



Australian Government

Department of Health

Response from
Medicines Australia
for Consultation on the
Community Service Obligation (CSO)
Funding Pool Obligations (2018)

A Single Entry Point

Question 1. Do your organisation and/or stakeholders support the proposed clarification to this requirement?

NO

Detailed information in support of your position:

The Consultation Paper provides insufficient information on the definition of the “full range of PBS medicines” and how that differs from the current requirement for CSO Distributors to provide for Community Pharmacies to “order any Brand of any PBS Medicine”.

The existing Compliance Requirement is consistent with CSO Service Standards and definitions relating to the breadth and depth of PBS medicines available to Community Pharmacies through CSO Distributors. In contrast, the proposed change could be interpreted to only require CSO Distributors to provide every PBS Item (noting that many PBS Items have multiple Brands, both Innovator Brands and Additional Brands).

A potential combination of changing this Compliance Requirement as proposed and changing the Stocking Requirement as proposed under Section B of the Consultation Paper, could result in CSO Distributors being required to stock only one brand of any PBS Item, thereby removing or reducing product competition at both the wholesale and pharmacy level.

The definition may also inadvertently result in manufacturers of PBS medicines being compelled to use a CSO wholesaler for the distribution of all PBS medicines even where a direct model is preferred. In the case of single brand medicines it would constrain the manufacturer to using a CSO wholesaler where this is neither in the best interests of the company nor the patients.

Question 2. What would be the impact of this clarification on your organisation and/or stakeholders if adopted?

HIGH

Detailed information in support of your position:

Any modification to the existing Compliance Requirements or Service Standards must not:

- artificially limit competition to the detriment of Community Pharmacies capacity to choose brands of PBS medicines
- restrict the rights of patients to choose brands of PBS medicines.
- restrict the rights of manufacturers to select the most efficient and cost effective distribution model for their business.

As described above, the proposed changes to the Compliance Requirement are anti-competitive as they enable CSO Distributors to restrict Community Pharmacy and patient choice to only one brand of PBS medicine where multiple brands might be available and may inadvertently restrict manufacturers to using CSO wholesalers to distribute their PBS medicines.

B **Stocking**

Question 3. *Do your organisation and/or stakeholders support the proposed change to this requirement?*

NO

Detailed information in support of your position:

The current Stocking Requirement in the CSO Deed allows for innovation and flexibility in supply arrangements while also ensuring any PBS medicine can be available to any Community Pharmacy within its jurisdiction.

The Stocking Requirement does not require a CSO Distributor to hold at least one Brand of every PBS Medicines, or for multi-Branded PBS Medicines at least one Innovator Brand and one additional Brand which is Benchmark priced, at every Distribution Centre for that CSO Distributor. The Stocking Requirement applies across the Distribution Centre network for any given CSO Distributor. For example, a CSO Distributor may choose to stock some low volume or high price PBS medicines at only one metropolitan Distribution Centre while its many regional Distribution Centres operate as short-line wholesalers but supplemented by rapid delivery from the metro Distribution Centre where required.

The existing Stocking Requirement fundamentally supports consumer access to choice of PBS medicine while also mitigating working capital risk for CSO Distributors and preserves manufacturers ability to compete in the market.

Additionally, and as noted previously in this response, in combination with proposed changes to the Compliance Requirement on Single Entry Point, this proposed change to the Stocking Requirement would provide CSO Distributors with the power to restrict competition for products provided by an external party including medicine manufacturers and suppliers.

Question 4. *If applicable, what would be the impact of this change on your organisation and/or stakeholders?*

HIGH

Detailed information in support of your position:

See Question 3

Question 5. *Specifically, how would removing the stocking requirement affect:*

- *The timely supply of CSO products to community pharmacies?*
- *A community pharmacy's ability to obtain all brands of CSO products for supply?*

Detailed information in support of your position:

See Question 3

Question 6. *If current stocking requirements were maintained, what would be the impact to your business if specific generic or biosimilar items were required to be included in this range of available stock?*

LOW

Detailed information in support of your position:

The addition of a further generic or biosimilar item, in addition to the existing Stocking Requirement could potentially increase competition within the PBS marketplace

The existing Stocking Requirement does not specify which Brand or Brands must be available, only that at least one Innovator Brand and at least one Brand at Benchmark price in multiple Brands are available. This requirement promotes market competition, as much as possible within the PBS arrangements, between Brands of PBS medicines. This provides for choice at the pharmacy level plus it enables consumer access to benchmark-priced Brands or Innovator Brands for QUM purposes.

C Commercially Acceptable Fees

Question 7. Do your organisation and/or stakeholders support the proposed changes to this requirement?

OTHER

Detailed information in support of your position:

The existing range and intent of restrictions on Commercially Acceptable Fees is to allow normal business or accounting fees to be charged by CSO Distributors while also protecting Community Pharmacies from charging practices which might circumvent or offset the CSO Distributor Obligations. It is also important to ensure that the absence, or restriction of, fees charged by CSO Distributors does not perversely encourage Community Pharmacies to manage stock and purchasing in an inefficient manner.

Question 8. Do the above examples sufficiently clarify the types of fees that are not permissible under the CSO arrangements?

NOT APPLICABLE

Detailed information in support of your position:

Question 9. Are there other types of fees that should not be permissible under the CSO arrangements? If so, please specify the type of fee and provide information supporting your position.

NOT APPLICABLE

Types of fees, and information in support of your position

D Minimum Order Quantity for High Volume PBS Medicines

Question 10. *Do your organisation and/or stakeholders support the proposed changes to this requirement?*

NOT APPLICABLE

MA members will respond to this question from an individual company perspective

Detailed information in support of your position:

Question 11. *What would be the impact of these changes on your organisation and/or stakeholders?*

NOT APPLICABLE

Detailed information in support of your position:

Question 12. *Should restrictions be placed on pharmacists to limit the number of orders placed within any 24 hour period, or a regular week (7 day period)? Note that this restriction would be specific to orders placed for PBS items under CSO arrangements.*

NOT APPLICABLE

Detailed information in support of your position:

E New PBS Payment Arrangements

Question 13. *What would be the impact of this additional reporting requirement on your organisation and/or stakeholders (if applicable)?*

OTHER

Detailed information in support of your position:

Medicines Australia supports the proposal that CSO Distributors provide data and information for the purpose of reconciling payments under any model for New PBS Payment Arrangements.

The accurate, timely and accountable operation of any robust model for New PBS Payment Arrangements is heavily reliant on data which can be reconciled and cross-matched at each step through the medicines supply chain. Should any part of the supply chain be omitted from data capture and provision requirements the chain of possession would be incomplete thereby introducing a requirement for assumptions in any reconciliation, reduced accountability and increased risk of dispute.

F Exclusive Supply Arrangements

Context regarding Exclusive Supply Arrangements

Question 14. What are the **benefits** to Government and patients associated with the provision of CSO products through Exclusive Supply Arrangements? Please provide evidence supporting your perspective.

Response and Evidence supporting your perspective:

Medicines Australia supports timely access to medicines for all patients including the most efficient distribution models. Distribution models should not hinder competition. Manufacturers should retain the right to select the most effective distribution approach for their business.

Currently through the existing arrangements the government is entirely reliant on the current wholesalers.

Through exclusive arrangements the benefits to Government and patient could include:

- Increased competition between existing and/or new distributors
- Flexibility for manufacturers to use and support the most efficient distributors
- Flexibility for manufacturers to choose the most appropriate distribution system for products requiring specialised handling and logistics arrangements
- Manufacturer retains control for quality of medicines to point of distribution

Experience from manufacturers using exclusive supply arrangements includes:

- Pharmacies and patients have maintained access to medicines
- Data on movement of product through the supply chain is maintained in a timely manner reducing risk of unexpected out-of-stock situations

Question 15. What are the **disadvantages and risks** to patients that Government should consider if CSO products are supplied through Exclusive Supply Arrangements? Please provide evidence supporting your perspective.

Response and Evidence supporting your perspective:

Medicines Manufacturers have not indicated any reports where there are risks to the patients or the government arising from the exclusive supply arrangements.

There are no identified or agreed risks to patients arising from the manufacturers use of exclusive supply arrangements. However in some cases manufacturers may not have the economies of scale to support supplying directly to pharmacies (e.g. manufacturers of speciality medicines and limited product lines). Therefore, manufacturers should retain the right to choose the most effective distribution approach for their business.

The supply of medicines is still governed by contractual agreements and service standards.

Question 16. *How do Exclusive Supply Arrangements support/not support the principles underpinning the CSO arrangements, including ensuring timely, efficient and affordable access to all CSO products? Please provide evidence supporting your perspective.*

Response and Evidence supporting your perspective:

Exclusive supply arrangements can effectively support the principles underpinning the CSO arrangements and uphold the values of the National Medicines Policy. Direct distribution enables manufacturers to have complete visibility of the demand for their products so that they can better manage supply. In doing so, direct distribution allows for innovative and more efficient processes, which can create flow on effects that benefit the wider health system. This provides a rich source of data that in practice translates to; lower inventory costs and less wastage for community pharmacies, prevention of pharmacy level out of stocks, and assists with patient medicine adherence.

Direct distribution also ensures that PBS listed medicines are available at community pharmacies across Australia. MA is aware some members use a direct distribution model to distribute to 5500+ community pharmacies across broad product portfolios in a timely manner. Indeed, our member companies who utilise a direct distribution model indicate that over 99% of all orders were delivered by the next business day. The result is that patients (particularly those who live in rural/regional areas), get the same access to medicines as patients who are located in more urban areas.

Our members indicate that direct distribution models can provide timely, efficient and affordable access to PBS listed medicines to patients regardless of where they live, thus upholding the principles underpinning the CSO and the National Medicines Policy.

Question 17. *If PBS medicines were required to be only distributed through CSO arrangements, what would be the impact of this change on your organisation and/or stakeholders, or the pharmaceutical supply chain more broadly?*

HIGH

Detailed information in support of your position:

Manufacturers are individually responsible for decisions regarding the supply and distribution of their medicines.

A copy of the *Medicines Australia Statement on Direct Distribution and the Supply Chain* is provided at [Attachment A](#). In response to Question 17, MA also highlight a number of specific extracts from that Statement.

Medicines Australia member companies reserve the right to employ a direct distribution model of ensuring their products reach Australian patients. Members have both the right and the responsibility to ensure their products are distributed correctly and efficiently.

Many products within a member's current portfolios require careful distribution conditions. This includes temperature control, continuous monitoring, rapid distribution and of course reliable traceability.

Manufacturers must therefore retain the freedom to choose the most efficient safe and cost effective method of distribution so that Australians continue to have access to their medicines through pharmacy (community and hospital).

The media release issued by the NPSA on 12 June 2018 contained a statement referring to the CSO that “All PBS medicines subsidised by government should be subject to regulated distribution requirements”. This equates to a call from a private enterprise for the Australian Government to require that a second private entity continue to contribute to the profitability of the first – a highly irregular restriction of a private company’s ability to formulate its own business strategies. Such a requirement would improperly impinge on market competition.

The MA Statement also notes, *Pharmaceutical companies are commercial entities. While their commercial dealings are unique within Australia, they are still under the obligation to abide by the Australian Competition and Consumer Act 2010.*

Also, under the Corporations Act 2001, a business operating within Australia, retains the right to make commercial decisions around the safe, effective and efficient distribution of their products.

From these extracts, it is clear that Medicines Australia supports the Community Service Obligation (CSO) wholesalers and also supports manufacturers’ ability to distribute medicines directly to pharmacies.

Question 18. *If PBS medicines were required to be made available to all pharmaceutical wholesalers for distribution to community pharmacies, what would be the impact of this change on your organisation and/or stakeholders, or the pharmaceutical supply chain more broadly?*

HIGH

Detailed information in support of your position:

Reiterating part of the MA Statement:

Medicines Australia member companies reserve the right to employ a direct distribution model of ensuring their products reach Australian patients. Members have both the right and the responsibility to ensure their products are distributed correctly and efficiently.

Many products within a member's current portfolios require careful distribution conditions. This includes temperature control, continuous monitoring, rapid distribution and of course reliable traceability.

Manufacturers must therefore retain the freedom to choose the most efficient safe and cost effective method of distribution so that Australians continue to have access to their medicines through pharmacy (community and hospital).

Also, under the Corporations Act 2001, a business operating within Australia, retains the right to make commercial decisions around the safe, effective and efficient distribution of their products.

The NPSA media release of 12 June 2018 also characterises the CSO as a “cross-subsidisation model, in which the delivery of higher-priced and higher-volume drugs pays for the delivery of lower-priced drugs.” The appropriateness of a cross-subsidisation model is a policy question

meriting further examination. Of more immediate interest is the fact that pharmaceutical wholesalers may also cross-subsidise supply of PBS medicines with supply of over-the-counter (OTC) and front-of-shop products. While PBS medicines have fixed prices, the price of OTC products remains within control of wholesalers and can be adjusted depending on market forces. Further, CSO funding effectively subsidises supply of both PBS and OTC products noting that a typical pharmacy delivery would likely include a mix of dispensary and front-of-shop stock.

While pharmaceutical industry does not fault wholesalers for designing business processes to minimise costs, it would be unreasonable for pharmaceutical manufacturers to be prohibited from taking similar steps.

CSO payment for PBS Medicines distributed through Exclusive Supply Arrangements

Question 19. *If the supply of Exclusive Supply products were eligible for CSO funding pool payments, what would be the impact of this change on your organisation and/or stakeholders, or the pharmaceutical supply chain more broadly?*

LOW

Detailed information in support of your position:

Metropolitan distribution represents in excess of 80% of PBS supply, however competitive market forces in densely populated areas could spur high quality service without recourse to public subsidy via the CSO. Noting the higher cost of rural and regional distribution, preferential support from CSO subsidy for supply of PBS medicines, including Exclusive Supply products, to these areas would be reasonable.

Question 20. *If the supply of Exclusive Supply products were eligible for CSO funding pool payments, what payment rate (if any) should Exclusive Supply products be eligible for?*

Payment rate for Exclusive Supply products as a percentage value:

N/A

Detailed information in support of your position:

N/A

Visibility of PBS Medicines distributed through Exclusive Supply Arrangements

Question 21. *Do your organisation and/or stakeholders support this proposed requirement?*

YES

Detailed information in support of your position:

Provision of data for movements of all PBS medicines, including Exclusive Supply Products, through CSO Distributors would contribute to a more complete data set being available for reconciliation processes.

Question 22. *If CSO Distributors were required to report any supply of Exclusive Supply products, what would be the impact on your organisation and/or stakeholders?*

HIGH

Detailed information in support of your position:

Provision of data for movements of all PBS medicines, including Exclusive Supply Products, through CSO Distributors would contribute to a more complete data set being available for reconciliation processes.

As noted previously, incomplete data could require introducing assumptions in any reconciliation, reduced accountability and increased risk of dispute and therefore adversely affecting the completeness, accuracy and timeliness of any associated payments.

Question 23. *How else might the Government's visibility of the distribution of Exclusive Supply products be improved, either within or outside of the CSO arrangements?*

Response:

N/A

G CSO Compliance and Regulation

Question 24. *Are there any areas of the current CSO Compliance Requirements and Service Standards which could potentially be removed or be streamlined for efficiency gains?*

Response and Detailed information:

N/A

H Other Comments

Question 25. *Are there any other matters that you consider to be relevant to the Department's review of the CSO obligations?*

Response and Detailed information:

There are several major issues omitted from the targeted consultation questions which, if unaddressed, would render the process of reviewing the CSO arrangements incomplete:

- the proportion of the PBS budget expended on distribution of medicines. The CSO funding pool has increased with each successive Community Pharmacy Agreement (\$150 million per annum in the 4th, \$190 million in the 5th and \$195 million in the 6th). The overall cost of pharmacy dispensing fees has been estimated to be as much as 40% of overall PBS expenditure once rebates are deducted. This amount of funding for supply purposes together with regular increases must be considered in the context of Budget rules that have required offsetting savings for new medicines from within the Health portfolio;
- the fundamental soundness of public funding for the CSO which, by the NPSA's assertion, supports a distribution model in which 90% of PBS medicines are already "uneconomic to distribute." The future appropriateness of the CSO has not been addressed in this consultation, however examination of that matter should be central to Government policy on medicines distribution. The CSO, introduced in the 4th Community Pharmacy Agreement, was initially intended as a temporary measure – it has been extended significantly past its intended end date through the 5th and 6th Agreements. The appropriateness of continually extending an interim funding model should be addressed to ensure the prudent disbursement of public money;
- The CSO Review should focus, as a priority, on distribution of medicines in rural and regional destinations. Metropolitan distribution represents in excess of 80% of PBS supply, however competitive market forces in densely populated areas could spur high quality service without recourse to public subsidy via the CSO. Noting the higher cost of rural and regional distribution, preferential support from CSO subsidy for supply to these areas would be reasonable.

Overall, MA is concerned by the high and growing percentage of total PBS cost consumed by the cost of medicine delivery. With public statements from wholesalers at the risk of a majority of PBS medicines are uneconomical under current arrangements, we consider it imperative that the CSO is thoroughly examined to determine whether it remains fit for purpose since it was introduced in 2006.



MEDICINES AUSTRALIA STATEMENT ON DIRECT DISTRIBUTION & THE SUPPLY CHAIN

Medicines Australia Principles

Australian patients deserve access to the medicines they need, when they need them.

Manufacturers are individually responsible for decisions regarding the supply and distribution of their medicines.

Manufacturers retain the freedom to choose the most efficient safe and cost effective method of distribution so that Australians continue to have access to their medicines through pharmacy (community and hospital).

Medicines Australia supports the Community Service Obligation (CSO) wholesalers and also supports manufacturers' ability to distribute medicines directly to pharmacies.

Medicines Australia information on direct distribution

Medicines Australia member companies reserve the right to employ a direct distribution model of ensuring their products reach Australian patients. Members have both the right and the responsibility to ensure their products are distributed correctly and efficiently.

Many products within a member's current portfolios require careful distribution conditions. This includes temperature control, continuous monitoring, rapid distribution and of course reliable traceability.

Pharmaceutical companies are commercial entities. While their commercial dealings are unique within Australia, they are still under the obligation to abide by the Australian Competition and Consumer Act 2010.

Also, under the Corporations Act 2001, a business operating within Australia, retains the right to make commercial decisions around the safe, effective and efficient distribution of their products.

Medicines Australia's review of PBS expenditure 2016-2017 against the DOH annual report highlights that actual cost of medicines on the PBS (less rebates) in 2016-2017 was \$8.8 billion (\$12 billion expenditure minus \$3.2 billion rebates)¹. The cost of distribution through wholesalers and community pharmacies was identified in the Review of Pharmacy Remuneration and Regulation² as being approximately 30% and appears to be increasing.

Medicines Australia and our members remain committed to supporting the CSO wholesalers as an important part of the supply chain that ensures Australians get access to the latest medicines through a pharmacy.

These matters, as well as related issues associated with distribution models for high value medicines have highlighted the importance of a sustainable and competitive distribution sector.

Members of Medicines Australia are committed to a continuing open dialogue with the Federal Government and the Department of Health to ensure that Australians continue to have access to high quality, life changing medicines as they have for the past 60 years through the PBS in the most efficient and reliable means possible.

¹ [Department of Health Annual Report 2016-2017](#); pg. 138 and 248; viewed 27 Nov 2017.

² [Review of Pharmacy Remuneration and Regulation](#); Department of Health, viewed 27 Nov 2017.