the Interim Report goes on to say that commercial-in-confidence information provided by NPSA "indicates that CSO Distributers *(sic)* are not earning economic rents"[7], the Review's preferred Alternative 6-1 assumes different mark ups could be negotiated for distribution across a number of dimensions (such as volumes, cold chain etc.) and that would provide sufficient return for wholesalers.

The Interim Report also makes repeated comments that it could not ascertain whether the existing 7.52 per cent capped mark-up represents good value to government or not. We believe NPSA has provided clear evidence that this mark up funding is insufficient and remain happy to discuss this in more detail, if required.

We note that both in the Report and expanded on by the Panel in our meeting there is a feeling that this area involves substantial cross subsidy by way of allocation of all of PBS/OTC joint costs to PBS. This is inaccurate. As part of our original submission, for the first time, all NPSA members provided commercial in-confidence financial data into a data room. L.E.K. Consulting were engaged by NPSA to independently assist them. They examined the data on a line by line basis and concluded that [redacted] of distribution costs are attributable to the PBS and [redacted] of costs are attributable to OTC. This data had not been available previously and we would encourage the Review to take it into consideration.

Finally, the Review appears to be of the view that something as complicated and substantial as PBS delivery can be achieved at a marginal cost of delivery. We would respectively suggest that this view is short term; economically irrational; not in operation anywhere in the world and specifically contrary to Term of Reference 3. It also ignores the history of how the existing infrastructure was put in place which was focussed on servicing the prescription product needs of retail pharmacies.

Before it completes its Final Report, we encourage the Review Panel to take every opportunity to better understand the comprehensive operating environment of pharmaceutical full-line wholesalers and the potential further rise of

[6] Interim Report, page 125
[7] Interim Report, page 125

non-full-line logistics services. If the information we have provided to the Review has proved insufficient to date, we will meet requests for additional data and information, preferably before the Final Report is completed

Review comments on the Community Service Obligation pool

It is quite clear from the Interim Report that the Review Panel considers the CSO pool as bad policy. It states:

> *An improved system of supply should have clear and enforceable rules covering delivery times, terms and conditions. These do not have to be placed on the pharmaceutical wholesalers; rather, they can be placed on the medicine suppliers (who then have multiple unregulated wholesalers / logistics companies to choose from when servicing community pharmacies).*
>
> *The Panel considers that the CSO therefore represents excessive and, when compared to the direct to pharmacy model, unnecessary regulation.*
>
> *By not separately regulating pharmaceutical distribution, the government will reduce bureaucracy and can allow for significant innovation.*[8]

It is also clear from the Interim Report that the Review considers the "unregulated" direct to pharmacy distribution model as superior and preferable to current arrangements, and that adjustments to the wholesale mark-up would both provide adequate remuneration to wholesalers and better reflect the range and volume of medicines supplied to pharmacies.

The NPSA does not share this view and we set out our reasons below. We believe the CSO has done a good job of meeting the expectations of both the NMP and Government to ensure medicines are delivered in very short time across Australia, and therefore patients have timely and equitable access to those medicines. We are also not clear how the CSO has failed to date.

We concede that the CSO is just another potential market distortion due to the need for significant government intervention to ensure the NMP is met (free market forces will not deliver the NMP). The CSO represents government intervention in the pharmaceutical supply chain. Nonetheless, in terms of its objectives, it *works*.

As the NPSA consistently has argued to the Review, where the CSO falls short is not as a mechanism, but in the quantum of compensation it affords full-line wholesalers which accept the NMP-linked supply and distributional obligations it imposes. That full-line support is something that a direct to pharmacy distribution model does not offer. We believe it would be missed by consumers, medicine prescribers and dispensers if, for whatever reason, it is wound back or abandoned. Further detail is provided below.

Relationships between wholesalers and pharmacists

The Medici Capital paper appended to the NPSA's original submission to the Review sought to describe and quantify the complex commercial relationships between wholesalers and community pharmacy. It is not obvious from the Interim Report that these relationships and their impacts were duly considered.

Medici's analysis indicates that, as of 30 June 2016, the total working capital utilised by community pharmacy from wholesalers was approximately $1.69 billion, averaging almost $310,000 per pharmacy. This is mostly in trading

[8] Interim Report, page 127.

terms, but [redacted] per cent of total working capital provided is outside trading terms. In addition, over five years wholesalers wrote off bad debts valued at approximately [redacted] million[9].

As Medici pointed out, a working capital contribution to community pharmacy equivalent to the better part of 20 per cent of its annual sales is "high and unique to pharmacy". Effectively, wholesalers' generous terms of trade, and back office and promotional support for pharmacies participating in wholesaler-funded banner groups are "soft" finance for pharmacy proprietors. It underpins the viability and profitability of community pharmacy. The cost of acquiring that working capital from institutional lenders and other formal sources would cost pharmacies a considerable deal more, which would in turn, be passed on in costs to consumers and tax-payers or pharmacies would be closed down.

It should also be noted that terms of trade and payment periods are usually of far greater benefit to pharmacies than wholesalers. The Interim Report quotes a submission made by a pharmacist ….

> *The big issue for me is the cash flow implications and remuneration. I have to purchase the cost of several medium sized cars and receive than 0.3% of the total cost as gross profit. Not to mention the fact that I have to wait until the end of the month to submit my BAS statement and claim my GST refund.*[10]

The Review does not highlight however that the wholesalers have to do exactly the same thing, only on a vastly greater scale.

Major changes to the PBS remuneration structure, notably the removal of the CSO, and making terms of trade subject to greater formal regulation along the lines the Interim Report suggests, would remove any incentive wholesalers have to provide valuable working capital funding to pharmacies. Further, without the CSO and/or appropriate funding, the funding of working capital would be unlikely and this would result in systematic market failure of the community pharmacy model.

In respect of the regulatory externalities noted earlier, state and territory restrictions on third parties' commercial relations with pharmacies and pharmacists provide no incentive for wholesalers to be de facto bankers to community pharmacy, even within a banner group arrangement. Should the current mark-up/CSO wholesaler remuneration framework be replaced by a negotiated mark-up, the impact on wholesaler's margins would be such as to leave no room for the important working capital funding that is currently available to pharmacies.

We would suggest this working capital funding is one of the major reasons that has both encouraged and allowed community pharmacy in Australia to evolve into a system that meets unique Australian challenges and provides an extremely high level of service to Australian consumers.

DETAILED COMMENTS ON THE ALTERNATIVES PROPOSED IN THE INTERIM REPORT

The Interim Report outlines three options in relation to the CSO and regulation of medicines:

Alternative 1: a manufacturer distribution model

Alternative 2: the current CSO arrangements with uniform implementation of standards

Alternative 3: a separate review of the CSO.

[9] Medici Capital paper, 23 September 2016, pages 2-3
[10] Interim Report, page 130

As indicated above, the NPSA does not support Alternatives 1 and 3 for the reasons outlined below. Alternative 2 is acceptable to the NPSA, provided that future sustainable funding requirements for wholesalers are addressed.

Alternative 1: Manufacturer Distribution model

Extract from Interim Report

***6-1. ALTERNATIVE 1**: The government should remove the Community Service Obligation (CSO), and suppliers of PBS-listed medicines should be placed under an obligation to ensure delivery to any community pharmacy in Australia within a specified period of time (generally 24 hours), with standard terms of trade offered to the pharmacy (such as four weeks for payment) using one or more of a specified panel of wholesalers.*[11]

The manufacturer distribution model, proposed under Option 6-1, represents a significant shift from the current model. We have identified a number of material drawbacks and risks that we respectively ask the Review Panel to take into account before they publish their final report.

Funding / cost of PBS medicines

The current PBS pricing mechanisms in place, especially price disclosure encourage free market competition and pricing below the PBS price once a product loses patent. Under the current model all manufacturers are able to compete on a level playing field when negotiating with pharmacy due to the regulated 7.52 per cent mark-up and the CSO (if distributing via full line wholesaler). Under the proposed model, this level playing field for manufacturers would be removed.

The manufacturer distribution model is likely to result in larger manufacturers achieving lower distribution and wholesale costs versus smaller manufacturers. For example, a very large manufacturer such as Novartis with $1.2bn[12] in Australian sales revenue in 2016 (supplying both branded and generic products), would likely be able to negotiate lower distribution costs than a new generic entrant with the same molecule, for example Dr Reddy's which generates $16m[13] of revenue in Australia.

For drugs that are on patent, the manufacturer would be able to exert significant market power when negotiating with wholesalers. Full-line wholesalers may be forced to accept uneconomic terms of trade from manufacturers to offer the full range of PBS products to pharmacies.

The imbalance in market power between the wholesalers and manufacturers may lead to a number of adverse consequences:

- One or more full-line wholesalers may choose not to distribute particular PBS products to community pharmacy as the market will likely evolve into a series of preferred arrangements with key manufacturers. This would remove a key redundancy in the current system particularly for originator products where there are no alternate sources of supply.

- Full-line wholesalers would likely be required to cross-subsidise compressed margins on products from large manufacturers through strategies such as seeking higher margins from smaller manufacturers with less negotiating power. This could act as an unintended barrier to competition on generic medicines and in turn reduce future savings to the PBS and the taxpayer

[11] Interim Report, pages 128-129
[12] Novartis Annual Report, 2016
[13] Dr Reddy's Financial Statement, 2017. Conversion rate from Indian Rupee to AUD = 0.02

- There is a risk wholesalers will choose only to distribute profitable lines to metropolitan areas, potentially leading to restricted access for consumers in rural and remote areas.
- Each of these outcomes would compromise the NMP objectives.

Cost of wholesale and distribution costs to government

As we have said a number of times before, the current level of CSO and mark-up funding is insufficient and unsustainable. Under the Manufacturer Distribution Model, the cost of distributing would be negotiated directly between distributor and each individual manufacturer or supplier. Given funding is already unsustainable, this implies that fees charged for wholesaling will need to increase in the future.

If the larger manufacturers were able to achieve distribution cost savings versus the current regulated mark-up plus CSO (assuming the same service standards), there is no guarantee these savings would be passed back to the government and not retained by the manufacturer. Any savings (even if extracted) could be offset by the increased costs for smaller manufacturers.

Funding of Working Capital

Currently, and as discussed above, wholesalers provide valuable working capital funding to pharmacies. Under the new model, it is likely wholesalers would decrease or remove these working capital benefits in order to compete. This would inevitably lead to systematic market failure of the community pharmacy model.

Regulatory burden

Under the manufacturer distribution model, minimum service levels will still be required to ensure equitable access, in accordance with the NMP. The Interim Report acknowledges that the system of supply will require regulation to be placed on the suppliers of medicine.

> *An improved system of supply should have clear and enforceable rules covering delivery times, terms and conditions. These do not have to be placed on the pharmaceutical wholesalers; rather, they can be placed on the medicine suppliers.* [14]

This system would expand the regulatory burden for government from four wholesalers to over 140 manufacturers. The monitoring and enforcement of rules covering delivery times, terms and conditions would likely involve an increase in regulatory burden versus today due to the decentralised nature of the activities and the increased administrative burden in auditing 140 manufacturers.

The proposed new system would also impose additional complexity on manufacturers and the government at the time of negotiating the PBS price and distribution cost for each individual product. The intended process could involve manufacturers ascertaining and negotiating distribution costs for individual products (of which there are over 6,000 listed on the PBS) with wholesalers/distributors to incorporate into the negotiations with government for PBS listing.

Given the PBS price is effectively fixed for the period a PBS listed product is on-patent (typically ten years) it may require manufacturers to create forward estimates of the distribution cost *over a ten year period* which introduces several uncertainties in terms of fuel prices, wages rate growth etc. While this is not entirely unfeasible, it would create additional burden for manufactures, particularly small manufacturers that have only a small portfolio of

[14] Interim Report, page 127

products and are not commonly listing products on the PBS. This in turn could drive up costs and we could see an increase in Out of Stocks, with manufacturers potentially less inclined to use their finite supply of global active ingredients to service an uneconomically unattractive Australian market. This has been explored further in the section on implementation risks below.

Administrative Burden

The proposed model would likely create additional complexity for pharmacy in relation to ordering and supplier management. Currently pharmacists typically deal with three suppliers - one main wholesaler, a back-up wholesaler and Pfizer.

Under the proposed model, it is likely that manufacturers will seek to consolidate supply of medicines through one main wholesaler so as to extract the best commercial terms possible. The implication of this is that a pharmacist will no longer be able to access the full range of products through two to three suppliers, and will need to expand the number of suppliers it deals with, to perhaps all of the wholesalers on the panel (if they are able to survive this model), plus those companies that choose to go direct. Doubling the number of suppliers means dealing with twice the number of ordering systems, receiving twice the number of deliveries per day and managing a larger number of invoices and payments. For a small pharmacy business this would have a material administrative impost.

Redundancy Risk

For the reasons outlined above, manufacturers are likely to consolidate supply through one main wholesaler to extract the best commercial terms. If this were to occur it would reduce the level of redundancy in the supply chain that currently results from having multiple companies and supply chains distributing a medicine. If a wholesaler were to experience an unexpected supply chain disruption, e.g. flood in a central warehouse, there would be no redundancy in the system to meet consumer demand. This is less of a concern for generic products where there are multiple options available on the market. For an originator product however, there is a high risk that access to medicines would be jeopardised.

This is a very real risk: one that has occurred in recent years. It is one of the reasons that the Attorney Generals Department classifies Australia's pharmaceutical manufacturing infrastructure as "Critical National Infrastructure".

Implementation risk

The transition of all PBS medicines to a manufacturer distribution model would add increased complexity and risk. Should it occur, during the transition to a new model, manufacturers, pharmacies and wholesalers would likely need to deal with different payment systems for a significant period of time, until all PBS products are transitioned to the new model, adding further administration time and cost.

There would likely be a significant transition cost for wholesalers and the government in negotiating and re-setting the wholesale costs for each individual product. For the over six thousand products listed on the PBS, the process of re-setting the distribution costs would be arduous and cost prohibitive. Further, a number of practical issues would need to be thought through, including:

- How would the government gain transparency as to the negotiated wholesale costs in the market to align government funding with cost to the manufacturer. Which party would benefit from negotiated efficiencies?
- What would be the process and timing for reviewing and re-setting the wholesale/ distribution funding for new products that are seeking PBS listing versus those already listed on the PBS? Having

multiple mark-up systems in place during the transition will add complexity for manufacturers, wholesalers, government and pharmacy.

- Following PBS listing, how frequently would the cost of distributing the medicine be revisited and renegotiated with government? Currently PBS prices for on-patent medicines are typically not renegotiated during the on-patent life which can span over ten years. Would a standard inflation rate be applied each year, or would the rates be renegotiated at fixed term intervals, e.g. every 3 years or 5 years? We believe that the introduction of distribution cost funding review at a product level on a regular basis, (e.g. every 1 to 2 years) would add significant administrative burden for manufacturers, government and wholesalers.
- Would the funding of distribution/wholesale costs be negotiated with the government at an individual product or manufacturer level? Currently PBS negotiations are at a product level. There are thousands of products listed on the PBS and differential mark-up rates across products would be complex for government, manufacturers and wholesalers to manage.
- If the manufacturer is responsible for supply how would government measure their success in getting product to community pharmacy? Would there be consequences for non-compliance? Is it feasible to create enforceable consequences for manufacturers in the same way that today that is very easy to track via the CSO mechanism and its reporting requirements?

Direct to pharmacy model

The Interim Report does not acknowledge the evidence submitted to the Review, and research commissioned by the Review, that highlights market participants and pharmacists are not supportive of a direct to pharmacy model. In fact, the Interim Report only puts forward the view that the direct to pharmacy model is better than delivery through wholesalers in certain locations.

> *The Panel has heard that, in some remote parts of Australia, this model is significantly better than the delivery through the wholesaler, despite neither DHL nor Pfizer receiving CSO payments.*[15]

The Review received a significant number of submissions regarding the Pfizer direct model of distribution and the majority of these were not supportive of the Pfizer direct model[16].

A report commissioned by the Panel, undertaken by Hall and Partners, indicates a number of important views by survey participants[17] in relation to distribution and wholesaling models. Only 24 per cent of respondents were supportive of manufacturers distributing medicines direct to pharmacies and 41 per cent were not supportive. The Interim Report also notes that 62 per cent of pharmacy owners disagree with the statement "I support manufacturers supplying PBS medicines direct to pharmacies".

[15] Interim Report, page 126
[16] PRRR Interim Report
[17] 2,298 respondents, of which 1,489 are Pharmacy Professionals and 809 are Consumers

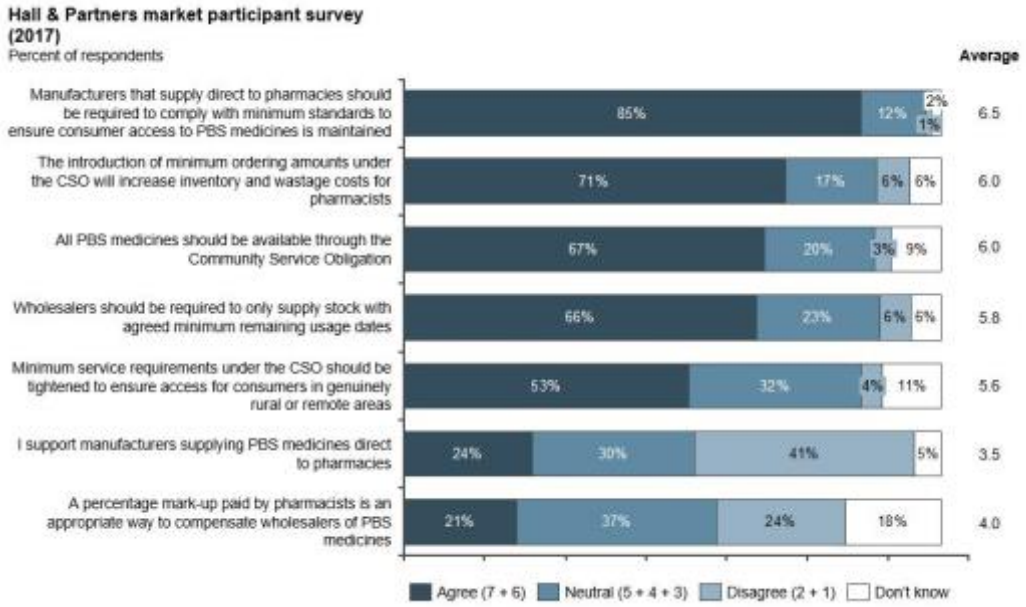


Figure 1 Hall & Partners Pharmacy Remuneration and Regulation survey findings

The Panel makes a number of assertions regarding the direct to pharmacy model, and its ability to meet the CSO:

> *From the Pfizer Direct model it is clear that the distribution of PBS-listed medicines can maintain a generally satisfactory standard without government regulation (i.e. the CSO)…*
>
> *…The Panel considers that the CSO therefore represents excessive and, when compared to the direct to pharmacy model, unnecessary regulation…*[18]

Pfizer's direct model involves bringing several activities in-house e.g. customer service, debtors etc. This would not be feasible for smaller manufacturers, and therefore the direct model is not an appropriate comparison for all manufacturers. Prior analysis suggests that only large scale manufacturers currently have the scale to support such a model nationwide. This is also evidenced by the fact that Pfizer is the only company to date to exclusively use a direct to pharmacy model in Australia.

The direct to pharmacy model, without the implementation of service standards risks compromising access to medicines, as required by the NMP. If manufacturers were to go-direct without regulation around service standards, there is a significant risk that access to medicines would be reduced as manufacturers trade off lower delivery costs for reduced delivery frequency, as is the case with the Pfizer model that does not meet the NMP standards.

Pfizer does not receive the CSO, but nor does Pfizer need to meet the stringent regulatory requirements imposed on it by the CSO Deed. The fact that DHL who currently supports the Pfizer direct model was previously a registered CSO distributor but subsequently exited the scheme is perhaps telling in terms of the imposition of CSO requirements.

[18] Interim Report, page 126

Even in unregulated international markets, with significantly smaller geographic footprints, direct distribution represents only 10-15% of the total market, indicating an important role for wholesalers in cost effectively distributing products to pharmacies.

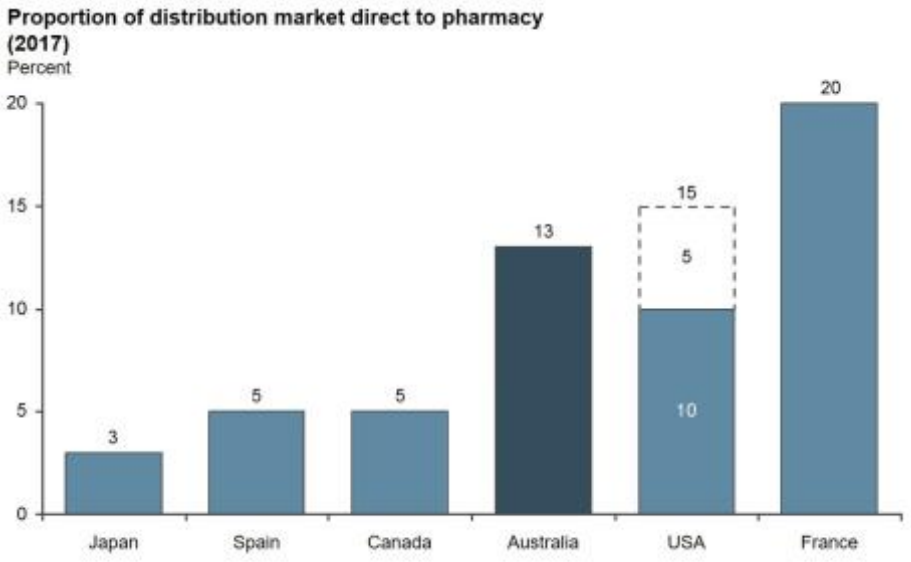


Figure 2 International comparison of direct to pharmacy distribution market share

Alternative 2: CSO with 24 hour requirements

> *Extract from Interim Report*
> ***6-1. ALTERNATIVE 2:*** *The government should retain the current CSO arrangements but ensure that all service standards, such as the 24-hour rule, are uniformly implemented.*[19]

As the Review Panel is aware (and is acknowledged in its Interim Report), the wholesale and distribution network in Australia historically has worked so well that the expectation that a medicine can be ordered by, dispatched to, and received by a community pharmacy within 24 hours is largely taken for granted.

In Chapter 6, the Review Panel effectively endorsed the 24-hour gold standard in its Alternative 6-1 proposal.

This is notwithstanding the Interim Report itself containing little discussion of the logistical operations that underpin the distribution and delivery of PBS medicines. Consequently, there is insufficient evidence that the Review fully considered the NPSA's submission and other detailed documentation provided to the Review, demonstrating the expensive standing infrastructure, having sufficient stock of listed medicines, and high unit costs in storing and moving any medicines long distances (all with built in redundancy) that is essential to continuous and reliable supply.

The Review's conclusions also overlook that the vast majority of PBS products are not profitable to range and distribute.

That the 24-hour turnaround is important to pharmacies and consumers is not disputed. The reality, however, is if wholesale remuneration arrangements change too radically, and the CSO pool no longer provides an offset recognising that delivery logistics are not a "one size fits all" cost for anywhere in Australia, the system and the NMP will ultimately be put at jeopardy.

[19] Interim Report, page 129

NPSA urges the Review Panel to consider more carefully the realities of delivering medicines in Australia across vast distances to honour NMP expectations of timely and equitable access to medicines, and ensuring sufficient margins and returns on all products, whatever their volume and logistical requirements.

The retention of the CSO is supported by the NPSA as an effective means of delivering the NMP. It is an approach that has been effective for the last 12 years. The specification of 24-hour delivery (without the ability for wholesalers to charge a fee) does not address the sustainable funding requirements as discussed below.

The NPSA is supportive, with these qualifications, of Alternative 2 on condition that sustainable funding requirements are also honoured.

Alternative 3: Review of the CSO

NPSA would need more information about the nature of the proposed review before it is able to substantially comment on this proposed alternative.

That said, NPSA stands by its original submission that the CSO is a cost-effective way to deliver the NMP. Alternatives may be delivered at lower cost, but would also likely significantly reduce timely access to medicines access for consumers (see pages 44 to 55 of the L.E.K. Consulting report contained in NPSA's original submission).

WHOLESALER SUSTAINABLE FUNDING

The Interim Report states that the information provided by the NPSA in its submission is not sufficient to ascertain if the 7.52% mark-up is appropriate.

In its original submission to the Review Panel the NPSA provided a robust and independent economic assessment undertaken by L.E.K. Consulting of the full-line wholesaler costs and funding in relation to PBS medicines.

The Interim Report suggests that all costs associated with the wholesalers' businesses were attributed to PBS medicines in calculating the sustainable funding requirements for the wholesaling and distribution of PBS medicines.

> *….An argument suggesting that all costs associated with these businesses' operations are also included with the distribution of PBS medicines ignores the revenue generated from non-PBS components of these businesses' operations.*[20]

As mentioned previously, this statement does not accurately reflect the analysis completed by L.E.K. Consulting in the NPSA's original submission to the Panel.

The wholesalers operating costs were in fact allocated between PBS medicines and non-PBS products to determine sustainable funding requirements for wholesaling activities and to determine if current funding is sufficient. The cost base allocated to the wholesaling of PBS products did not include any operating costs or assets that were solely used for the distribution of non-PBS products, or assets and operating costs attributed to other parts of a parent company. The following approach was used.

L.E.K. Consulting used a Long Run Marginal cost approach to calculate the sustainable funding requirements. Cost allocation was based on the following principles:

[20] Interim report, page 125

- Costs associated with PBS wholesaling as a standalone business
- Incremental costs associated with the distribution of non-PBS products to community pharmacy

In order to accurately allocate PBS costs, each NPSA Member was required to complete a detailed review of each part of its distribution business and its relative share of PBS vs non-PBS costs. Cost components allocated included:

- Operating costs (wages, maintenance, utilities, insurance, freight)
- Facility and lease costs, including depreciation and amortisation
- Stockholding costs
- Overheads

Each wholesaler then consulted with relevant subject matter experts in the business to ascertain the standalone cost to distribute PBS products, within CSO guidelines. A number of 'cost allocators' were used to apportion costs to PBS and non-PBS products, e.g. number of SKUs, warehouse space utilised, proportion of sales etc.

This methodology resulted in [redacted] per cent of aggregated full-line wholesale costs attributed to PBS activities[21]. PBS units represent [redacted] per cent of all units distributed by the full-line wholesalers. The proportion of costs allocated to PBS activities [redacted] is slightly greater than the proportion of units attributed to PBS products [redacted] for a number of reasons:

- The distribution of PBS products requires specialist infrastructure such as cold-chain storage, vault storage for high cost drugs, and security for drugs of dependence.
- Although the distribution of OTC products typically requires a greater footprint, due to the bulky nature of some products, it does not require the same infrastructure as items do not need to be maintained at a specific temperature or with security measures. For example, distributing a pack of Humira which costs approximately $1,600 per pack requires cold chain storage and attracts higher working capital cost than say a non-PBS item such as shampoo or toilet paper.
- PBS products are typically distributed in lower quantities, and more frequently than OTC products. The ability to order products in low volumes, generally within 24 hours, alleviates working capital and secure storage constraints in community pharmacies

Diversification and cross-subsidisation claims

The Interim Report notes that the wholesalers have diversified their product offering and moved into more profitable lines of business.

> *Furthermore, many CSO Distributors are moving into other areas of the pharmaceutical supply chain, such as more vertically integrated models of pharmacy franchising and banner groups as well as supply and distribution of non-PBS product lines. This diversification is proving profitable as evidenced by the positive financial performance of these publicly listed companies.*[22]

Analysis undertaken by L.E.K. Consulting and included in the NPSA's submission to the Review demonstrates that projected PBS funding under the current 6CPA arrangements is not adequate, and as such the wholesalers have moved to supplement PBS delivery with OTC and front of shop products, e.g. health and beauty categories. Such cross-substitution is not sustainable in the long term, and may ultimately lead to one or more of the national

[21] NPSA Member data
[22] Interim Report, page 125

wholesalers exiting from the CSO. As previously noted, the ACCC has previously ruled that a reduction from three to two full-line wholesalers would likely be detrimental for customers[23].

There are a large number of competitors that compete in the distribution of OTC and front of store products which clearly demonstrates that the wholesalers have not been able to leverage their PBS distribution businesses to create dominant positions in the distribution of OTC/non-PBS products to pharmacy. For example, Chemist Warehouse has insourced the distribution of many front of shop products, but retains a full-line wholesaler for distribution of prescription products. Additionally, a number of OTC or front of shop product suppliers have chosen to go-direct to pharmacy, e.g. vitamins and mineral supplement companies such as Blackmores and Sanofi have elected to distribute via a 3PL[24] instead of using a wholesaler.

International comparisons

The value for money provided by the pharmaceutical supply chain must be considered in the context of a number of policy decisions made by the Australian Government:

- **National Medicines Policy** providing timely and cost efficient access to all Australians, regardless of location
- **Pharmacy ownership and location rules** result in a landscape with a large number of independently owned pharmacies. While these rules encourage small businesses, they place a number of restrictions on the supply chain.
- **Geographic spread of Australian patients.** The size of Australia and the varied population distribution means that international comparisons are not valid when considered in the context of timely and efficient access to medicines.

As such, the Australian regulated wholesale mark-ups are competitive and represent good value for money when compared with countries that have:

- Regulated service levels to pharmacy and access policies
- Fragmented pharmacy ownership and the need to protect small business owners from large manufacturers
- Vast geography / low population density in certain regions, making distribution costly to those areas.

Our analysis shows that the Australian cost of distribution, and cost to government is in line with regulated supply chain economies such as France and Spain. These results must also be considered in the context of the significant geographical challenges presented by delivering to small populations across a broader geographical area, as occurs here.

[23] ACCC Decision in response to proposed API and Sigma merger, Sept 2002
[24] Third Party Logistics provider

Table 1 Selected international examples of pharmaceutical distribution landscapes

Country	Land mass ('000 km^2)[25]	Population density (per km^2)	**Distribution margin (% of** ex-man. price)[26]	Regulation	Cost / capita [27](USD)
Australia	7,682	3	7.52% (capped at $69.96, CSO payment for eligible wholesalers of c. 1.6%)[28]	Margin and service obligation	590
France	548	122	6.68% (€0.30 floor, capped at €30.06)	Margin and service obligation	656
Spain	500	93	7.6% (capped at €91.63)	Margin and service obligation	489
Canada	9,094	4	6 – 30%[29]	Margin regulation varies by province	761
USA	9,147	35	2 – 4%[30] (Model differs as wholesalers receive significant supplier rebates; mark up range based on per capita c.1.75 times greater than Australia)	No regulation	1,034
Sweden	407	24	2 – 3%	Service standards regulated	496
Norway	365	14	5 – 7%[31]	Service standards regulated	437
Denmark	42	136	6 – 7%[32]	No regulation	288
The Netherlands	34	505	18%[33]	No regulation	397

In its consultations, it was apparent the Review was attracted by wholesale and distribution regimes in other jurisdictions, particularly those where the sector is not as tightly regulated as in Australia.

[25] The World Bank online, July 2017
[26] Deloitte Access Economics (2016) *Remuneration and regulation of community pharmacy – Literature review*
[27] Deloitte Access Economics (2016) *Remuneration and regulation of community pharmacy – Literature review*
[28] Australian effective distribution margin, including CSO revenue, has been derived from NPSA Member data
[29] National Prescription Drug Utilisation Information System (2012) *Wholesale Up-charge Policies of Canada's Public Drug Plans*; Alberta Blue Cross (2012) *Pharmaceutical Strategy Policy Options for the Government of the Northwest Territories*; Office of the Auditor General (2006) *Audit of the Pharmacare Program – Manitoba Health;* Patented Medicine Prices Review Board (2016) *Private Drug Plans in Canada – Part 1: Generic Market 2005-2013*
[30] U.S. Food & Drug Administration (2011) *Profile of the Prescription Drug Wholesaling Industry Section 2.4;* HAD Research Foundation (2016) *87th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare (2016-2017)*
[31] CESinfo (2007) *Distribution Mark-ups and Value-added Tax (VAT) for Pharmaceuticals*
[32] Kanavos et al (2011) *The pharmaceutical distribution chain in the European Union: Structure and impact on pharmaceutical prices*
[33] CBI Market Survey (2010) *The Pharmaceutical Products Market in the Netherlands*

Canada was frequently mentioned as a comparison, presumably on the basis that Australia and Canada are Commonwealth countries and have federal systems of government, similar healthcare characteristics, a large land mass and a dispersed population.

In the NPSA's view, Canada is not an ideal comparison, because:

- In Australia, the federal government funds and regulates the distribution and dispensing of medicines through the PBS. In Canada that is a provincial responsibility resulting in a range of wholesale mark-ups across provinces - ranging from 6 per cent to 30 per cent.

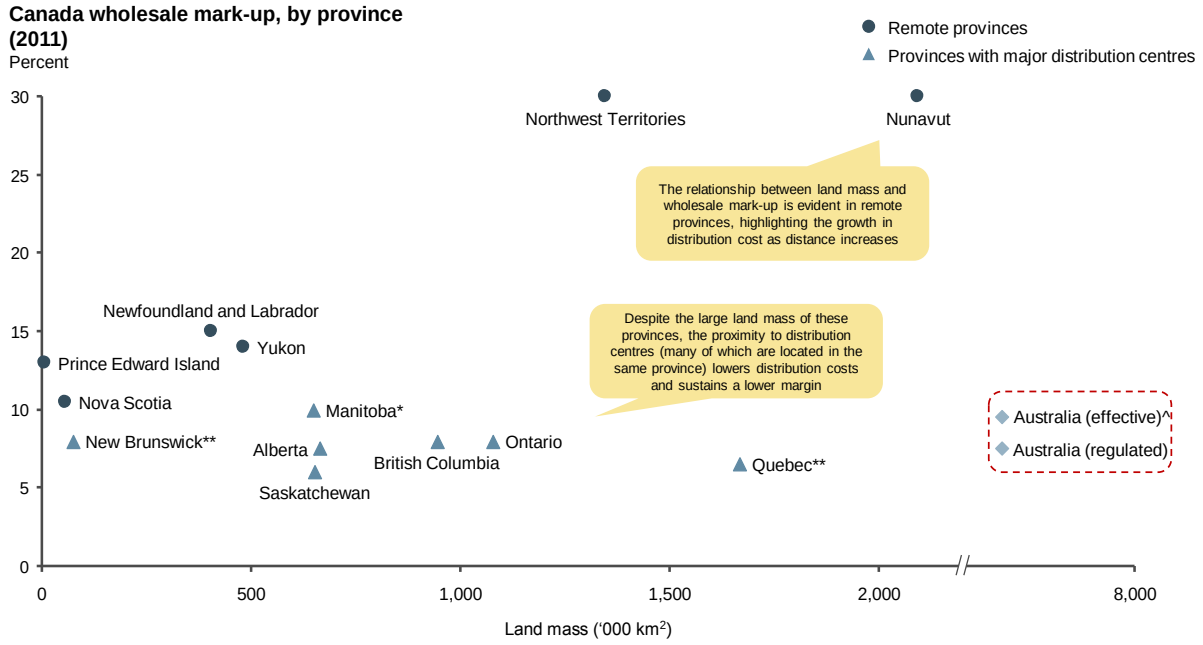
- 66 per cent of the Canadian population lives within 100 kilometres of the United States border, an area that represents approximately.4% of Canada's territory[34]. In Australia, roughly one quarter live more than 50 kilometres away from the eastern seaboard.

- The higher cost of distribution to Northern provinces, where there are no major distribution centres and population density is typically lower is reflected in mark-ups of approximately 11-16 per cent. These margins are much higher than the (approximately) 8 per cent mark-up charged in provinces where major distribution centres are based, such as Ontario, British Columbia and New Brunswick. Additionally, analysis of the very remote provinces shows a mark-up of approximately 30% (Nunavut and Northwest Territories.)

While there are no service-related requirements similar to the CSO, the peak body for pharmaceutical distributors in Canada has a self-imposed service requirement for same or next-day service. As a result, similar to Australia, distributors incur high costs in transporting medicines to highly dispersed populations on such a regular basis. The Canadian comparison demonstrates that Australia's mark-up and CSO costs are not inconsistent with the rates achieved in comparable countries.

We believe the challenges of serving Australians are significantly more complex than for Canada given Australia's remote communities and the longstanding commitment by consumers, industry and Government to the expectations of the NMP.

[34] Statistics Canada, 2016



Note: * As at 2006; ** As at 2013; ^ Effective distributor mark-up considers $69.94 mark-up cap and CSO funding available to full-line wholesalers

Figure 3 Comparison of Canadian province pharmaceutical distribution landscape

Discounts

NPSA's original submission to the Review Panel demonstrated that discounts to pharmacy were declining as a result of reductions in funding to wholesalers. The most recent analysis of NPSA Member data (undertaken in July 2017) demonstrates that discounts have continued to decline at an annual rate of approximately 26 per cent as noted in the Interim Report.

> *…It has been put to the Panel that the sustained impact of price disclosure reforms on pharmaceutical wholesalers has also led to some wholesalers reducing the discounts or trading terms traditionally offered to community pharmacy. This exerts further pressure on pharmacy profit margins….*[35]

The ability to provide discounts to pharmacy will likely be exhausted before the end of the 6CPA, and may result in wholesalers charging fees to pharmacy.

[35] Interim Report, page 13

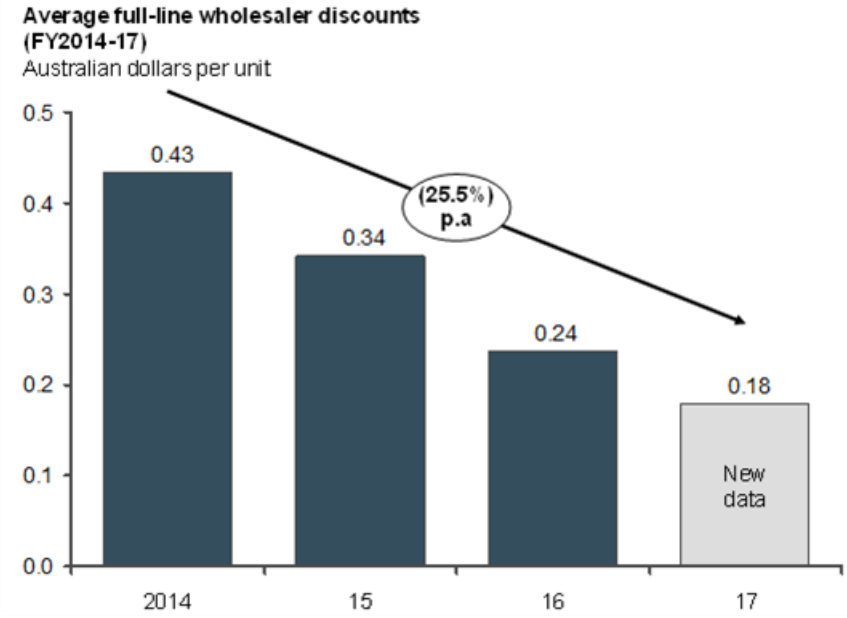


Figure 4 Australian full-line wholesaler discounts[36]

REPORTING REQUIREMENTS AND BREACHES

Reporting breaches

In accordance with the CSO Distributor Deed wholesalers are required to file monthly reports with the CSO Administration Agency. Each filing consists of an aggregated report of sales and any reports of non-compliance ("breach") with the CSO Agreement[37]. Monthly reporting primarily relates to the supply of CSO products and compliance with service standards. The Interim Report identifies that 176 breaches were recorded.

> *To date, the Agency has recorded 176 breaches in relation to the provision of timely and accurate data and reports. For each of these breaches, any inaccurate data was corrected, where applicable, and the CSO Distributor was only paid for CSO claimable products to community pharmacies.*[38]

The 176 breaches noted in the Interim Report relate to five wholesalers over an eleven-year period. Historically, approximately 97 per cent[39] of these breaches have been deemed to be minor, with little to no impact on the supply of medicines

[36] NPSA Member data. Discounts available for two Members only for 2017
[37] CSO Distribution Deed of Agreement, 2017
[38] Interim Report, page 133
[39] NPSA Member data

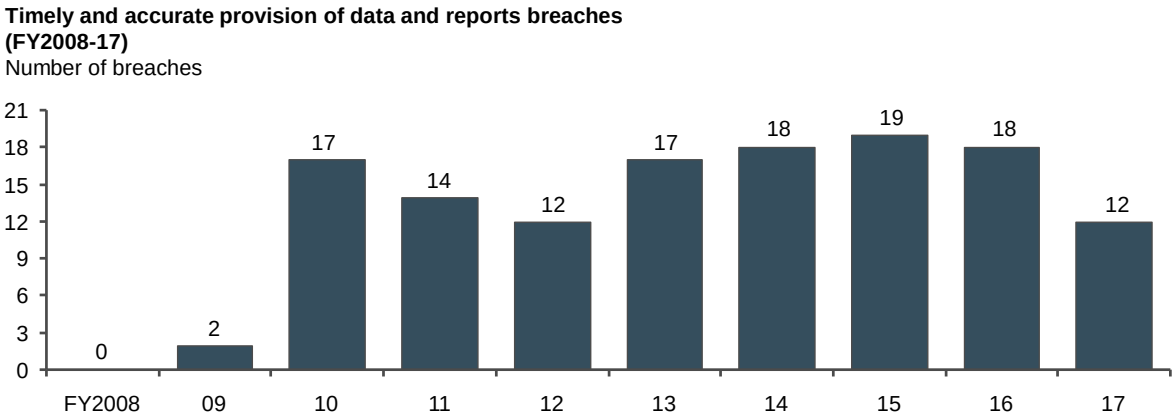


Figure 5 Full-line wholesaler reporting breaches

The breaches often refer to minor issues such as:

- Postcode errors for Community Pharmacies
- Address errors for Community Pharmacies
- Pharmacy Approval Number (PAN) errors for Community Pharmacies

It is also important to note that Medicare Australia will not provide CSO distributors with PAN, Address and Postcode data for Community Pharmacies. If this data were available approximately 20-40% of these breaches could have been averted. The remaining errors are manual or administrative omissions, all inadvertent in nature, and none of which had any material impact on the supply of medicines to Community Pharmacies during this 10-year period.

Timely access breaches

Under the arrangements in the CSO Deed, full-line wholesalers are required to supply PBS medicines within the Guaranteed Supply Period, notwithstanding special circumstances.

> *While current minimum CSO requirements such as the '24-hour rule' generally ensure timely access, the Panel has heard this rule is not always being met.*[40]

As part of monthly reporting requirements, any non-compliance with the Timely Supply of medicines must be submitted to AHA[41]. Distributor non-compliance reports must include details of the cause of the breach, even in cases where the distributor is not at fault (e.g. supplier stock-out).

Over the six years from 2010-16, ten timely supply breaches[42] were reported across two wholesalers, of which only one was reported to be major. All other breaches had little to no impact on the supply of medicines to pharmacies. Over this same period, the wholesalers delivered over 1.2 billion units.

[40] Interim Report, page 131
[41] CSO Distributor Deed of Agreement, 2017
[42] NPSA Member data

PROPOSED APPROACH TO HIGH COST MEDICINES

The Panel outlines a model where the government directly funds a large proportion of the cost of high cost medicines.

The NPSA is largely supportive of this model to cap costs for pharmacy at $700-$1000. There is however, no acknowledgement of the NPSA recommendation or supporting L.E.K. analysis that demonstrates high cost drug funding for wholesalers should be increased. The recommendation to cap cost to pharmacy of $700 to $1000 should not negate the need to increase wholesaler funding in the future.

If this approach were adopted, a number of practical issues would need to be addressed, including appropriate remuneration to wholesalers for high costs drugs, GST treatment for wholesalers as well as policies around product returns from pharmacy.

We were disappointed that the Review seemed to have looked at the issue of high cost medicines as they relate to pharmacy in depth. However, a similar analysis as to the effect on wholesalers, if undertaken, is not obvious from the Interim Report.

CONCLUSION

Before signing off on its Final Report, NPSA strongly encourages the Review to reconsider its overall analysis, findings and recommendations to ensure they reflect reasonably operating, regulatory and policy environments of the whole pharmaceutical supply chain. Similarly, the Review should also ensure that is recommendations are practical and implementable.

Further Assistance

The NPSA Executive, Secretariat and members are ready and very willing to assist the Review as it finalises its Report. We are happy to provide further data on information, if required. We believe it is vital for our industry, and for the whole pharmaceutical supply chain, that whatever is given to government for decision is comprehensive, realistic and affordable.

Thank you for the opportunity to comment on the Interim Report.

Yours sincerely,

Donna Staunton
Chief Executive Officer
National Pharmaceutical Services Association