



POLICY

Distribution and Delivery of Pharmaceutical Benefits

Position

The Pharmacy Guild of Australia (Guild) believes that all Australians should have timely and affordable access to the full range of pharmaceutical benefits through their community pharmacy to achieve better health outcomes, consistent with the objectives of Australia's National Medicines Policy¹. A reliable, efficient and effective pharmaceutical distribution system is essential to achieving this.

The Guild believes that the best channel for distribution of all pharmaceutical benefits listed on the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS) is through full line CSO (Community Service Obligation) compliant distributors (CSO Wholesalers) that the whole community pharmacy network can readily access. Where medicine companies believe they can provide a more effective and efficient service through direct supply, in the interests of patient care this should be in addition to supply through CSO Wholesalers.

The Guild also believes that the distribution and delivery of pharmaceutical benefits should be supported by service and delivery standards predicated on the right of an Australian health consumer to readily access any pharmaceutical benefit (in accordance with any eligibility restrictions) and to commence treatment as soon as possible. These standards must reflect the criticality for access to their medicine by patient groups such as those with an urgent need to commence a new treatment or maintain treatment continuity such as when travelling.

With the above points in mind, the Guild's position is that it should be a condition of listing on the PBS or RPBS that in addition to meeting the requirements of the current Australian code of good wholesaling practice for medicines² and relevant federal, state and territory laws, the distribution and delivery of a pharmaceutical benefit must be compliant with standards that enforce the following service and delivery requirements guaranteeing a community pharmacy access to the pharmaceutical benefit in order to meet the prescriptions needs of Australian health consumers:

- **Guaranteed Delivery Time** – Delivery of medicines within one working day, noting that for some remote locations this is not always possible and that reasonable efforts are made to ensure delivery is made within a timeframe not exceeding three working days
- **Order Quantities** – No minimum order quantities with pharmacies able to order single items if needed to meet a patient's prescription needs

¹ <http://www.health.gov.au/nationalmedicinespolicy>

² Australian Code of good wholesaling practice for medicines in schedules 2, 3, 4 & 8; <https://www.tga.gov.au/publication/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8>

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- **Urgent supplies** – A system in place to ensure community pharmacies have urgent access to medicines in cases of emergency
- **Additional fees** – Prohibiting distributors from imposing any additional fees such as an administrative surcharge or delivery fee, unless these fees are able to be passed on to the consumer at the discretion of the pharmacist
- **Independent Oversight** – An independent authority must be responsible for managing and enforcing compliance with these standards
- **Removal of delivery containers** – Prompt collection and removal of delivery containers (including those used for cold chain delivery) so pharmacies can maintain a hazard free working area
- **Guaranteed Price** – In addition to meeting all of the above requirements, there must be a guarantee that the delivery of any pharmaceutical benefit to the community pharmacy is at no more than the approved Price to Pharmacists³

In order to achieve these service and delivery standards, there must be appropriate remuneration for the distribution of pharmaceutical benefits which also recognises the additional administrative, handling and security arrangements associated with the distribution of medicines such as those requiring cold chain management, cytotoxics, Controlled Drugs and other medicines subject to diversion as well as high cost medicines. The Guild believes the CSO Funding Pool arrangements is a cost-effective and efficient means of ensuring compliance with service and delivery standards for the distribution of pharmaceutical benefits.

The Guild supports the CSO funding pool being limited to full line distributors, but for this to be effective, arrangements should be in place to enable full line distributors to distribute the whole range of pharmaceutical benefits.

The Guild believes exclusive direct supply arrangements in which pharmaceutical benefits are supplied directly to community pharmacy by only one distributor undermine the principle of the National Medicines Policy and puts the profits of medicine companies ahead of patient-centric healthcare. Companies that engage in exclusive direct supply are not held to the service and delivery standards implemented through the CSO and there is no oversight by an independent industry authority. Such arrangements also undermine the PBS remuneration system which allocates a wholesale mark-up for pharmaceutical benefits listed on the General Schedule. As a result, exclusive direct supply has consequences for the whole medicine supply chain. Should the Government support any proposal not to supply a pharmaceutical benefit through all CSO Wholesalers, it is critical that the following criteria are met:

- All exclusive direct supply distribution arrangements must be compliant with all of the standards described above.
- Pharmacists must have public access to information about all exclusive direct supply arrangements in order to manage orders for these medicines to ensure timely patient access.
- There must be no hindrance or delays to community pharmacies establishing accounts so that orders can be placed to meet urgent patient needs.

³ Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015; <https://www.legislation.gov.au/Details/F2017C00523>

The Guild also supports improving ordering efficiency within community pharmacy so that the distribution of PBS medicines is efficient and cost-effective, however this should be achieved through incentivising efficient pharmacy ordering practices (e.g. via trading terms), rather than permitting the application of penalty surcharges such as delivery fees for multiple orders, as the latter is a disincentive for pharmacists to meet urgent patient needs.

Background

Community Pharmacy Stock Management

Clause 62 of the *National Health (Pharmaceutical Benefits) Regulations 2017*⁴ requires an Approved Pharmacist⁵ to 'as far as practicable, keep in stock an adequate supply of all drugs and medicinal preparations that he or she may reasonably be expected to be called upon to supply as pharmaceutical benefits'. This is also reflected in clause 7.3 of the Sixth Community Pharmacy Agreement agreed between the Guild and the Australian Government.

A community pharmacy's dispensary stock is based on the pharmacy's prescription history. Dispensing requirements are dynamic and it is not uncommon for a pharmacy to require medicines to meet unanticipated urgent patient needs e.g. patients who are travelling or new medicines started by a specialist or other prescriber. In these situations, the community pharmacist needs prompt access to these medicines without being penalised by any surcharges.

Application of Additional Fees

Under Australian Competition and Consumer Law, businesses are free to set the prices for their goods and services as they see fit. This generally allows a business the option to pass on any additional costs to their customers.

With the exception of being able to apply a fee for supplying a pharmaceutical benefit outside the normal trading hours of a pharmacy⁶ or for delivery of a pharmaceutical benefit to a patient⁷, clause 87 of the *National Health Act 1953* prohibits Approved Pharmacists from demanding payments for supply of a pharmaceutical benefit above the concessional or general co-payment, as applicable. As a result of this, a community pharmacy is unable to pass on any surcharges applied by distributors for the delivery of a pharmaceutical benefit to the pharmacy. As such these costs must be borne by the pharmacy.

Community Service Obligation

The CSO Funding Pool⁸ was introduced in the Fourth Community Pharmacy Agreement (4CPA) in July 2006 in recognition of the additional costs faced by some pharmaceutical wholesalers in providing the full range of PBS medicines to pharmacies. The aim of the CSO Funding Pool is to ensure there are arrangements in place for all Australians to have access to the full range of PBS medicines, via their community pharmacy, regardless of where they live and usually within 24 hours.

⁴ <https://www.legislation.gov.au/Details/F2017L00313>

⁵ A pharmacist approved under Section 90 of the National Health Act 1953 to dispense pharmaceutical benefits

⁶ National Health Act 1953; clause 87(6)

⁷ National Health (Pharmaceutical Benefits) Regulations 2017; clause 56

⁸ <http://www.health.gov.au/internet/main/publishing.nsf/Content/community-service-obligation-funding-pool>

The following amendments were made to the CSO requirements from 2015 to 2016:

- a High Volume PBS Medicine List (High Volume List) was formulated
- the Guaranteed Supply Period for delivery to community pharmacies was extended from 24 hours to 72 hours for medicines on the High Volume List
- a Minimum Order Quantity was introduced for medicines on the High Volume List
- distributors were permitted to apply uncapped surcharges for orders of medicines on the High Volume List requiring delivery in under 72 hours or for a quantity below the Minimum Order Quantity

The application of CSO requirements is limited to pharmaceutical benefits listed on the General Schedule of the PBS. Non-dual listed pharmaceutical benefits listed on the PBS under Section 100⁹ of the *National Health Act 1953* or non-dual listed items listed on the RPBS are exempt from the CSO, and as such, there are no service and delivery standards that apply to the distribution of these pharmaceutical benefits. It is not uncommon for pharmacists to be charged more than the approved Price to Pharmacists for Section 100 or RPBS items and the Guild is aware of many instances in which its members have dispensed Section 100 and RPBS prescriptions at a loss. And while the Australian Government has arrangements in place to manage such anomalies, the process for the pharmacist to apply for the cost difference can be complex and slow and places additional administrative burdens on a small business.

The CSO is administered by an independent authority to which CSO Wholesalers must regularly report and which has the responsibility to monitor and manage complaints. The CSO administrator ensures CSO Wholesalers meet performance criteria and is also responsible for calculating payments from the CSO funding pool.

Direct Supply

Exclusive direct supply is increasingly becoming commonplace with more medicine companies changing their distribution model for financial reasons. Companies that have opted for such arrangements include Pfizer, Pharmacor, AstraZeneca and Amgen. There are also companies with low volume specialised medicines listed on the PBS that opt for direct supply.

While the CSO is based on the premise that compliant distributors supply the full range of PBS medicines listed on the General Schedule, it also recognises exclusive direct supply by exempting these PBS medicines from the funding pool calculations. However, there is no transparency as to which medicines are exempt because of exclusive direct supply arrangements as the CSO Exclusive Supply List is not published.

While non-CSO distributors must meet legal obligations under federal, state and territory laws relating to the storage and distribution of medicines, there is no obligation to meet the additional performance criteria for service, delivery, reporting, compliance monitoring and complaints management required of CSO Wholesalers.

The problems with exclusive direct supply arrangements include:

- Delivery arrangements at discretion of the medicine company and/or the exclusive distributor with no guarantee of delivery time to the pharmacy
- The capability to apply minimum order quantities irrespective of the pharmacy's needs, with potential wastage and additional costs for the pharmacy

⁹ <http://www.pbs.gov.au/browse/section100>

- Absence of any requirement for pharmacies to receive the medicines at no more than the approved Price to Pharmacists
- Absence of an independent agency responsible for monitoring the service, enforcing standards or managing complaints
- Lesser standards can mean that a patient is not able to start treatment in a timely manner due to
 - pharmacies needing to order certain items on demand in order to meet unanticipated or urgent demands for pharmaceutical benefits without the guarantee of a delivery time and possible minimum order requirements
 - increased potential for errors and omissions in the ordering process as it becomes more complex and more disparate
- Supply chain fragmentation may affect the distribution of less lucrative (but equally essential) medicines
- The sustainability of CSO Wholesalers is threatened, putting pressure on the whole pharmaceutical benefits supply chain with a potential reduction in services
- Reduction in critical redundancy at times of natural disaster
- Increased administration burden and workload on pharmacies with duplicated processes for placing and receiving orders from multiple distributors
- Additional costs to pharmacy, including potential delivery fees and surcharges as well as reduced trading terms from CSO Wholesalers

Related Policies

Nil

Authority

Endorsed

National Council – January 2018

Reviewed

Pharmacy Viability Committee – December 2017