NPSA

Submission to the Review of Pharmacy Remuneration and Regulation

28 September 2016

NPSA National Pharmaceutical Services Association

L.E.K.

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Agenda

- **Executive summary**
- Context and introduction
- Pharmaceutical wholesale market overview and history
- Changing regulatory landscape and impact on wholesale sustainability
- Proposed sustainable funding model

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Full-line wholesalers play a vital role in the delivery of the National Medicines Policy

- The National Medicines Policy ("NMP") framework was established by the Australian Government to ensure equitable access to cost effective and quality medicines for all Australians

- Wholesalers play a vital role in the efficient delivery of the NMP, supplying approximately 6,200 PBS products and brands* from over 100 manufacturers to over c.5,500 community pharmacies, generally within 24 hours. This vital service enables the dispensing of over 295,000,000 prescriptions by community pharmacists. The wholesaler model provides efficiencies in what would otherwise be an extremely fragmented and inefficient supply chain between over 100 manufacturers and thousands of pharmacies

- The effectiveness and sustainability of the NMP depends on a clear and stable set of regulations. Adopting a "free market" unregulated approach would result in poorer service levels and higher costs for consumers in rural and remote areas, and availability of medicines in many areas would become challenging

- A number of full-line wholesalers, short-line wholesalers and distributors compete, utilising different business models. There are three main types of distribution models that operate today:
  - four full-line wholesalers, (three national and one state based supplying Victoria and South Australia), competing to deliver the full range of PBS products to all community pharmacies in Australia, generally within 24 hours
  - several short-line wholesalers and distributors providing a limited range of PBS products and services, predominantly in metro areas
  - several pharmaceutical manufacturers delivering all or part of their product range direct to pharmacy utilising third party logistics (3PL) providers
- The current market structure is the result of consolidation of smaller wholesalers over many years to achieve economies of scale and efficiency

Note: * Stock Keeping Units (SKUs)

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Full-line wholesalers receive funding from the CSO Funding Pool to compensate for activities that are nationally important but otherwise financially unviable

- Wholesale and distributor remuneration for PBS products is provided through two key funding mechanisms
  - a regulated mark-up percentage of 7.52% applied to the ex-manufacturer PBS price, capped at a mark-up of $69.94, and
  - a share of a Community Service Obligation (CSO) Funding Pool
- The CSO Funding Pool was introduced in 2006 to compensate wholesalers for the following CSO activities
  - delivery of the full range of PBS products to any pharmacy in Australia generally within 24 hours
  - delivery of low volume and difficult to handle products (i.e. cold-chain, cytotoxic and drugs of dependency)
- The CSO Funding Pool was created by reducing the wholesale mark-up from 11.1% to 7.52% and allocating a portion of the reduction to a fixed pool, divided between eligible wholesalers, based on market share. The Funding Pool is open to any company that meets the community service standards and compliance requirements
- Full-line wholesalers are subject to head office audits at least once a year and a number of site audits by the independent CSO audit agency to ensure compliance to standards. Short-line wholesalers and distributors are not subject to the same audit requirements
- Prior to the introduction of the CSO Funding Pool, many elements of CSO wholesaling activities had become unviable. This was largely due to short-line wholesalers “cherry-picking” the more profitable, high volume product lines and metropolitan delivery areas. Without the CSO Funding Pool, the National Medicines Policy objectives would not have been met

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

- A suite of PBS reforms introduced by the government over the last decade, in particular price disclosure, has been effective in reducing the costs of medicines by and providing significant savings of c.$4bn from FY10 to FY15* to government and consumers. However, these reforms have also unintentionally impacted the profitability and viability of full-line wholesalers in two ways:

    1. **Falling unit prices of PBS medicines** have reduced the per unit mark-up available to wholesalers, who are remunerated based on a fixed percentage mark-up on the PBS price. Since 2011, the proportion of PBS products dispensed that are priced under $15 ex-manufacturer has increased from 55% to 77%, and this is forecast to increase to 84% by 2020

    2. At the same time, **the wholesaling business has become more complex**. Since 2011 the number of individual product items (i.e. Stock Keeping Units or "SKUs") listed on the PBS and distributed by full-line wholesalers has increased by 41%. This is largely the result of an increase in the number of competitors for off-patent medicines, which has in turn delivered savings to the government through price disclosure. Increased choice is also a benefit to consumers, but imposes greater complexity and increased cost on wholesalers

- Wholesalers have responded to these changes by driving efficiency and productivity gains in their businesses. Over the period FY13 to FY16 unit costs were reduced by approximately 16% on average across the three national full-line wholesalers. This was achieved via investments in automation and business restructuring

- Despite these initiatives PBS products continue to be distributed at a loss once discounts to pharmacy have been included, and do not deliver a minimum industry return on capital (WACC) of 11%. Full-line wholesalers remain profitable only due to cross-subsidisation of PBS lines by other non-PBS sales (e.g. OTC products)

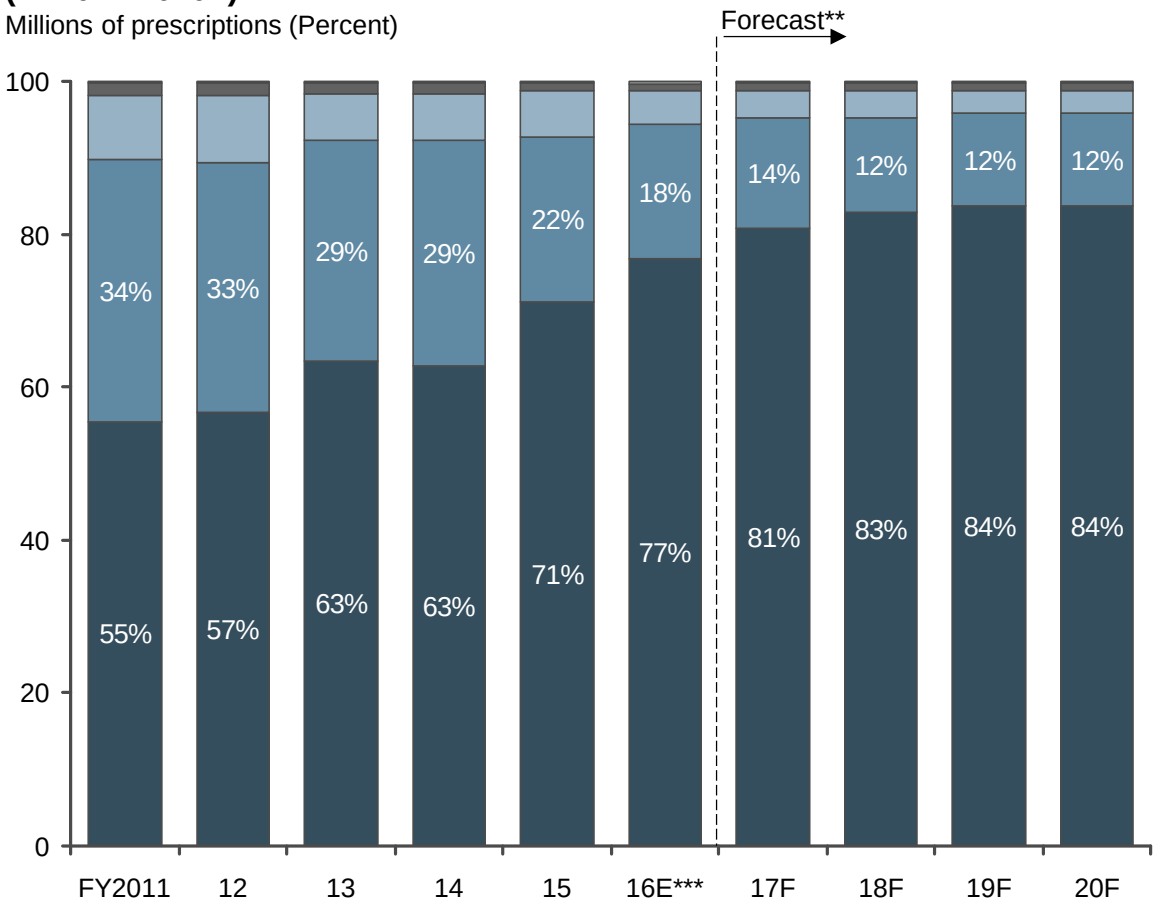
- In the past wholesalers offered discounts and rebates to pharmacies to compete for share and drive scale economies. The ability to offer these discounts has fallen significantly, and discounting will not be viable as the mark-up declines. The removal of these discounts will negatively impact on the financial position of pharmacists going forward

Source: * Savings of actual PBS expenditures compared to forecast published in Intergenerational Report, 2010

Price disclosure has significantly reduced the price of medicines such that 77% of products dispensed are now priced below $15, increasing to 84% by 2020

PBS product mix, by PBS price band* (FY2011-2020F)

Millions of prescriptions (Percent)



Percentage point change in share of total prescriptions **(FY2011-16E) (FY2016E-20F)**

	(FY2011-16E)	(FY2016E-20F)
>$930	0.1	(0.1)
$100-930	(0.7)	0.1
$50-100	(4.0)	(1.5)
$15-50	(16.7)	(5.4)
<$15	21.3	7.0

The knock-on effect to wholesalers has been a reduction in funding due to the regulated fixed percentage mark-up funding structure

Note: * Ex-manufacturer price, excludes PBS code "9999Z"; ** Forecast based on aggregate volume growth of 1.5% p.a. (in line with historical growth) and forecast molecule price reductions; *** FY2016 product mix estimated by scaling up available Date of Supply PBS prescription, published through April 2016

Source: Department of Health; PBS; L.E.K. analysis

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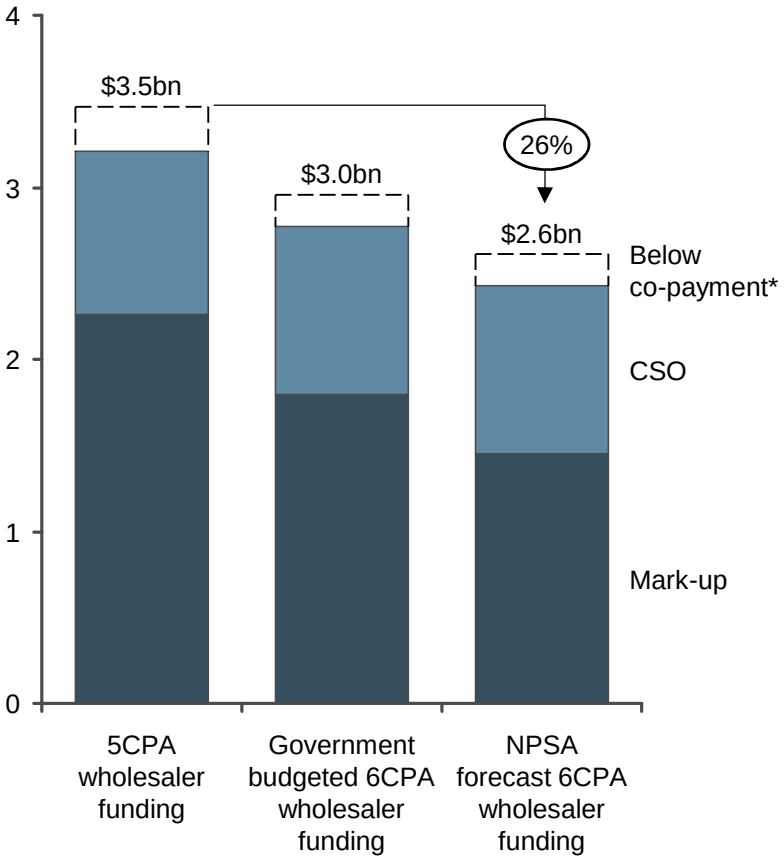
The implication for wholesaler viability due to revised funding in the 6CPA is significant: they will receive 26% less funding than under the 5CPA

Wholesaler and distributor funding under the Community Pharmacy Agreement, by funding source (FY2011-20F)

Billions of Australian dollars



- Funding to wholesalers is comprised of three key elements, of which only the first two are included in the Federal Budget
  - standard mark-up of 7.52%, capped at a mark-up per unit of $69.94
  - CSO Funding Pool
  - consumer contributions for PBS scripts that fall below the PBS co-payment thresholds
- The NPSA forecast for 6CPA wholesaler funding is less than the level budgeted by the government
  - this is due to differences in molecule price reduction forecasts
  - the forecast takes into account price reductions published in 2016, which have been more significant than expected
- As a result, overall funding to wholesalers in the 6CPA is forecast to decline by 26% from the 5CPA, leading to sustainability issues across the value chain

Note: * Below co-payment value estimated using Date of Supply data from FY2010-2015 for 5CPA and forecast model results for both the Government budgeted 6CPA and NPSA forecast 6CPA

Source: Department of Health; PBS; ANAO; L.E.K. Analysis

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Changes to the wholesale and distribution funding model are required to ensure a sustainable and viable sector and achievement of the goals of the NMP

- The current Pharmacy Review is a very timely consideration of the regulations that enable achievement of NMP outcomes
- Under the current funding arrangements, the PBS wholesaling model is unsustainable in the long term. In response, full-line wholesalers will need to find additional sources of value, for example by charging service fees to pharmacies for the delivery of 'high volume' products in 24 hours and / or reducing terms of trade
- Responses that increase fees and costs to pharmacies will impose cost on all pharmacies but have a greater impact on the smaller independent pharmacists, many of which operate in rural and remote areas. This will jeopardise the financial viability of pharmacies, and in turn, the consumers who rely on these pharmacies, and the delivery of the NMP
- Full-line wholesalers provide significant working capital (trade debtors) to pharmacies, estimated at c$1.69bn as at 30 June 2016. There is a strong possibility of market failure if the funding from NPSA members were to be withdrawn. Current and expected conditions in capital markets, including bank funding, and existing lending ratios of banks to pharmacy mean it is unlikely this level of additional funding would be readily available*
- A more sustainable wholesale funding model is required and must consider both the funding quantum, and the funding mechanisms
- Sustainable long term investment in the sector depends on a funding model that provides confidence to participants that running an efficient business will allow them to earn returns at or above the cost of capital and encourage ongoing investment and innovation in the sector. This is particularly important for wholesalers, because assets such as warehouses and logistics systems, IT for inventory management and warehouse management systems are 10-20 year lifecycle investments
- The sustainable funding range has been calculated using a return on capital approach with required return of between the Weighted Average Cost of Capital (WACC) of 11% and the average internal investment hurdle rate of 15% for each of the full-line wholesalers. The level of funding required over the period of the 6CPA to meet this threshold return on capital is between $3.0bn and $3.1bn
- This level of funding is at the lower range of what has been budgeted under the 6CPA, assuming the government budgeted amount of $2.775bn plus c.$0.2bn of below co-payment consumer contributions. Moreover, a funding gap of $0.4bn to $0.5bn is expected to emerge, based on the NPSA forecast of wholesaler PBS remuneration that is likely to eventuate ($2.6bn) taking into account current views of price disclosure impacts

Source: * Medici Capital

Compared to alternatives, the current CSO Funding Pool mechanism is the most efficient and effective model to meet the needs of the NMP

- An important tenet of the NMP is the achievement of equitable access to medicines for all Australians, irrespective of where they live. This “community service obligation” is currently achieved by providing sufficient compensation for wholesalers to make the full range of products available to any pharmacy
- There are numerous alternative ways to deliver a community service obligation, investigated further in the report, including:
  - Tendering
  - Fixed fee per item funding
  - Fees paid directly to pharmacists in rural and remote areas
  - Manufacturers taking responsibility for distribution of medicines
- Each of these models has benefits and downsides. Under several of the alternative models, the direct cost to government could potentially be reduced (at least in the short term). However, under each alternative model this benefit would be off-set by negative impacts on patients and taxpayers, either in the form of reduced access to medicines or higher costs
- A tendering approach brings significant risk that government would be faced with higher costs in the longer term as the competitiveness of subsequent tender rounds is eroded due to incumbency advantages such as an installed infrastructure base. Unsuccessful tenderers in the first round would be deterred from investing in infrastructure in that region, reducing contestability into the future, with likely flow-on impact in terms of increased prices
- Restructuring the CSO Funding Pool, which is a well-functioning and reliable mechanism to meet the NMP, would bring significant risk to consumers and (in some cases) even raise the cost to government. When compared to these alternatives, the current CSO Funding Pool represents a more efficient and effective approach to meet the needs of the NMP
  - it provides confidence to wholesalers that funding will be available to offset the higher cost of services relating to low volume medicines, 24 hour delivery and responsive services that benefit non-metro pharmacists and consumers
  - the ‘share of pool’ funding mechanism also provides a powerful incentive for healthy competition between full-line wholesalers on the basis of responsive service to pharmacists and cost efficient operations
  - the pooled funding prevents cherry-picking of profitable lines that an activity-based funding model would not achieve
- While the CSO Funding Pool is regarded as the most effective model for achieving NMP outcomes, the funding should be indexed to ensure compensation keeps pace with inflation and increasing volumes

A change in the mark-up structure is required to provide sustainable levels of remuneration given the bifurcation of drug prices

- Currently the wholesaler price to pharmacists is regulated via a 7.52% mark-up, up to a maximum of $69.94, based on the PBS ex-manufacturer price. The wholesaler mark-up is the primary revenue source from the distribution of PBS products

- The recent and expected trend in PBS prices has been a bifurcation towards very low and very high prices
  - over 75% of PBS products dispensed are now priced below $15 (on an ex manufacturer basis)
  - meanwhile, an increasing number of products have PBS prices in the thousands of dollars, e.g. Hepatitis C medications

- As prices have moved towards these extremes, the fixed percentage mark-up structure and ceiling at $930.06 ($69.94 wholesaler cap) has resulted in an unsustainable reduction in mark-up per unit. This decline in mark-up will continue as price disclosure drives down prices, and innovative high cost drugs dispensed grow in number

- A change in the mark-up structure is required to provide greater stability and sustainable levels of remuneration into the future
  - holding constant the existing mark-up of 7.52%, with the introduction of a mark-up floor at an ex-manufacturer PBS price of $8.00 - $9.25 (equivalent to a mark-up of $0.60 - $0.70), similar to the AHI structure in place for pharmacists, would enable appropriate remuneration for the distribution of PBS products in light of forecast price reductions. The NPSA forecasts that a mark-up floor price of $8.00 - $9.25 would provide certainty to wholesalers that sustainable funding requirement of $3.0 - $3.1bn would be paid over the period of the agreement
  - the mark-up ceiling of $930.06 is no longer appropriate at the current level; an alternative structure for the funding of high cost drugs that recognises the significant stock holding costs and risks through the supply chain is required. Further details on alternative structures will be provided by NPSA as an addendum to this report

- The wholesaler and distributor funding mechanism for s100 products delivered to community pharmacy is currently different to s85, the large majority of products dispensed via community pharmacy. There is value in capturing all products dispensed via community pharmacy under the CPA funding mechanism, including extending the CSO to include s100 products

In summary, a sustainable wholesaler funding model that effectively and efficiently delivers the NMP would be comprised of the following

Recommended Funding Quantum

- Achieving returns at or above the cost of capital is important to encourage ongoing investment in the sector, including investment in innovation to bring about efficiency gains. The level of funding required for wholesalers and distributors over the period FY2016-2020 to meet this threshold return on capital is equivalent to $3.0bn-$3.1bn
- The level of funding budgeted under the 6CPA, of $2.775bn plus patient below co-payment contributions of $0.2bn, would only deliver $3.0bn – the lower end of the required sustainable funding
- Moreover, when compared to the NPSA forecast of PBS expenditure and wholesaler funding that is likely to eventuate ($2.6bn), a funding shortfall of $0.4bn to 0.5bn will emerge if no changes are made to wholesaler funding

Recommended Funding Mechanism

CSO

- The CSO Funding Pool be retained as the most effective way to deliver the CSO
- The CSO pool should be indexed to ensure funding keeps pace with inflation and increasing volumes
- The CSO Funding Pool should be expanded to include s100 products distributed to community pharmacy

Mark-up

- Holding constant the mark-up percentage of 7.52%, the introduction of a mark-up floor price of $8.00 - $9.25 (equivalent to a unit mark-up of $0.60 - $0.70) will provide sustainable compensation to wholesalers and will recognise the significant decline in PBS prices. A mark-up floor of $8.00 - $9.25 will deliver funding of $3.0bn-$3.1bn
- The current mark-up ceiling does not adequately compensate wholesalers for the costs related to the holding and distribution of high cost drugs. An alternate mechanism for compensation should be considered. The NPSA will provide an addendum to this report outlining and assessing the alternatives

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Report context and objectives

- The NPSA (National Pharmaceutical Services Association) engaged L.E.K. Consulting to prepare an independent, fact based report on the regulation and remuneration of pharmaceutical wholesalers to inform its submission to the Review of Pharmaceutical Remuneration and Regulation

- The L.E.K. Report addresses the following four topics
  - An overview of the Australian pharmaceutical market, value chain economics and the regulations in place to meet the Government's National Medicines Policy
  - An economic assessment of the impact of pharmaceutical regulatory changes on the wholesaling and distribution sector
  - An economic assessment of the funding required to support a sustainable, competitive and efficient wholesaling and distribution sector
  - An assessment of possible alternative wholesaler funding mechanisms to the current CSO Pool and Mark-up arrangements
- This report has utilised both primary and secondary information sources including
  - cost analysis undertaken by Verve Economics
  - cost, revenue and operating data provided by the three national full-line wholesalers (API, Sigma and Symbion (EBOS))
  - third party industry reports, industry expert interviews, company annual reports and press releases
- This report was prepared during August and September 2016

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The Australian Government's National Medicines Policy ("NMP") is designed to ensure timely access to quality medicines for all Australians

National Medicines Policy

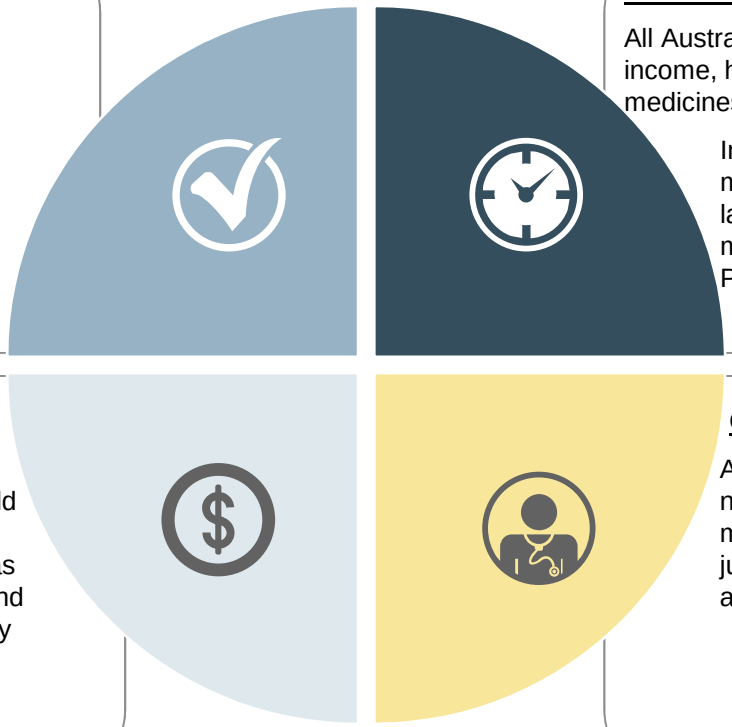
Quality, safety & efficacy

Ensure that the quality, safety and efficacy of medicines in Australia is equal to that of comparable countries and regulated nationally through an active body (the Therapeutic Goods Administration)

Access to medicines

All Australians, regardless of location or income, have access to cost effective medicines

In order to provide access to medicines for all Australians a large proportion of prescription medicines are funded by the PBS



Viable and responsible pharmaceutical industry

Industry policy and health policy should provide a consistent and supportive environment for the industry, as well as appropriate returns for the research and development, manufacture, and supply of medicines

Quality use of medicines

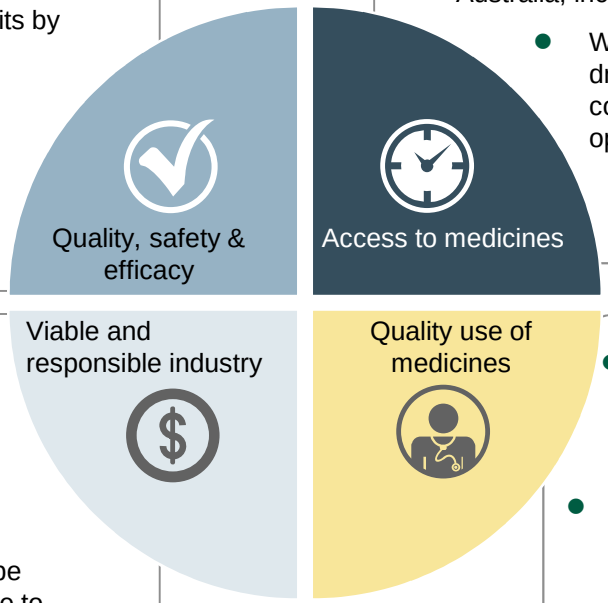
Australia has a well accepted national policy that aims for medicines to be used judiciously, appropriately, safely and effectively

Source: National Medicines Policy

Full-line wholesalers play a central role in enabling the NMP by enabling efficient, responsible and reliable delivery of PBS medicines

- Full-line wholesalers must comply with the CSO Operational Guidelines, Code of Good Wholesaling Practice, TGA and State Government standards, which regulate compliance and wholesaling service standards
- Full-line wholesalers are subject to head office audits at least once a year and several site audits by the independent CSO audit agency to ensure compliance to standards
- Full-line wholesalers facilitate national product recalls on behalf of the government or manufacturer

- Full-line wholesalers invest in national distribution networks with system redundancy to ensure that consumers in all regions have access to the full range of PBS products
- Full-line wholesalers must deliver the full range of PBS products, generally within 24 hours, to all pharmacies in Australia, including during states of emergencies
  - Wholesalers have responded to lower mark-up by driving efficiencies through the supply chain and competing on the basis of effective, efficient operations and service delivery at a reasonable cost
    - Formal continuity of business plans are required as part of the CSO deed



- Full-line wholesalers ensure that products from a range of manufacturers are delivered efficiently to approximately 5,500 pharmacies throughout Australia, regardless of location
- Full-line wholesalers support access to pharmaceuticals by providing working capital funding to pharmacies that may not otherwise be able to cost-effectively access trade finance due to their status as small business owners

- Wholesalers minimise the risk that counterfeit products do not enter the supply chain by limiting the channels for medicine delivery to pharmacies
- Wholesalers provide appropriate storage for cold chain and dangerous drugs to minimise the risk of damage
- Wholesalers provide appropriate storage security for drugs of dependency to minimise the risk of theft, and reduce risks of crime at pharmacies

Source: National Medicines Policy

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To meet the goals of the NMP the pharmaceutical supply chain is subject to tight regulations that protect the integrity of distribution

	Manufacturer	Wholesaler	Pharmacy
Activities	• Manufacture medicines according to TGA standards • Invest in research and development to deliver new and innovative medicines	• Distribute products from many manufacturers to many community pharmacies across Australia in a safe and efficient manner	• Dispense prescription medicines to the community
Role in NMP delivery	• Ensure drugs are manufactured to GMP and TGA quality standards • Supply products in an efficient manner at affordable prices • Undertake post-market monitoring • Provide information to consumers and healthcare providers to support quality use of medicines	• Full-line wholesalers supply the full range of PBS products in a timely manner to all pharmacies in Australia • Provide working capital funding to small business pharmacy owners • Provide other support services, such as return of unwanted medicines	• Advise consumers on how their medicines are to be taken or used in the safest and most effective way • Advise about medicine use, including appropriate selection, dosage and drug interactions, potential side effects and therapeutic effects
Regulation	• The Therapeutic Goods Administration (TGA) regulates the medicines in Australia through pre-market assessment, post-market monitoring and enforcement of standards and licensing and verification of manufacturers • PBS prices are established through PBAC economic assessment of the benefits of the medicines	• The Community Service Obligation (CSO) requires that full-line wholesalers supply the full range of PBS products to any pharmacy in Australia, generally within 24 hours • Wholesalers may charge a regulated mark-up • Full-line wholesalers must comply with the Code of Good Wholesaling Practice in Australia, TGA and State Government standards	• Pharmacy location and ownership regulated by Federal and State governments • Remuneration regulated for dispensing of medicines • Medicines can only be dispensed by a registered pharmacist

The pharmaceutical wholesaling model is efficient, it delivers products from over 100 manufacturers to c.5,500 community pharmacies throughout Australia

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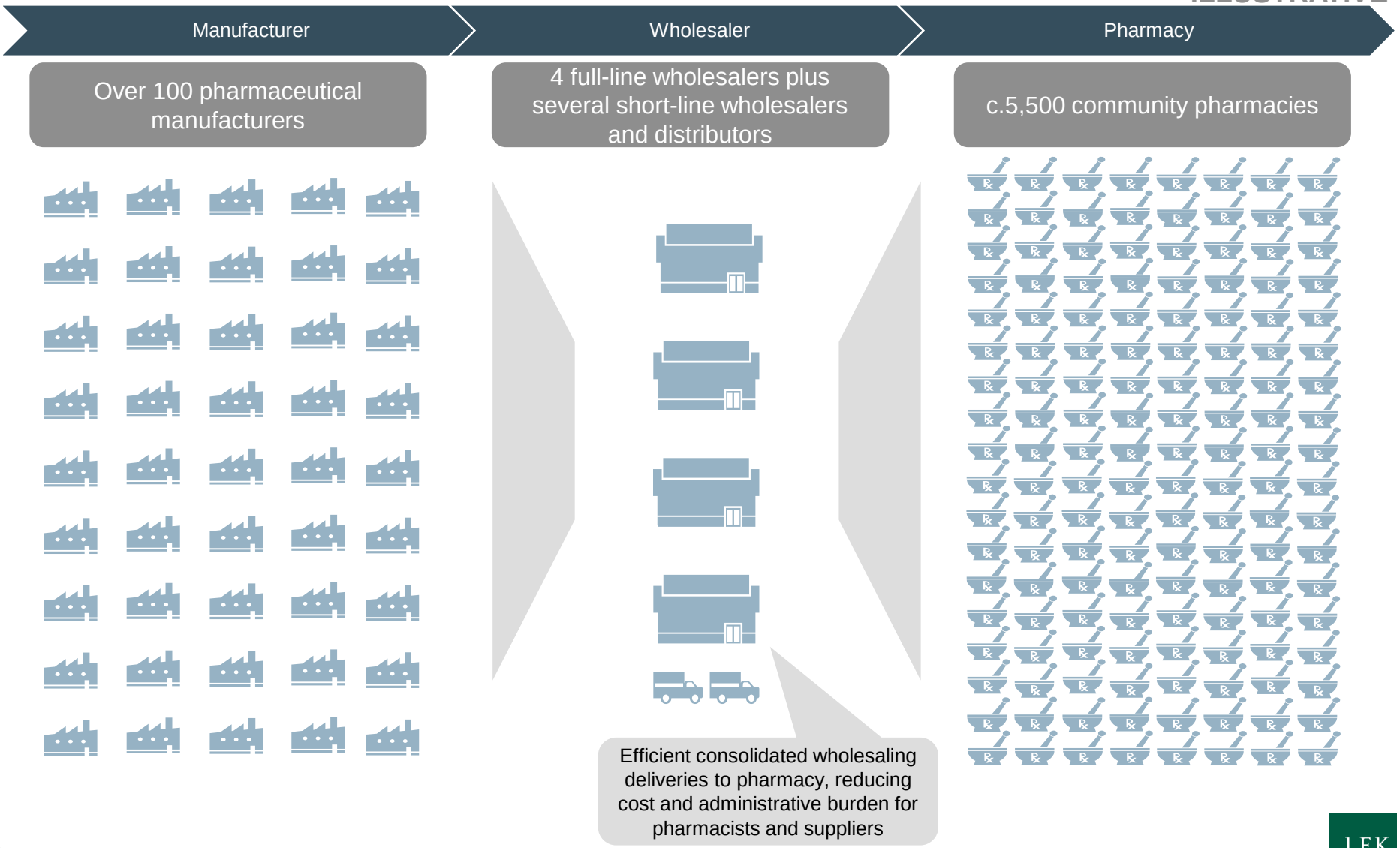
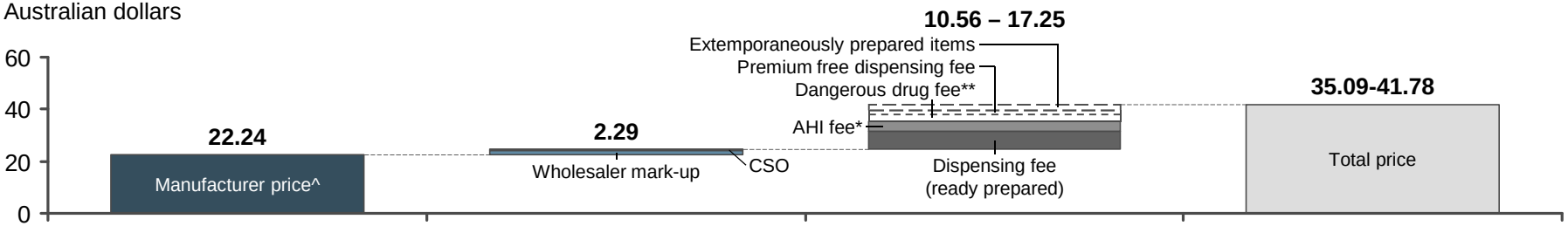


The economics of the pharmaceutical value chain are heavily influenced by industry regulation

Funding breakdown by value chain segment for an 'average' priced PBS listed drug (2016)

Australian dollars



	Manufacturer price	Wholesale regulated mark-up and CSO	Pharmacy regulated mark-up and fees	Total price
Proportion of total price	63.4%	6.5%	30.1%	100%

- PBS caps the maximum ex-manufacturer price for government funded drugs

- Wholesalers receive a regulated mark-up on ex-manufacturer price of 7.52%, up to $69.94
- Payment to compensate full-line wholesalers for meeting Community Service Obligations are also available via CSO Pool funding. Full-line wholesalers receive approximately $0.55-0.65 per unit for CSO items

- Pharmacists receive a dispensing fee of $7.02 on ready prepared items or $9.06 for extemporaneously prepared items
- AHI fee* is also provided, replacing the former mark-up. It varies between $3.54 and $70.92 depending on the price to pharmacy
- Pharmacists receive a premium free dispensing fee of $1.74 for dispensing a cheaper generic
- Not included above is funding for additional services provided by pharmacists to consumers

- Total cost includes payments made by PBS and out of pocket payments by consumers
- Consumer out of pocket payments can be up to $38.30, although Concession card holders pay $6.20
- Safety nets apply for both General and Concessional payments, capping maximum total out of pocket payments in a single year

Note: * The Administration, Handling and Infrastructure (AHI) fee is dependent on product price band.; ** As at July 2016. Additional dangerous drug fee of $2.91 per dispense may apply to ready prepared prescriptions depending on the drug type; ^ Average PBS dispensed price

Source: Pharmacy Guild of Australia; Department of Health; PBS

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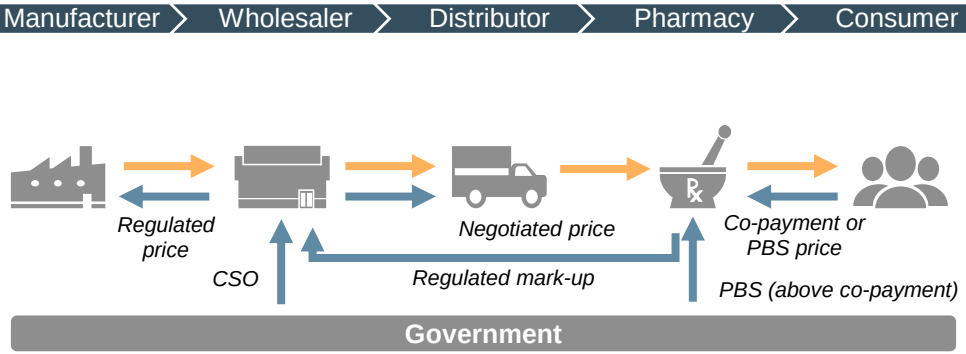
Three wholesale and distribution models currently operate to distribute products to community pharmacy



Full-line wholesale
Wholesale and distribute the full range of PBS products to any pharmacy in Australia

4 full-line wholesalers

- Ex-manufacturer price is regulated by PBS
- Wholesaler owns stock and recovers debt from pharmacy
- Pharmacy pays the wholesaler directly
- Eligible for CSO

Short-line wholesale
Distribute a limited range of products – typically high volume products in metro areas

Short-line wholesalers and distributors

- Ex-manufacturer price is regulated by PBS
- Wholesaler owns stock and recovers debt from pharmacy
- Pharmacy pays the wholesaler directly

Direct to pharmacy
Manufacturer engages third party distributor to deliver products to pharmacy

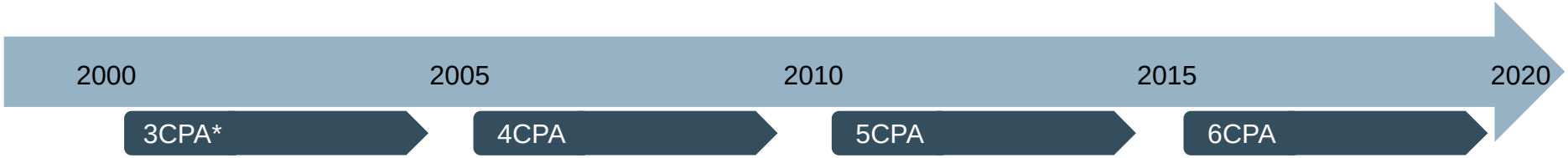
Pfizer Direct and some generic and innovative companies

- Ex-manufacturer price is regulated by PBS
- Manufacturer retains ownership of stock
- Pharmacy pays the manufacturer directly
- Manufacturer contracts 3PL

Product flow | Funding flow

Note: Business models for hospital distribution not covered
Source: PBS; Department of Human Services

The current wholesaler funding model was established 16 years ago and has been adapted by government to respond to industry changes and meet NMP goals



Phase

Inception — *Refinement* — *Expenditure constraint*

Regulation

3CPA (2000-05)
- 1CPA, 2CPA and 3CPA stipulate a 11.1% wholesale mark-up
- No obligation to deliver full range of products or delivery to rural and remote areas within a defined timeframe

4CPA (2005-10)
- Regulated mark-up reduced from 11.1% to 7.52%, with a $69.94 mark-up ceiling
- CSO funding pool introduced to cover the cost of distribution to rural and remote areas, low volume and difficult to handle products
- CSO is partially funded by reduction in mark-up and indexed to inflation
- Independent audit of CSO distributors begins

5CPA (2010-15)
- Regulated mark-up of 7.52% and mark-up ceiling are maintained
- CSO indexed to inflation from 2011 onwards

6CPA (2015-20)

CSO indexation is frozen as part of broader cost saving measures

Market activity

2000-04

Short-line wholesalers increase market share, servicing profitable high volume, metro lines driven by high available mark-up

2005

Five competitors eligible for CSO: Sigma, Symbion, API, FSMA and DHL

2007

DHL withdraws from CSO

2008

$63m in additional CSO funding provided to wholesalers to compensate for impact of PBS F2 reforms

2011
- Pfizer distributes retail pharmacy ethical products exclusively through the direct-to-pharmacy model to community pharmacy
- DHL chosen as the logistics provider

2014

Pfizer renews contract with DHL for direct-to-pharmacy arrangement

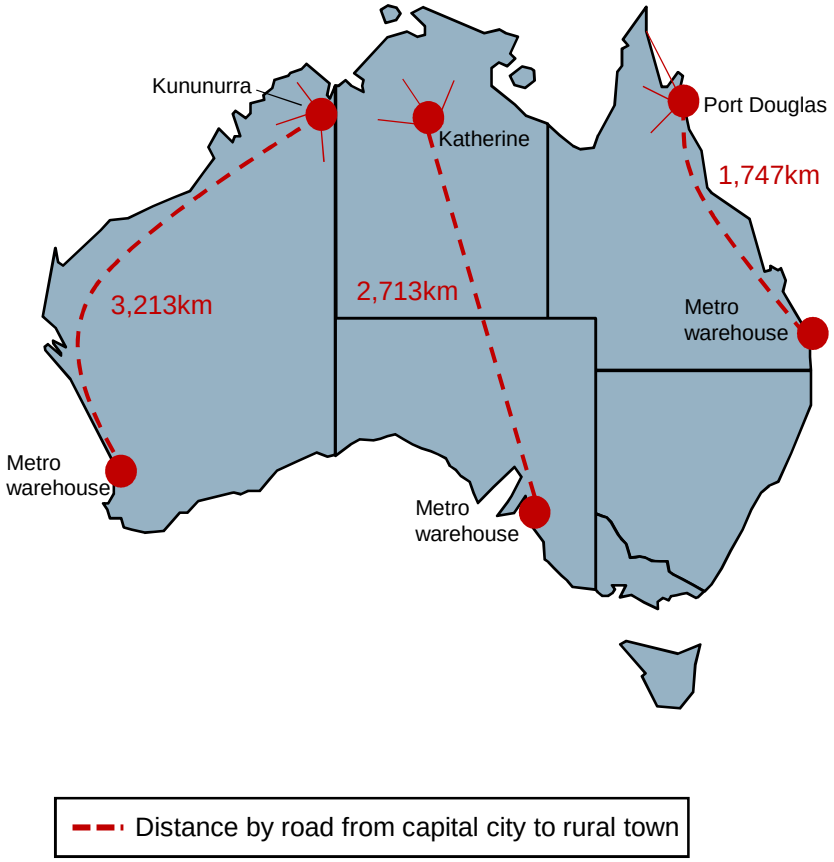
Note: * CPA = Community Pharmacy Agreement
Source: NPSA; Department of Health; PBS; Press search

L.E.K.

The CSO was introduced in 2006 to compensate full-line wholesalers for nationally important but financially unprofitable activities

ILLUSTRATIVE

Examples of remote locations provided for under the CSO Funding Pool



- Australia's unique geography means that distributors may need to cover more than 1,000kms to serve all community pharmacies
- The CSO compensates full-line wholesalers for the extra costs incurred in order to deliver all PBS medicines to all Australians in a timely manner
  - full-line wholesalers are subject to extra costs for freight, storage and labour to deliver low volume and difficult to handle medicines, and to rural and remote areas
- Service standards must be met in order to be eligible for CSO funding
  - supply volumes to rural and remote pharmacies must be no more than 10% less than the industry average (by state)
  - all PBS medicines must be available for supply, unless under an Exclusive Supply Arrangement (e.g. Pfizer direct) or out-of-stock by the manufacturer
  - items must be delivered generally within 24 hours, with some exceptions

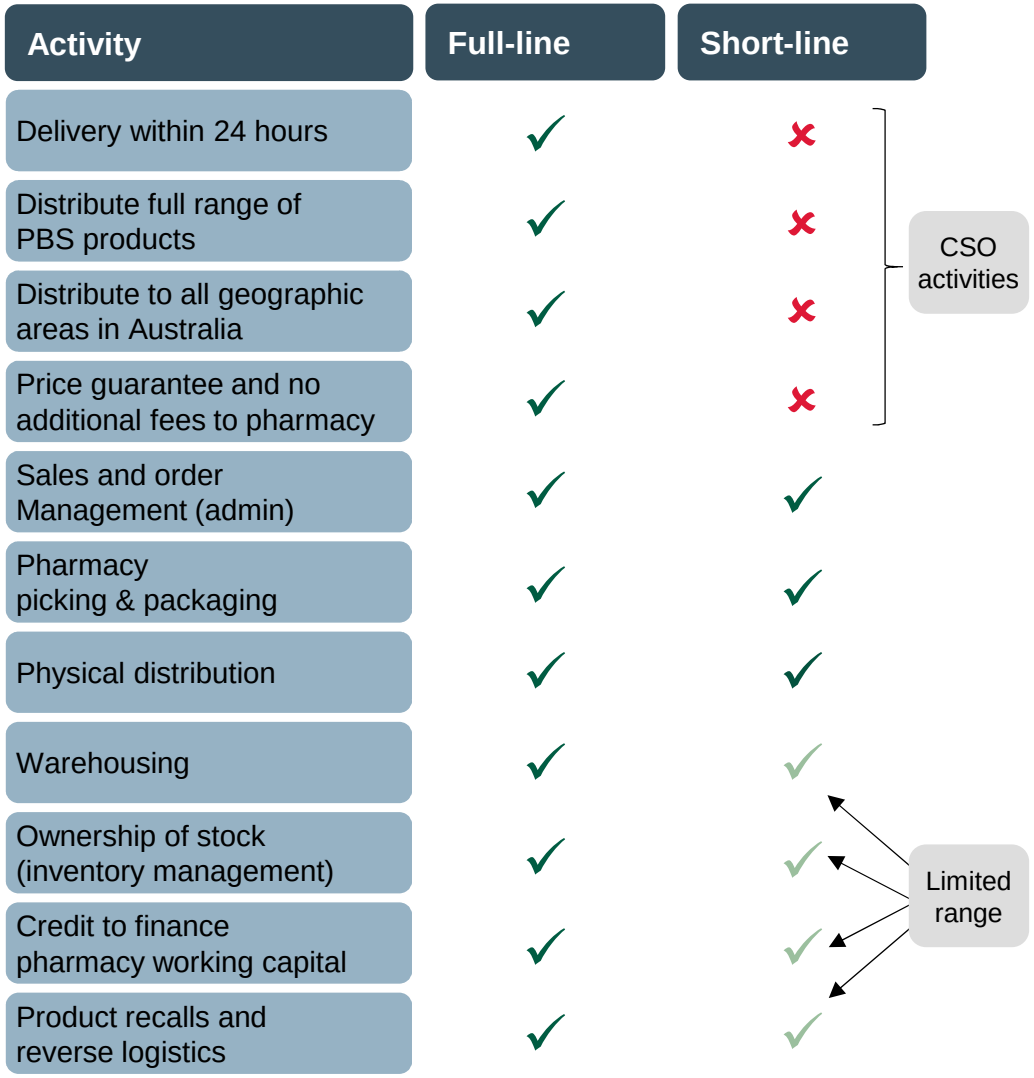
Source: Department of Health; Google Maps

L.E.K.

Full-line wholesalers perform important services not provided by short-line wholesalers

Comparison of short-line and full-line wholesale services for high volume lines to metro pharmacies

- Short-line wholesalers invest in specific distribution networks but are not required to deliver products within 24 hours
- Short-line wholesalers have the ability to distribute only high volume PBS products in high density areas at competitive prices for consumers and government
- Short-line wholesalers do not have the same government regulated audits or standards as full-line wholesalers
- Short-line wholesalers provide finance and warehousing relating only to the selected lines that they distribute
- Full-line wholesalers also facilitate national product recalls on behalf of manufacturers and the government, ensuring rapid removal of unsafe products from retailers and consumer access*
- Full-line wholesalers provide an estimated $1.69bn in working capital to community pharmacies. This funding is further discussed in the Medici Capital report which forms part of the NPSA submission to the Review Panel



Source: * Short-line wholesalers do undertake recalls, but only for their limited range

Summary: Pharmaceutical wholesale market overview and history

- The Australian Government delivers equitable access to quality medicines through the National Medicines Policy framework. This framework has four key components:
  - timely access to the medicines that Australians need, at a cost individuals and the community can afford
  - medicines meeting appropriate standards of quality, safety and efficacy
  - quality use of medicines
  - maintaining a responsible and viable medicines industry
- Wholesalers play a vital role in the efficient delivery of the NMP, supplying approximately 6,200 PBS products and brands* from over 100 manufacturers to over c.5,500 community pharmacies, generally within 24 hours. This vital service enables the dispensing of over 295,000,000 prescriptions by community pharmacists. The wholesaler model provides efficiencies in what would otherwise be an extremely fragmented and inefficient supply chain between over 100 manufacturers and thousands of pharmacies
- Regulation is required to ensure equitable access to medicines for all Australians at an affordable price to the government and community, particularly in rural and remote areas, or for low volume and difficult to handle products (i.e. cold-chain, cytotoxic and drugs of dependency)
- Several wholesaling and distribution models currently operate in the market, competing for market share. These business models include full-line wholesaling, short-line wholesaling and direct distribution by manufacturers
- Wholesalers are funded under two key mechanisms, a regulated mark-up percentage and a community service obligation program (i.e. CSO Funding Pool)
- The CSO Funding Pool was introduced in 2006 to compensate wholesalers for nationally important but financially unviable distribution activities. The CSO is a fixed funding pool, open to any wholesaler that meets the Community Service Obligations, including: delivery of the full range of PBS products to any pharmacy in Australia within 24 hours, maintenance of the quality of all PBS medicines and compliance with the Code of Good Wholesaling Practice
- Prior to the introduction of the CSO Funding Pool, a number of CSO activities had become unviable for wholesalers. This was largely due to short-line wholesalers “cherry-picking” the more profitable, high volume products lines within metropolitan delivery areas. Without the CSO Funding Pool, many of the National Medicines Policy objectives would not have been met

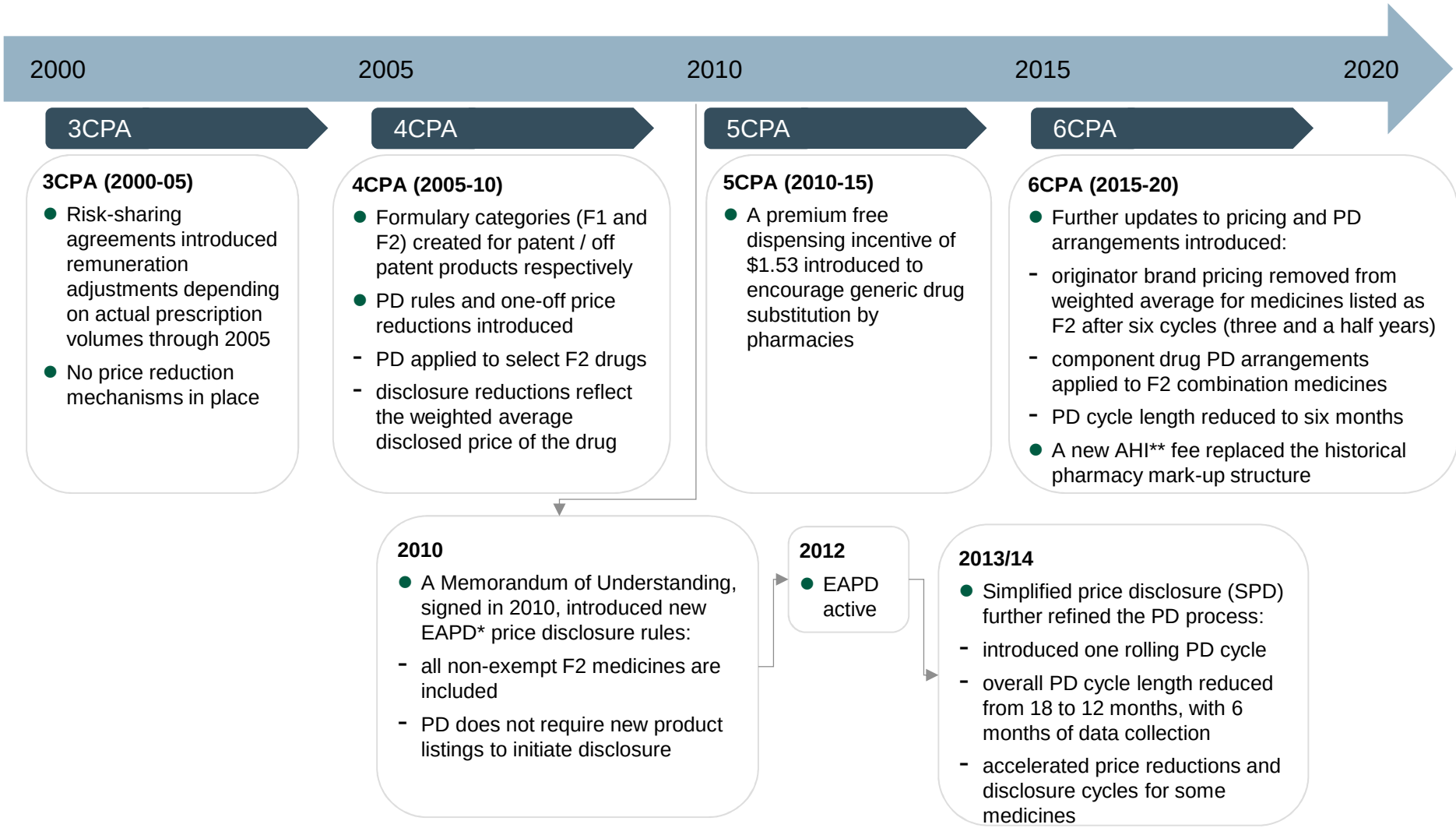
Note: * Stock Keeping Units (SKUs)

Agenda

- Executive summary
- Context and introduction
- Pharmaceutical wholesale market overview and history
- **Changing regulatory landscape and impact on wholesale sustainability**
- Proposed sustainable funding model

L.E.K.

First introduced in 2005, price disclosure ("PD") reforms are aimed at reducing PBS expenditure and ensuring market transparency

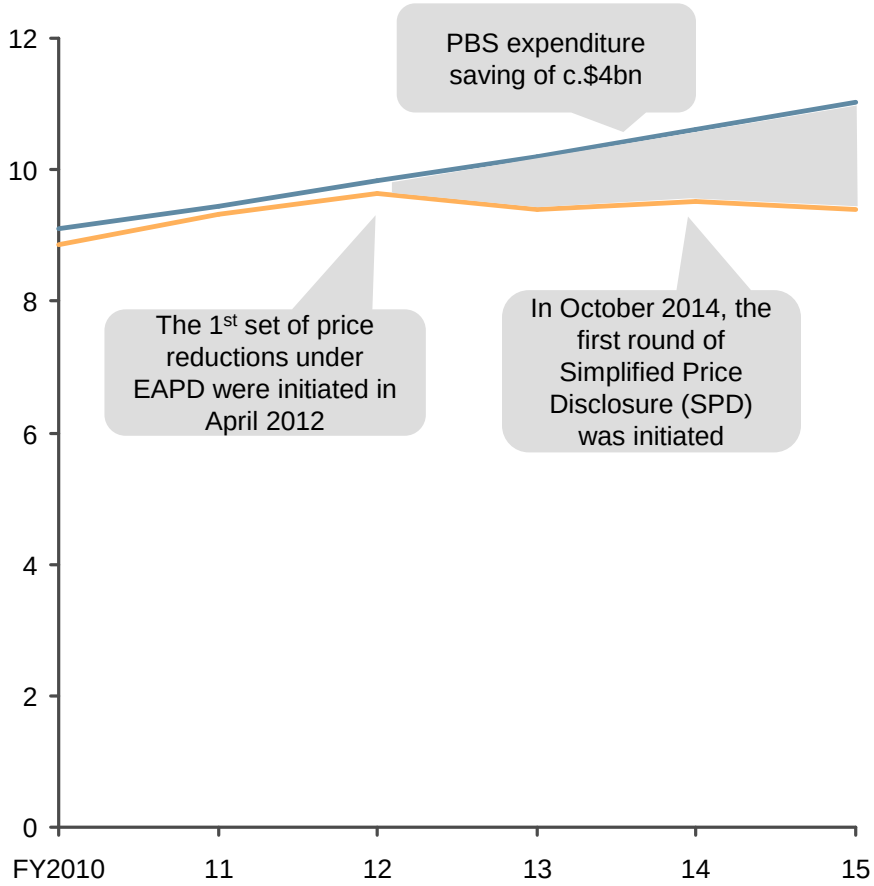


Note: * Expanded and Accelerated Price Disclosure; ** Administration, Handling and Infrastructure fee
Source: NPSA; Department of Health; PBS; Pharmacy Guild of Australia; Press search

Expanded and Accelerated Price Disclosure commenced in 2012, contributing to total PBS savings of approximately $4bn from FY2012 to FY15

Actual PBS expenditures and forecast PBS expenditures* (FY2010-15)

Billions of Australian dollars**



	Compound annual growth rate% (FY2010-15)
Government expenditures (forecast)	3.9
Government expenditures (actual)	1.2

- The 2010 Intergenerational Report (IGR) predicted that PBS funding would increase by c.4% p.a. from FY2010-15
- Actual PBS expenditure has grown at c.1.2%, lower than both inflation and the forecast growth rate, representing savings of c.$3.7bn from FY12 to FY15 when compared with forecasts in the 2010 IGR
- PBS expenditure has been curbed despite script volumes growing at c.2.4% p.a. from FY2010-15

Note: * Difference between forecast and actual spend represents figure driven by difference between forecast IGR figure and actual PBS expenditure in the period; ** Forecast Government expenditure is reported as real Australian dollars as at FY2010;

Source: PBS; Intergenerational Report (2010); L.E.K. analysis

L.E.K.

While beneficial to consumers and the Budget, PBS reforms now challenge the sustainability of full-line wholesalers by deflating prices and increasing complexity

Decreasing PBS prices

- The PBS reforms, and in particular price disclosure, have been successful in reducing overall PBS expenditure. For example, the price of atorvastatin, the highest value drug on the PBS in 2011 fell from $42.70 to $13.11 over a 5 year period. The savings generated have been well in excess of budgeted savings
- A result of the reforms is that the average price of PBS products has fallen. The proportion of products dispensed with an ex-manufacturer PBS price below $15 has risen to 77% from 55% in 2011
- The indirect effect is that wholesaler compensation is reduced, because wholesalers are remunerated on the basis of a fixed percentage mark-up (7.52%, up to a cap of $69.94)
- The trend of decreasing prices is expected to continue as the price disclosure mechanism is applied in the future. The October 2016 price disclosure round will decrease the prices of more than 2,000 medicine brands^

Increasing SKUs and complexity

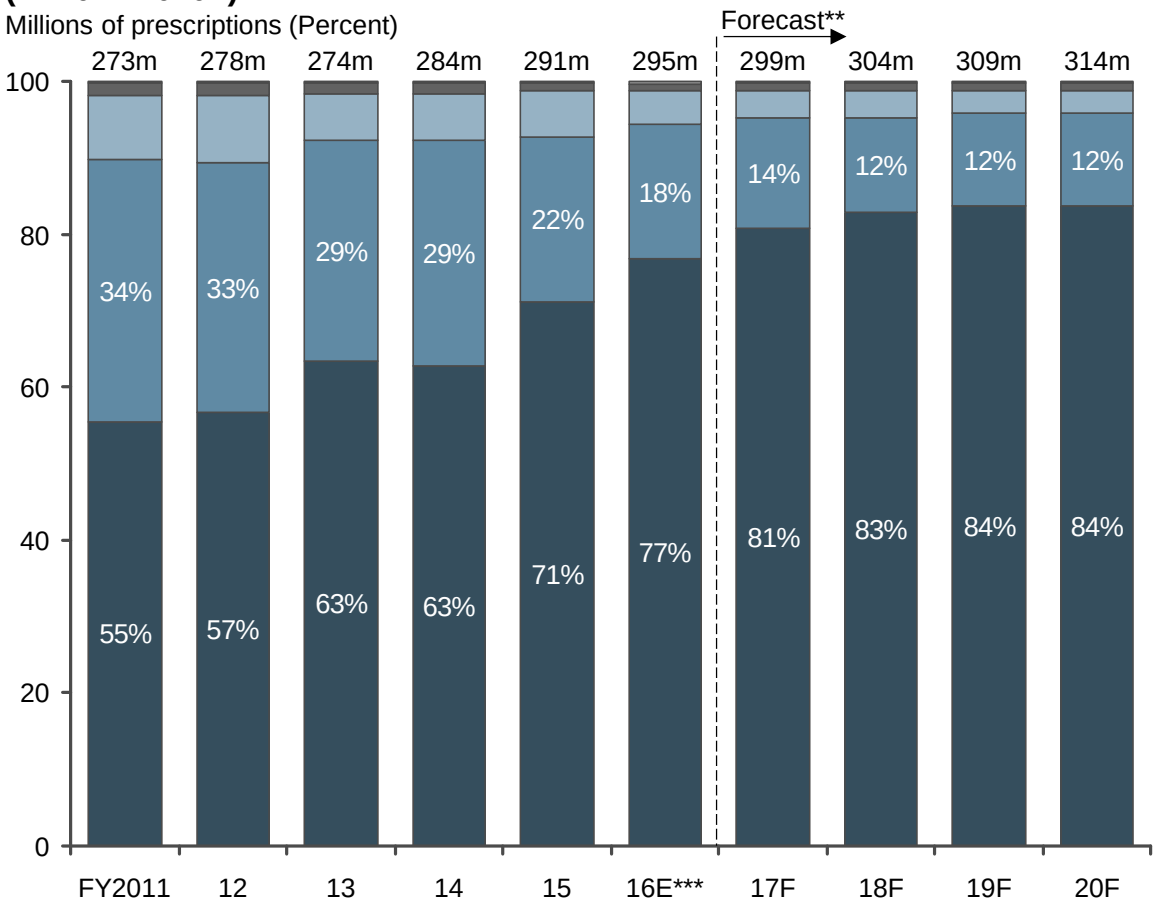
- The number of brands on the PBS has risen strongly in the last five years, driven by the increased number of generics. Since 2011 an additional 1,800 SKUs were added to the PBS (a 41% increase since 2011*)
- It is common for a drug with large market value to experience more than 6 generic competitors following the loss of patent, e.g. atorvastatin, which came off patent in 2011, now has 15 brands listed on the PBS
- Increased SKUs increase operational complexity, as wholesalers now pick across multiple brands for the same volume and incur additional cost due to the working capital costs associated with holding a larger more diverse portfolio of products and increased safety stock levels
- For multi-branded PBS products, full-line wholesalers are required to carry at least one originator brand and at least two generics, but will often carry more to meet the preferences of customers and the obligation for 24 hour delivery

Note: * See appendix for further information; ^ Sussan Ley September 2016
Source: Department of Health; Medicines Australia; IMS Health; PBS; NPSA member data on volumes of PBS products distributed by PBS price level

L.E.K.

Price disclosure has significantly reduced the price of medicines such that 77% of products dispensed are now priced below $15, increasing to 84% by 2020

PBS product mix, by PBS price band* (FY2011-2020F)



Percentage point change in share of total prescriptions **(FY2011-16E) (FY2016E-20F)**

	(FY2011-16E)	(FY2016E-20F)
>$930	0.1	(0.1)
$100-930	(0.7)	0.1
$50-100	(4.0)	(1.5)
$15-50	(16.7)	(5.4)
<$15	21.3	7.0

The knock-on effect to wholesalers has been a reduction in funding due to the regulated fixed percentage mark-up funding structure

Note: * Ex-manufacturer price, excludes PBS code "9999Z"; ** Forecast based on aggregate volume growth of 1.5% p.a. (in line with historical growth) and forecast molecule price reductions; *** FY2016 product mix estimated by scaling up available Date of Supply PBS prescription, published through April 2016

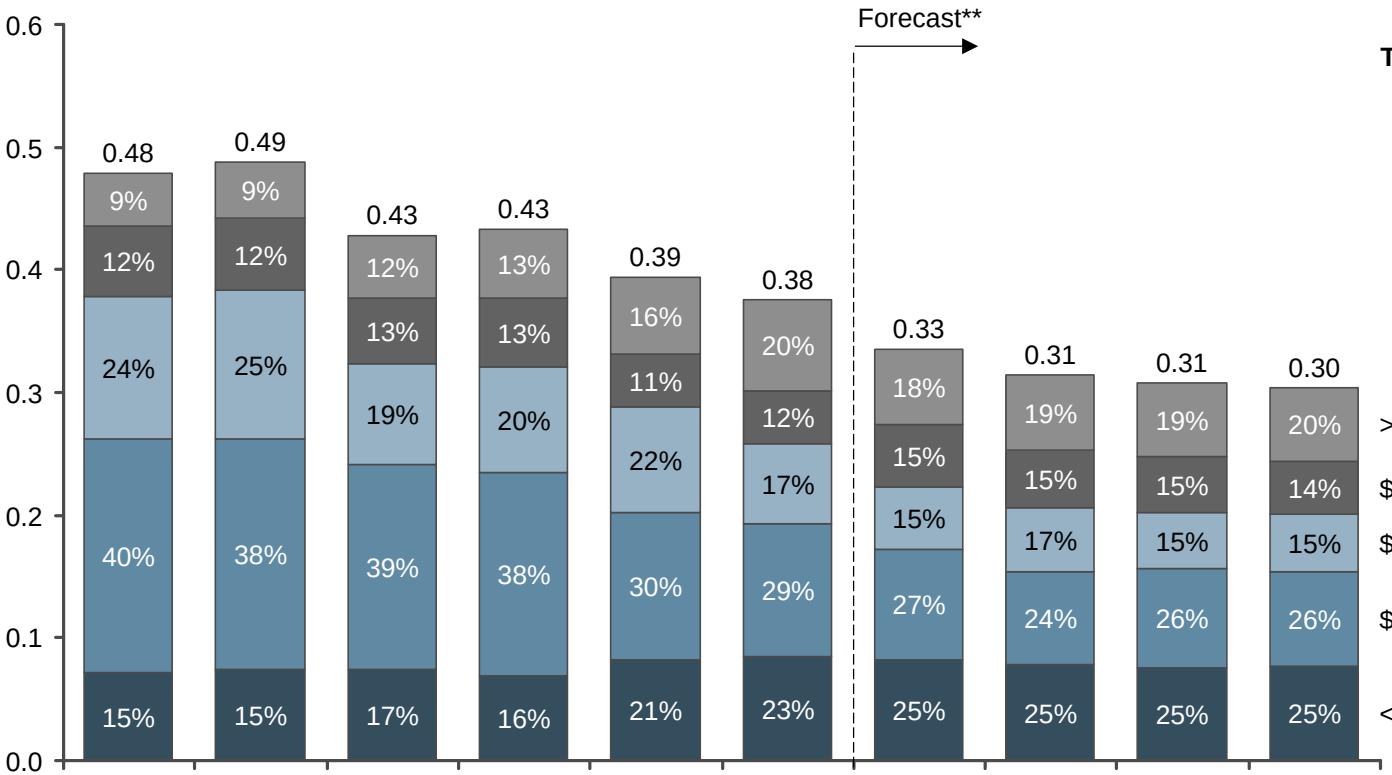
Source: Department of Health; PBS; L.E.K. analysis

L.E.K.

Due to PBS reforms and a higher proportion of low volume products, wholesale mark-up funding is expected to further decline by 5.1% p.a. between FY2016E-20F

PBS wholesaler mark-up, by PBS price band* (FY2011-2020F)

Billions of Australian dollars



	Compound annual growth rate% (FY2011-16E)	(FY2016E-20F)
Total	**(4.7)**	**(5.1)**
>$930	11.5	(4.8)
$100-930	(5.2)	(0.4)
$50-100	(11.2)	(8.0)
$15-50	(10.8)	(7.9)
<$15	3.7	(2.7)

FY2011	12	13	14	15	16E***	17F	18F	19F	20F	
26.66	26.87	24.33	23.93	21.92	22.24	19.59	18.22	17.61	16.95	**Average price per unit dispensed ($)^**

Note: * Ex-manufacturer price; mark-up values represented are those with published PBS ex-manufacturer prices and volumes for PBS Section 85 PBS and RPBS programs as published in the April 2016 Date of Supply data, excludes PBS code "9999Z"; ** Forecast based on aggregate volume growth of 1.5% p.a. (in line with historical growth) and forecast molecule price reductions. Includes products dispensed below co-payment; *** FY2016 values estimated using Date of Supply PBS prescription data though April 2016, average price per unit dispensed increases due to increased volume of Hep C drugs; ^ Price to pharmacy

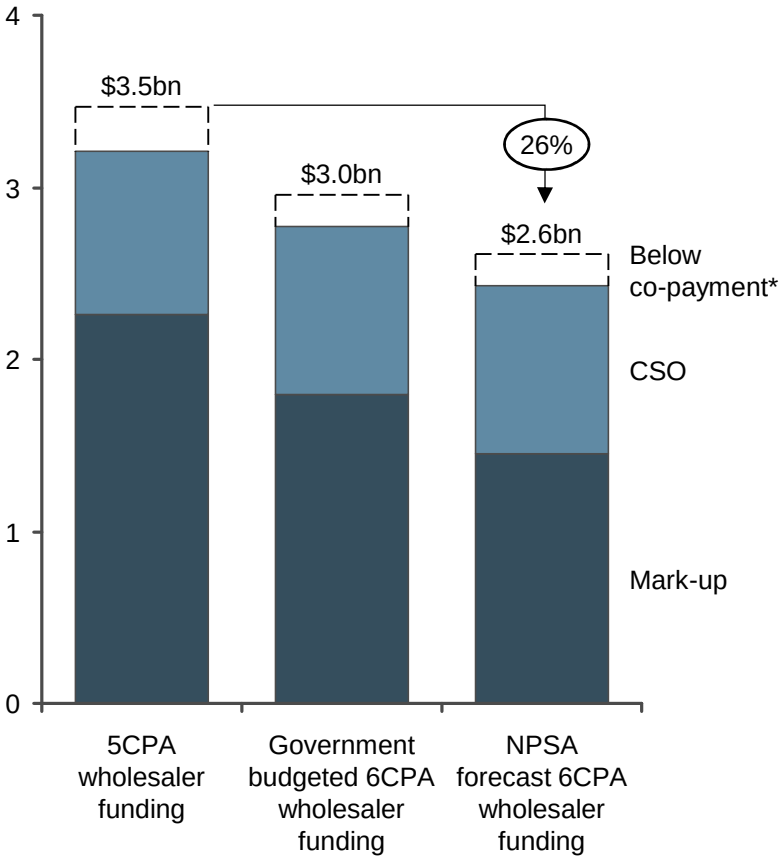
Source: Department of Health; PBS; L.E.K. analysis

L.E.K.

The implication for wholesaler viability due to revised funding in the 6CPA is significant: they will receive 26% less funding than under the 5CPA

Wholesaler and distributor funding under the Community Pharmacy Agreement, by funding source (FY2011-20F)

Billions of Australian dollars



- Funding to wholesalers is comprised of three key elements, of which only the first two are included in the Federal Budget
  - standard mark-up of 7.52%, capped at a mark-up per unit of $69.94
  - CSO Funding Pool
  - consumer contributions for PBS scripts that fall below the PBS co-payment thresholds
- The NPSA forecast for 6CPA wholesaler funding is less than the level budgeted by the government
  - this is due to differences in molecule price reduction forecasts
  - the forecast takes into account price reductions published in 2016, which have been more significant than expected
- As a result, overall funding to wholesalers in the 6CPA is forecast to decline by 26% from the 5CPA, leading to sustainability issues across the value chain

Note: * Below co-payment value estimated using Date of Supply data from FY2010-2015 for 5CPA and forecast model results for both the Government budgeted 6CPA and NPSA forecast 6CPA

Source: Department of Health; PBS; ANAO; L.E.K. Analysis

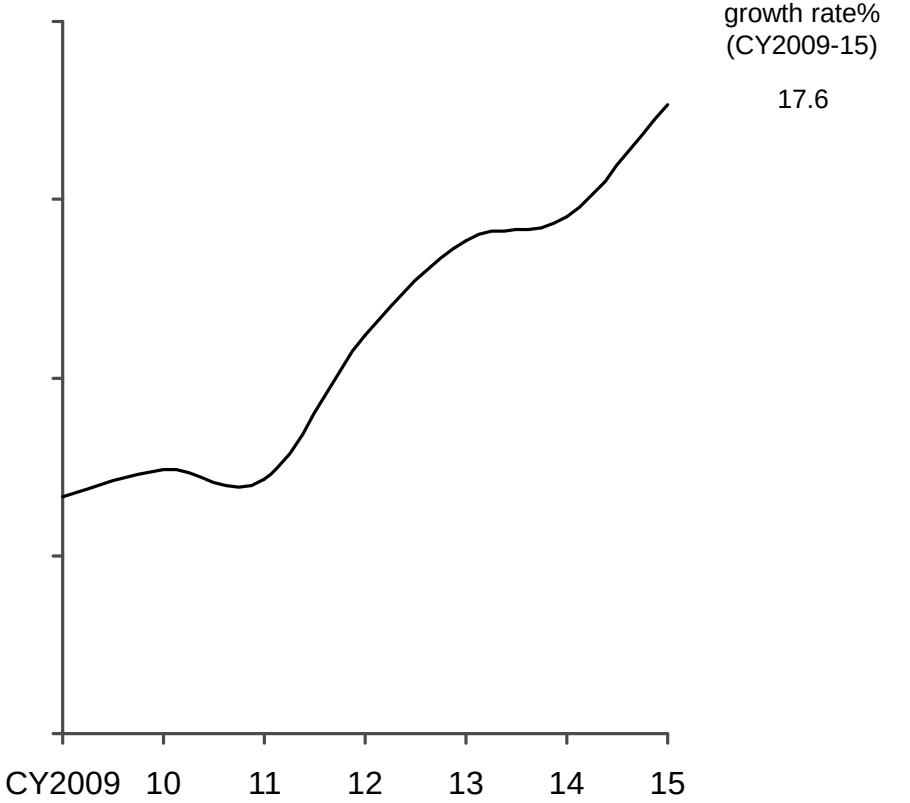
L.E.K.

Wholesalers have responded to the changing market environment by driving greater productivity and have improved operating efficiency by 16% since 2013

Increased labour productivity

Number of lines per attended hour (CY2009-15)

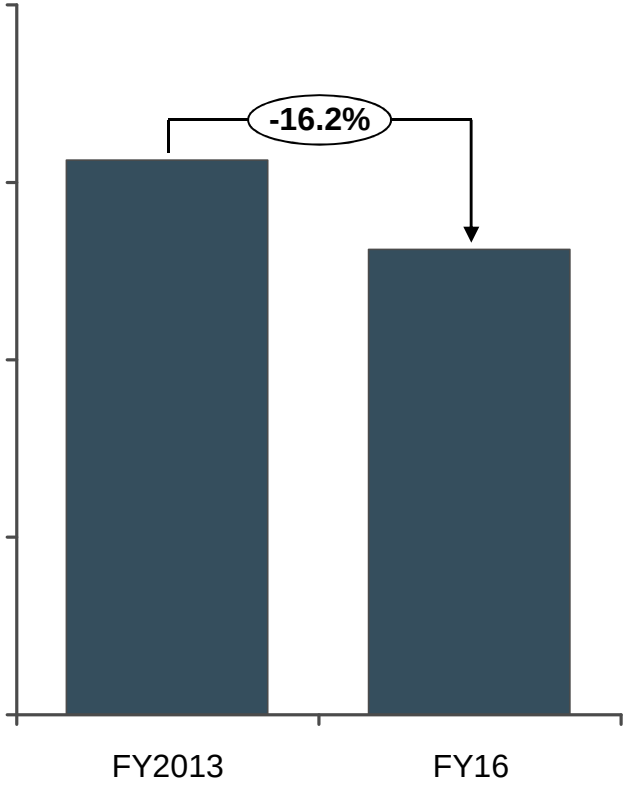
Number of lines



Reduced cost per unit

Full-line wholesaler PBS operating expenditure per unit* (FY2013-16)

Australian dollars

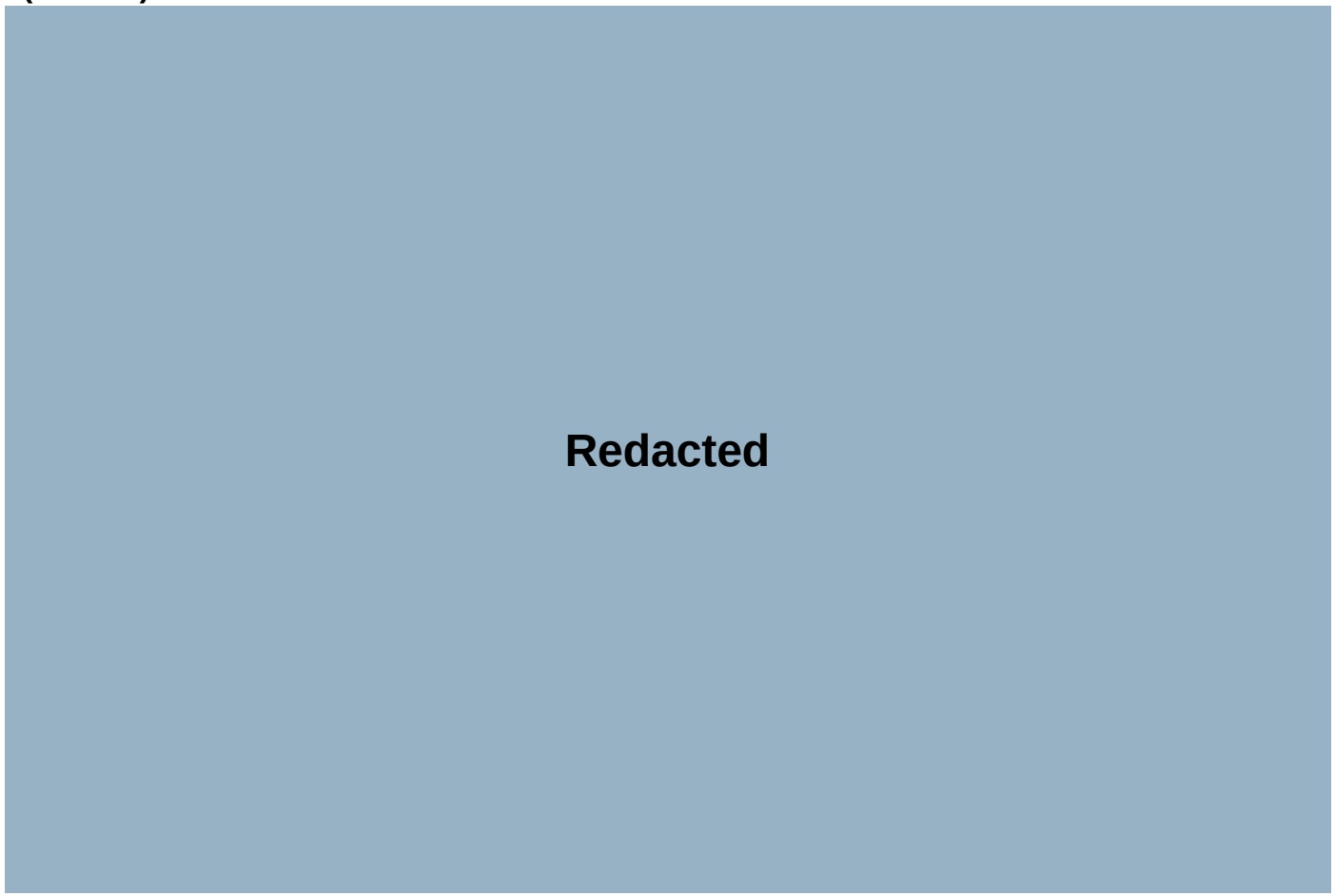


Note: * Includes operations and maintenance expenditure; Chart scales are redacted due to commercial confidentiality

Source: NPSA member company data; Verve Consulting; L.E.K. analysis

Despite the efficiency gains, full-line wholesalers are currently distributing PBS medicines at an economic loss

Average full-line wholesaler revenue* and economic profit per PBS unit distributed (FY2016)

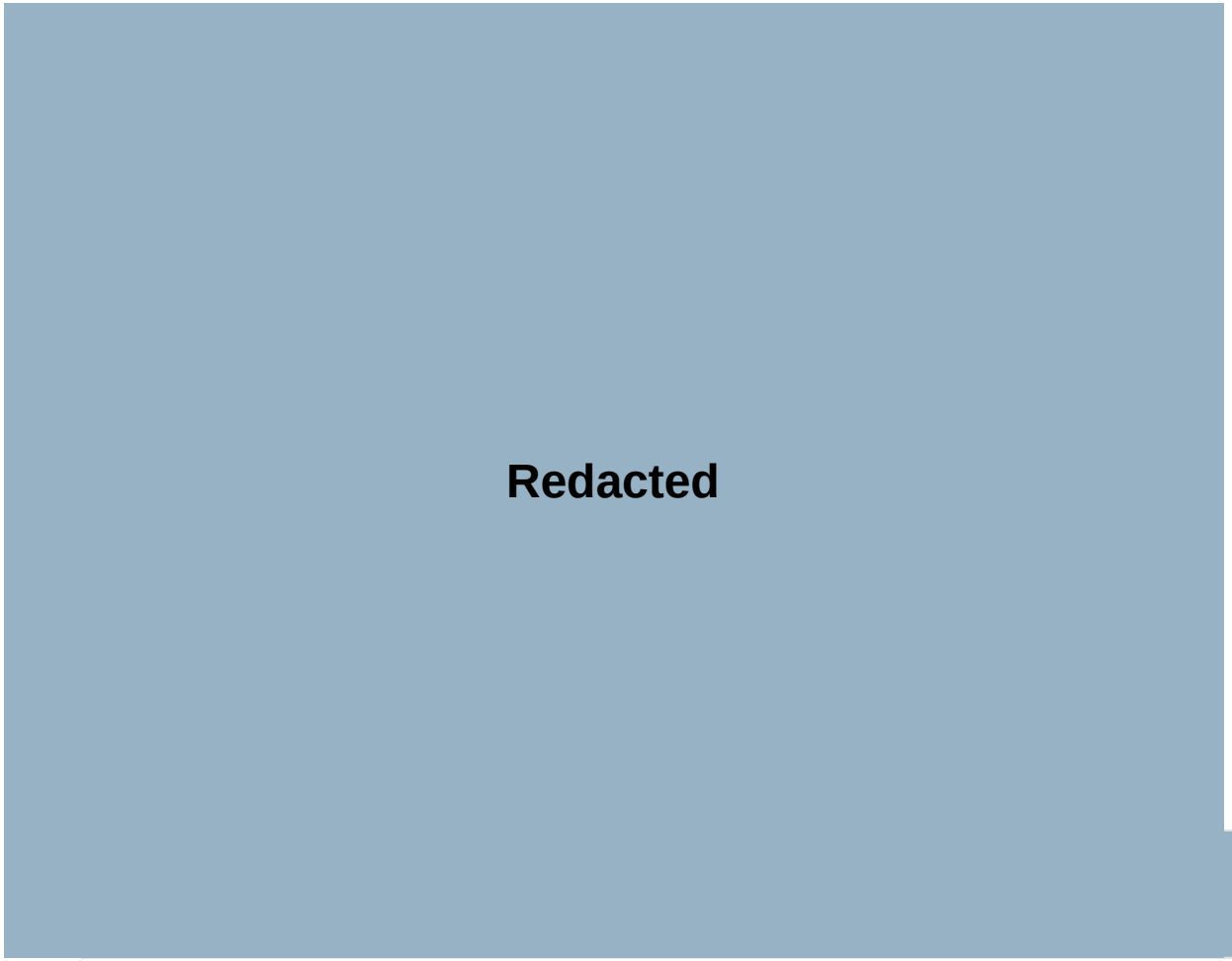


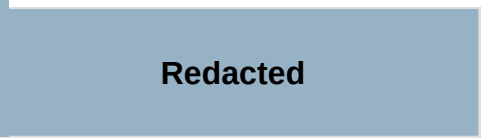
- Full-line wholesalers currently distribute PBS products at an economic loss
- Discounts have been a key mechanism by which wholesalers compete for market share and has driven efficiencies across all full-line wholesalers
- The fixed cost nature of wholesaling generates significant economic benefits from increased volumes, and as a result the wholesalers compete vigorously for market share through discounts

L.E.K.

The practice of discounting to win share and obtain the benefit of scale economies has been in decline and will not be viable as margins fall

Average full-line wholesaler discounts (FY2011-16)



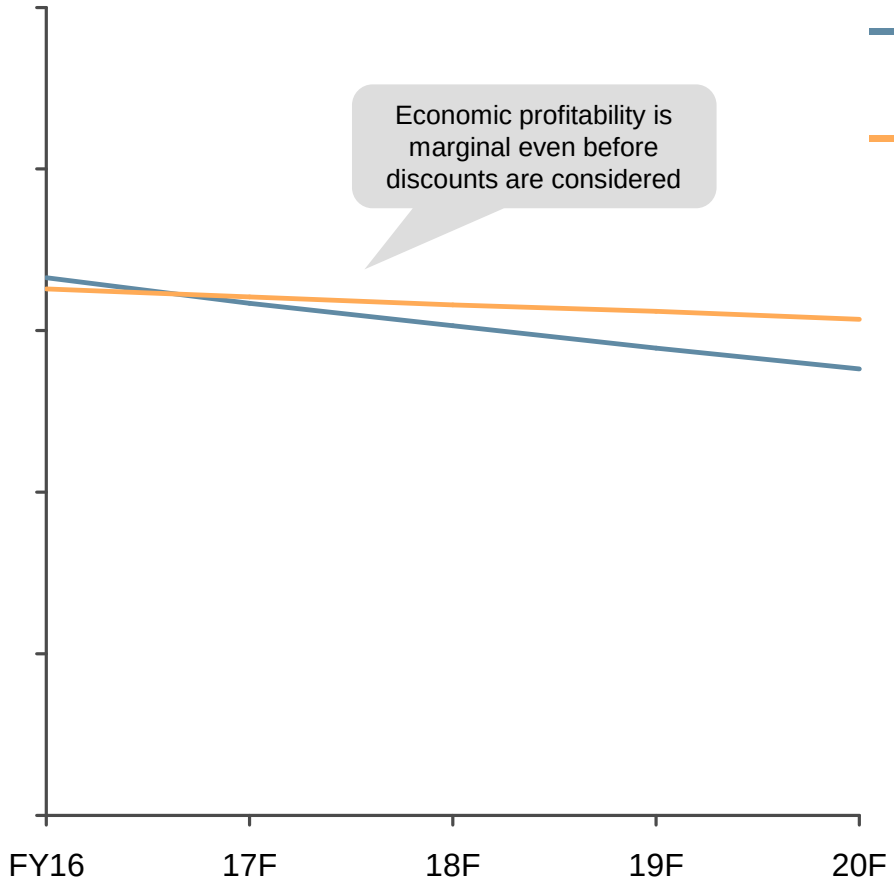


- Wholesalers now have the ability to charge a service fee for 24 hour delivery of high volume products
  - as yet, this fee has not been introduced by any full-line wholesalers
- The implication of wholesaler viability depending more on service fees is that achievement of NMP outcomes will rely on the willingness / ability of Pharmacists to absorb or pass through 24 hour service fees to consumers

L.E.K.

At projected funding levels, full-line wholesaling of PBS items will become unviable by the end of FY2017, even with removing all discounts to pharmacy

Average full-line wholesaler mark-up and cost per unit of PBS items (FY2016-2020F)
Australian dollars per unit



	Compound annual growth rate% (FY16-20F)
Gross (wholesale) mark-up and CSO Funding per unit, before discounts	(4.6)
Distribution cost per unit including capital charge*	(1.5)

- Under current funding arrangements in the 6CPA, full-line wholesaling of PBS items will become unviable by FY2017, even after ceasing discounts to pharmacy
- Without the introduction of a mark-up floor, revenue per unit is expected to decline, falling below distribution costs by FY2017
  - additionally, wholesaler mark-up available for pharmacy discounts will face continual downward pressure, with flow on impacts to pharmacy profitability

Note: * Cost per unit calculated based on total PBS Verve costs divided by total volumes distributed in the period
Source: NPSA member company data; Verve Economics; L.E.K. analysis

Summary: the changing regulatory environment has jeopardised the sustainability of full-line pharmaceutical wholesaling

- Price disclosure reforms, introduced in 2005, focused on decreasing PBS spend and ensuring market transparency. These reforms have been successful in reducing PBS expenditure by an estimated $4bn from FY10 to FY15; however, they have impacted the profitability and viability of full-line wholesalers
  - reduced unit prices have led to a decrease in the per unit mark-up available to wholesalers. Since 2011, the proportion of PBS products dispensed that are priced under $15 (ex-manufacturer) has increased from 55% to 77% and is forecast to rise to 84% by 2020
  - increased SKUs lead to increased complexity and cost for wholesalers. Price disclosure has resulted in a 41% increase in the number of PBS products and brands, from c.4.4k in 2011 to c.6.2k in 2016
- At the same time, the number of high cost drugs dispensed through community pharmacy has increased. The current funding mechanisms do not sufficiently compensate for very high cost drugs such as the Hepatitis C drugs
- In response to declining PBS revenue, wholesalers have introduced efficiency initiatives. The national full-line wholesalers have achieved significant unit cost reductions of 16% from FY2013 to FY16 through these measures
- Despite these initiatives PBS products continue to be distributed at a loss once discounts have been included, and do not deliver a minimum industry return on capital (WACC) of 11%. Full-line wholesalers remain profitable only through cross-subsidisation of PBS lines by other non-PBS sales (e.g. OTC products)
- In the past wholesalers offered discounts and rebates to pharmacies to compete for share and benefit from scale economies. The ability to offer these discounts has been nearly exhausted due to PBS price reforms. The removal of these discounts will negatively impact on the financial position of pharmacists going forward
- The current PBS wholesaling model is unsustainable in the long term. In response, full-line wholesalers will need to find additional sources of value by charging service fees to pharmacies for the delivery of ‘high volume’ products in 24 hours and / or reducing terms of trade
- Responses that increase fees and costs to pharmacies will impose cost on all pharmacies but have a greater impact on the smaller independent pharmacists, many of which operate in rural and remote areas, with a flow on impact to the recoverability of pharmacist debt. This will jeopardise the financial viability of pharmacies, and in turn, the consumers who rely on these pharmacies going forward

Agenda

- Executive summary
- Context and introduction
- Pharmaceutical wholesale market overview and history
- Changing regulatory landscape and impact on wholesale sustainability
- **Proposed sustainable funding model**

A change to wholesale and distribution funding levels and mechanisms is required to ensure a sustainable industry and achieve the goals of the NMP

1

Funding levels

Continued investment and innovation depends on funding levels whereby wholesalers are confident they can achieve a threshold return on capital for often longer term investments

2

Community service obligation

The CSO Pool as a funding structure should be retained and paired with an indexation mechanism because it is more effective and efficient in achieving NMP outcomes than alternative models. Indexation will allow wholesaler funding to keep pace with inflation and growth in volumes

3

Mark-up structure

To avoid an expected collapse in funding, the current mark-up structure needs to be revised to include a floor to adapt to the cost of distributing low priced PBS items. The funding structure for high cost drugs must be altered to appropriately manage risk and remunerate supply chain participants

A Long Run Marginal Cost (LRMC) methodology was used to calculate the sustainable funding requirement for wholesaling distribution of PBS medicines

- A long run marginal cost approach has been used to ensure that the cost base is appropriately allocated to the relevant segment of each of the businesses, that is PBS wholesaling, and other wholesaling activities (e.g. hospital wholesaling and OTC to community pharmacy)
- The long run marginal cost (LRMC) methodology builds up the total cost base for full-line wholesalers as follows:
  - the total cost base required to supply PBS products. The cost base was developed on the basis that it would operate as a standalone business
  - the incremental cost base required to supply OTC and other products
- This allocation approach is appropriate as it reflects the commercial realities of how the different business segments are operated and the basis of market competition
  - PBS assets are operated as the core of each of the full-line wholesaler businesses and they have expanded from PBS sales into OTC
  - there are no examples of businesses focused on OTC distribution that have then used that position and asset base to expand into full-line PBS wholesaling. For example, Chemist Warehouse self-manages distribution of its high volume OTC products but contracts with Sigma for the supply of pharmaceuticals and its low volume OTC products
- The sustainable funding requirement has been calculated using a return on capital approach using the Weighted Average Cost of Capital (WACC) and internal investment hurdle rate range for each of the full-line wholesalers. The WACC (11%) represents the rate of return that a company expects to compensate its shareholders while the internal investment hurdle rate (15%) represents the average internal threshold return set for investments by the full-line wholesalers
- The sustainable funding elements can be considered in two categories for PBS related wholesaling activities
  - operating costs: expenses associated with the day to day maintenance and administration of the business
  - capital charge: the funding required to cover the cost of using the asset base, over the defined economic life of the asset

Note: * Replacement costs of assets include the asset base, as well as returns on assets (i.e. WACC)
Source: L.E.K. analysis

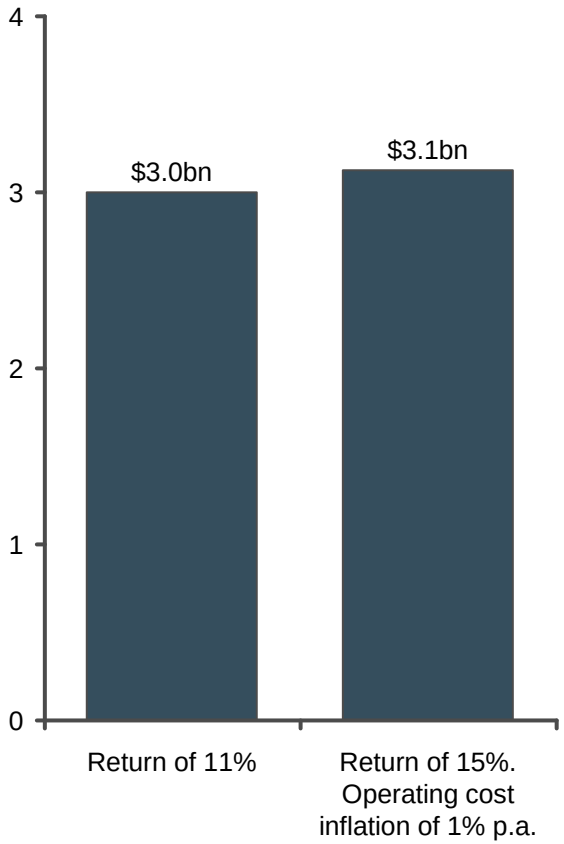
Sustainable funding required for the wholesaling and distribution of all PBS products is estimated between $3.0 - $3.1bn over the period FY2016-20

1

Sustainable full-line wholesaler funding for distribution of PBS products (FY2016-20F)
Billions of Australian dollars

Redacted

Sustainable total wholesaler and distributor funding for distribution of PBS products (FY2016-20F)
Billions of Australian dollars



The total funding required for all wholesaling and distribution of PBS products is estimated to be between **$3.0 – $3.1bn** during the 6CPA***

This funding is comprised of
- Between $2.0 and $2.1bn of mark-up funding, payable to wholesalers and distributors of PBS medicines^
- Approximately $1bn of CSO funding payable to eligible full-line wholesalers

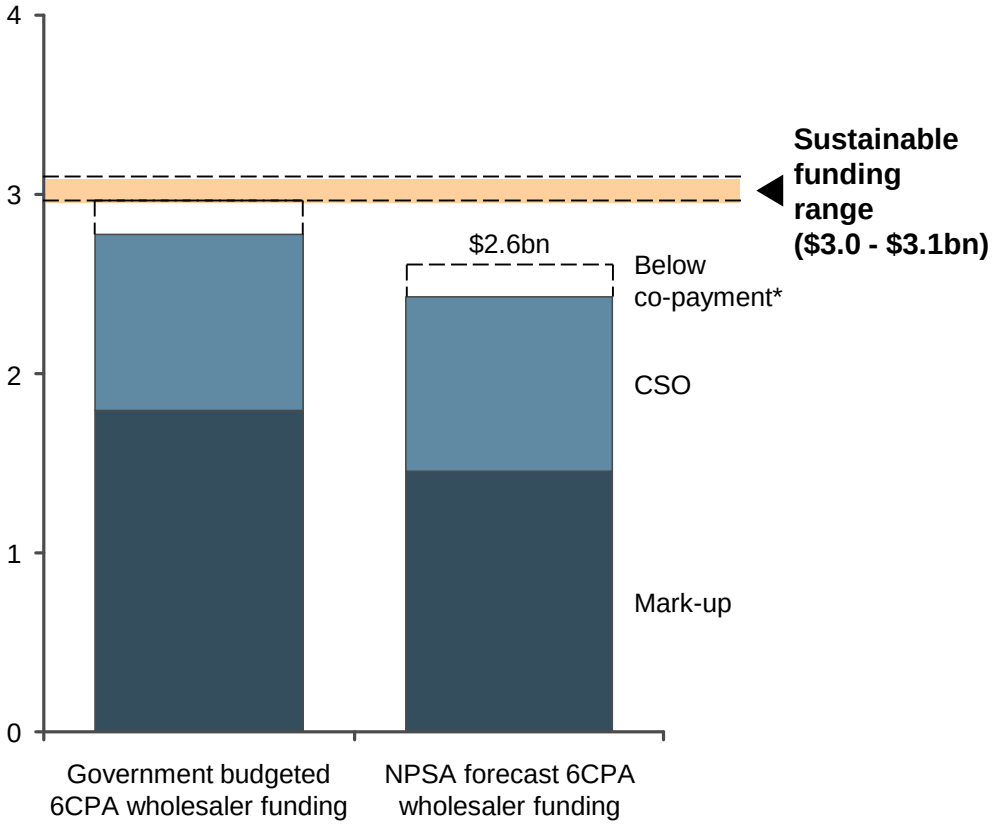
Source: Verve Consulting; L.E.K. Analysis

Currently, government budgeted wholesaler funding of c.$3.0bn over the 6CPA secures the minimum funding of the sustainable funding range

1

Budgeted and forecast wholesaler funding for PBS distribution, by funding source (FY2016E-20F)**

Billions of Australian dollars



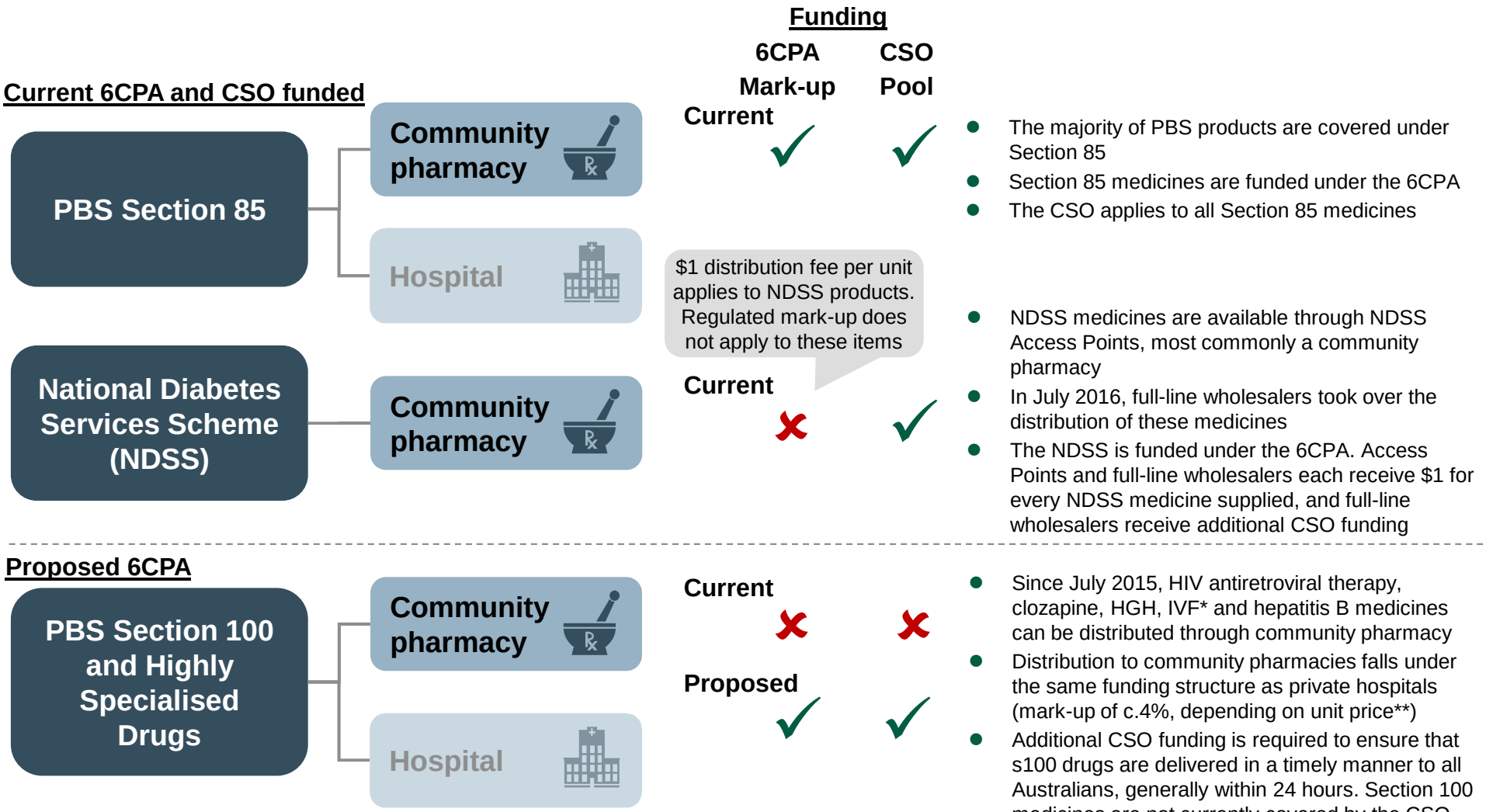
- The current government budgeted wholesaler funding over the 6CPA of $2.775bn plus expected consumer below co-payment funding of $0.2bn is at the lower end of the sustainable funding range of $3.0bn
- Moreover, based on the NPSA forecast for the 6CPA, wholesaler funding is expected to only account for c.$2.6bn in funding leaving a funding shortfall of $0.4 to $0.5bn over the period

Note: * Below co-payment value estimated using Date of Supply data from FY2011-2016 for 5CPA and forecast model results for both the budgeted 6CPA and forecast 6CPA;
**FY2016 data estimated by scaling up Date of Supply data to April 2016

Source: Department of Health; PBS; ANAO; Verve Consulting; L.E.K. Analysis

L.E.K.

Aligning funding mechanisms for medicines dispensed through community pharmacy will simplify the system and ensure efficient and reliable access



- The majority of PBS products are covered under Section 85
- Section 85 medicines are funded under the 6CPA
- The CSO applies to all Section 85 medicines

- NDSS medicines are available through NDSS Access Points, most commonly a community pharmacy
- In July 2016, full-line wholesalers took over the distribution of these medicines
- The NDSS is funded under the 6CPA. Access Points and full-line wholesalers each receive $1 for every NDSS medicine supplied, and full-line wholesalers receive additional CSO funding

- Since July 2015, HIV antiretroviral therapy, clozapine, HGH, IVF* and hepatitis B medicines can be distributed through community pharmacy
- Distribution to community pharmacies falls under the same funding structure as private hospitals (mark-up of c.4%, depending on unit price**)
- Additional CSO funding is required to ensure that s100 drugs are delivered in a timely manner to all Australians, generally within 24 hours. Section 100 medicines are not currently covered by the CSO

Note: * Human Growth Hormone, In Vitro Fertilisation; ** The remuneration rates for s100 prescribed through private hospitals comprise the normal PBS ready-prepared dispensing fee plus a mark-up ascertained as follows: 10% for drugs priced less that $40; $4 for drugs priced between $40 and $100, 4% for drugs priced between $100.01 and $1000 and $40 for drugs >$1000, all prices are ex-manufacturer

Source: Department of Health, New South Wales; National Diabetes Services Scheme; The Pharmacy Guild of Australia

A change to wholesale and distribution funding levels and mechanisms is required to ensure a sustainable industry and achieve the goals of the NMP

1

Funding levels

Continued investment and innovation depends on funding levels whereby wholesalers are confident they can achieve a threshold return on capital for often longer term investments

2

Community service obligation

The CSO Pool as a funding structure should be retained and paired with an indexation mechanism because it is more effective and efficient in achieving NMP outcomes than alternative models. Indexation will allow wholesaler funding to keep pace with inflation and growth in volumes

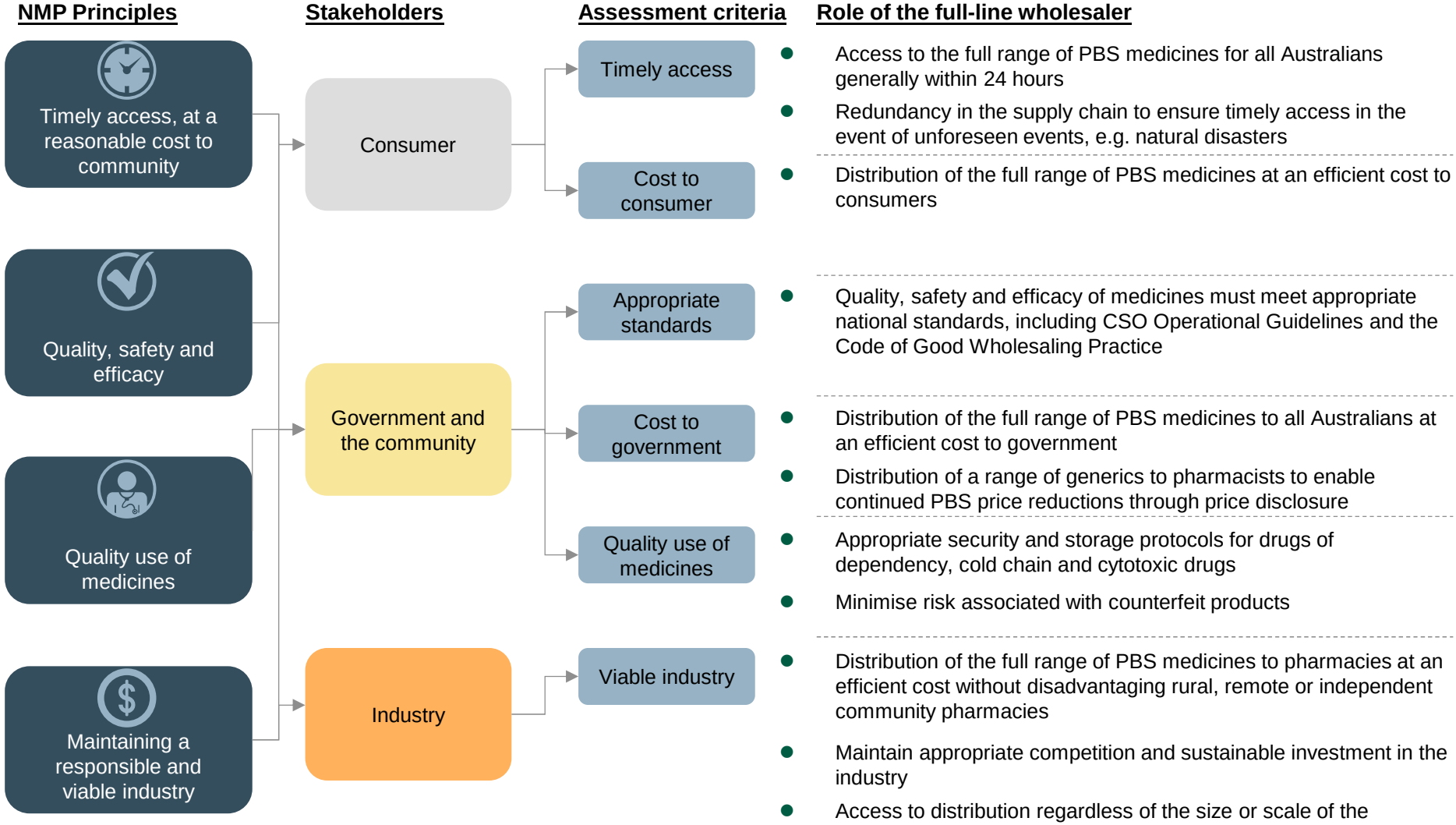
3

Mark-up structure

To avoid an expected collapse in funding, the current mark-up structure needs to be revised to include a floor to adapt to the cost of distributing low priced PBS items. The funding structure for high cost drugs must be altered to appropriately manage risk and remunerate supply chain participants

The benefit of the CSO can be assessed in terms of alignment with the NMP and contribution to meeting the needs of consumers and the broader community

2



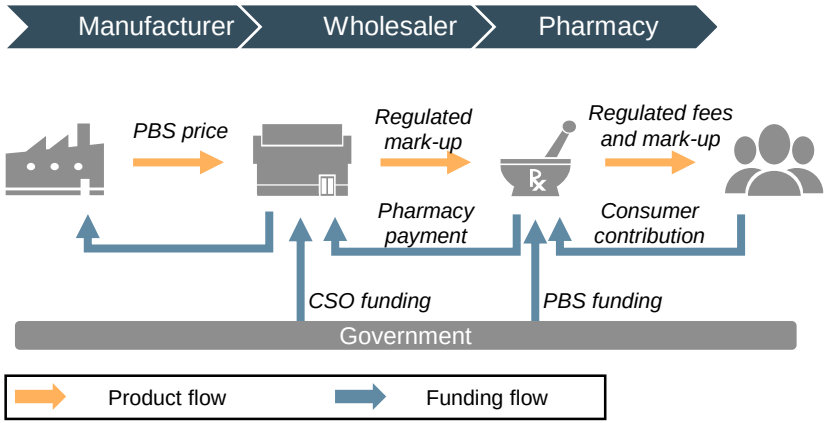
Source: Department of Health

L.E.K.

The current CSO provides a full range of PBS medicines to all Australians in an efficient manner, and encourages competition for otherwise unprofitable lines

2

Supply chain



- The current CSO provides a fixed pool of funding for wholesalers. This funding compensates wholesalers for distribution of low volume, difficult to handle medicines and distribution of the full range of PBS products to rural and remote postcodes, generally within 24 hours
- The funding pool encourages competition between full-line wholesalers for delivery of product lines that are otherwise unviable
- A fixed funding pool ensures full-line wholesalers have the incentive and confidence to continue to invest in infrastructure to serve rural and remote industries

Stakeholder	Criteria		Commentary
Consumer	Timely access	✓	The current CSO requires wholesalers to deliver the full range of PBS products to any pharmacy in Australia, generally within 24 hours
	Cost to consumer	✓	Consumers incur the same cost of PBS medicines, regardless of location
	Appropriate standards	✓	Wholesalers must comply with Code of Good Wholesaling Practice. Full-line wholesalers are subject to ongoing independent audits to qualify for funding
Government and taxpayer	Cost to government	✓	Current funding levels are effective in encouraging continued competition and reinvestment amongst the four full-line wholesalers
	Quality use of medicines	✓	Wholesaler incentives through the CSO Funding Pool ensure that the full range of PBS medicines is available to all Australians in a timely and secure manner, enabling the quality use of medicines
Industry	Viable industry	✓	All community pharmacies have access to the full range of PBS products within 24 hours without discriminating on the basis of location Medicines listed on the PBS are available to all Australians, regardless of manufacturer size or scale

Several potential alternatives to the CSO have emerged during consultation

2

	Option		Key features	Community service obligation		Wholesaler / Distributor funding		
				Rural and remote	Metro	Rural and remote	Metro CSO	Metro other
A	CSO (rural and remote only)		A fixed pool of CSO funding is provided for wholesalers to deliver the full range of PBS products to rural and remote areas only No CSO funding allocated to any products in metro areas	✓	✗	Fixed CSO Pool and regulated mark-up	Regulated mark-up	
B	Tendering	State-based	Wholesalers tender for exclusive State contracts to distribute the full range of PBS products and to all pharmacies	✓	✓	Fixed or variable funding as per terms of contract		
		Rural & remote	Wholesalers tender for exclusive contract to distribute to designated rural and remote pharmacies	✓	✓			
		Rural & remote and difficult to handle	Wholesalers tender for exclusive contract to distribute to rural and remote pharmacies and to distribute difficult to handle medicines	✓	✓			
C	Matrix model (fixed fee per item)		Wholesaler is paid a fixed fee per unit, with fees varying by product type and location	✗	✗	Fixed fee per item delivered and regulated mark-up		Regulated mark-up
D	Delivery fee paid directly to rural and remote pharmacies		Rural and remote pharmacies are paid directly to compensate for increased delivery cost Pharmacies are responsible for negotiating delivery terms with wholesalers	✗	✗	Negotiated delivery fee + per unit mark up	Regulated mark-up	
E	Manufacturer distribution	Direct government funding	Manufacturers negotiate with pharmacy for distribution fees and terms Government provides regulated distribution fee to pharmacy (similar to Pfizer model)	✗	✗	Regulated mark-up, then negotiated with manufacturer		
		Indirect government funding	Manufacturer includes cost of distribution into PBS listing price	✓	✓	Negotiated fee with manufacturer		

Source: Review of Pharmacy Remuneration and Regulation, Discussion Paper; L.E.K. research and analysis

L.E.K.

Considering expected performance in terms of NMP outcomes, each of the alternatives to the CSO provides inferior outcomes

2

	Option		Criteria: Consumer – Timely access	Consumer – Cost to consumer	Government and community – Appropriate standards	Government and community – Cost to Government	Government and community – Quality use of medicines	Industry – Viable industry	Commentary
A	CSO (rural and remote only)			Metro					While savings to government could be achieved, consumers will face reduced access to medicines in metro areas. The removal of the obligation to supply the full range of PBS products in metro areas will incentivise 'cherry-picking' of profitable lines by wholesalers
B	Tendering	i) State-based				Short / Long			Tendering of pharmaceutical wholesaling is likely to result in the formation of natural monopolies in the medium to long term, leading to increased cost for government and pharmacy
		ii) Rural & remote				Short / Long			Overall industry and regional investment will decline as losing bidders acknowledge significant incumbent advantages The lack of redundancy in the supply chain will impact timely access for consumers
		iii) Rural & remote, difficult to handle				Short / Long			State based tendering is likely to unwind the natural efficiencies that have come from aggregation
C	Matrix structure (Fixed fee per item)	Greater than current funding							Wholesalers will respond to incentives to cherry-pick profitable product ranges and locations and may elect not to distribute unprofitable lines and locations
		Less than current funding							The administrative burden to government is likely to increase as wholesalers are compensated per unit on a matrix structure
D	Delivery fee paid directly to rural and remote pharmacies								Wholesalers will be incentivised to build dominant positions in regional areas to maximise return on fixed cost infrastructure, reducing competition in the longer term. Pharmacists would not have sufficient power to negotiate optimal outcomes, likely increasing costs to government
E	Manufacturer distribution	i) Direct government funding							The requirement to distribute medicines may increase barriers to entry for smaller manufacturers and compromise consumer access to innovative products or lower price generics Pharmacies will experience a greater administrative burden as they need to engage multiple distributors / wholesalers to access the full range of PBS products The administrative burden to government and manufacturers to negotiate distribution costs on an ongoing basis by brand/product would be significant
		ii) Indirect government funding							

Key: Assessment relative to current CSO model

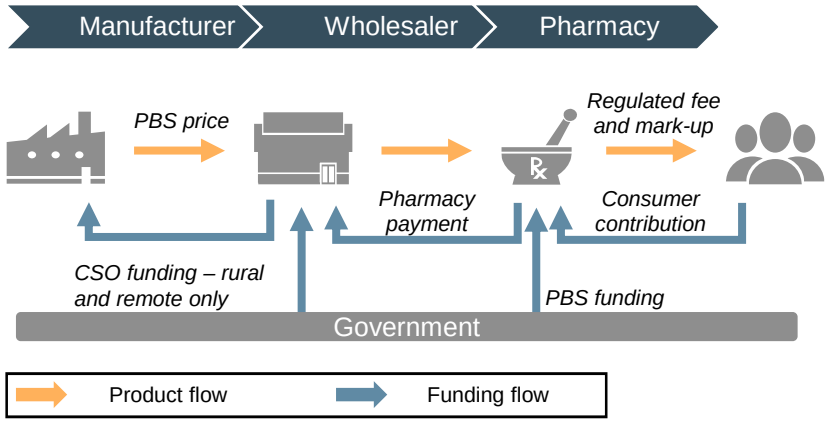
Worse outcome | Slightly worse outcome | Similar outcome | Slightly better outcome | Significantly better outcome

L.E.K.

Providing CSO only to rural and remote pharmacies risks reducing access to low volume and 'difficult to handle' medicines

2 A

Supply chain



Description of model

- A fixed pool of funding is provided for wholesalers to deliver the full range of PBS products to rural and remote areas only
- Low volume and difficult to handle medicines will be delivered to metro areas without additional CSO funding

Key risks and benefits associated with model

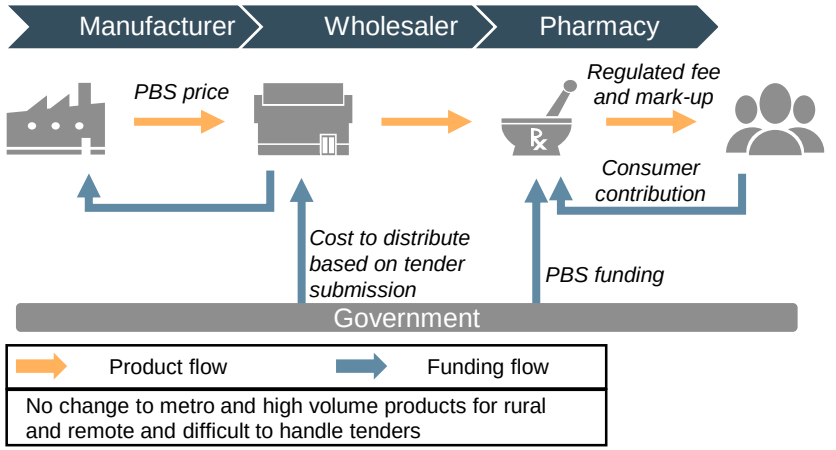
- While savings to government could be achieved, consumers will face reduced access to medicines in metro areas. The removal of the obligation to supply the full range of PBS products in metro areas will incentivise cherry-picking of profitable lines by wholesalers

Stakeholder	Criteria		Commentary
Consumer	Timely access		Potential for a negative impact on the distribution of low volume / difficult to handle medicines in metro areas due to wholesaler incentives to cherry-pick profitable lines
	Cost to consumer		The cost to consumer in metro areas may increase for below co-payment medications due to related costs in finding pharmacies that carry low volume or difficult to handle products
	Appropriate standards		No direct impact
Government and taxpayer	Cost to government		The funding requirement for government will be lower due to a reduced CSO pool
	Quality use of medicines		No direct impact
Industry	Viable industry		No direct impact

Tendering may drive efficiencies in the initial tender phase but reduce contestability in subsequent tender rounds, increasing cost to government

2 B

Supply chain



Description of model

- Wholesalers compete for an exclusive contract to distribute the full range of PBS products to all pharmacies under the respective tendering model (state, regional or difficult to handle)

Key risks and benefits associated with model

- Tendering of pharmaceutical wholesaling is likely to result in the formation of natural monopolies in the medium to long term, leading to increased cost for government and pharmacy
- Overall industry and regional investment will decline as losing bidders acknowledge significant incumbent advantages and cease investment in
- The lack of redundancy in the supply chain will impact timely access for consumers

Stakeholder	Criteria		Commentary
Consumer	Timely access		The lack of redundancy in the supply chain will impact timely access for consumers. For example, in New Zealand where pharmaceutical manufacturing is tendered stock-outs often occur limiting patient access to medicines
	Cost to consumer	Short / Long	No direct impact in the short term; however costs for below co-payment medication may increase as competition lessons
	Appropriate standards		No direct impact
Government and taxpayer	Cost to government		Initial cost savings will be eroded by reduced contestability of subsequent tender rounds due to advantage of incumbents (potentially more severe for state-based tendering)
	Quality use of medicines		Quality use of medicines may decline due to reduced redundancy in the supply chain
Industry	Viable industry		Tendering of pharmaceutical wholesaling is likely to result in the formation of natural monopolies in the medium to long term, leading to increased cost for pharmacies. Overall industry and regional investment will likely decline as losing bidders acknowledge significant incumbent advantages

L.E.K.

Lessons from other industries: Bus operations are franchised in most major cities, but the government typically retains asset control to ensure contestability

2 B

- Melbourne, Sydney and Brisbane private bus operations were traditionally run by small, family-owned operators that retained control of both depots and fleet
- These cities struggled to incentivise operators to reduce costs and improve customer service due to weak contracts and lack of contestability
- Access to depots is seen as a key driver of contestability and, as such, modern tender contracts include purchase or access rights at the end of the tender period
- For example,
  - when Melbourne looked to consolidate its routes in 2013 the Melbourne Metropolitan Bus Franchise (MMBF) the contract was structured so that the government retained control of assets
  - the operator (Transdev) may build new depots; however, these depots must be made available to the government at the end of the contract term to ensure subsequent tender rounds are competitive
- Adelaide and Perth bus franchises operate under similar conditions

Implications for pharmaceutical wholesaling: A tender model can be successful in encouraging cost savings and competition, but this is challenging to achieve in an industry where government does not control key assets, such as warehouses, to support future contestability

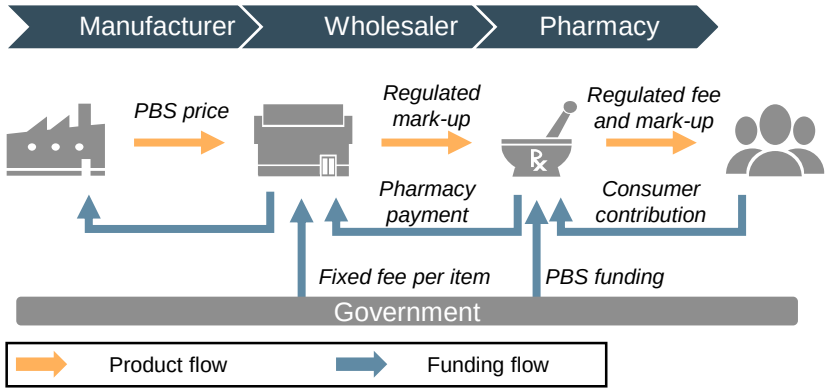
Note: * Brisbane services are delivered under contract but not subject to open tendering
Source: Tourism and Transport Forum; Press

L.E.K.

Charging a fixed fee per item will likely lead to "cherry-picking" of profitable product ranges and reduce timely access to medicines

2 C

Supply chain



Description of model

- The wholesaler or manufacturer is paid a tiered per unit cost, depending on the type and location of PBS medicine distributed (e.g. rural and remote area, low volume or difficult to handle)
- The fixed fee would, in theory, reflect the cost to distribute the item, and would be paid directly to the wholesaler

Key risks and benefits associated with model

- Slight savings to government could be achieved, but consumer access will be diminished
- Wholesalers will respond to incentives to cherry-pick profitable product ranges and locations and may elect not to distribute unprofitable lines
- The administrative burden to government is likely to increase as wholesalers are compensated per unit on a matrix structure

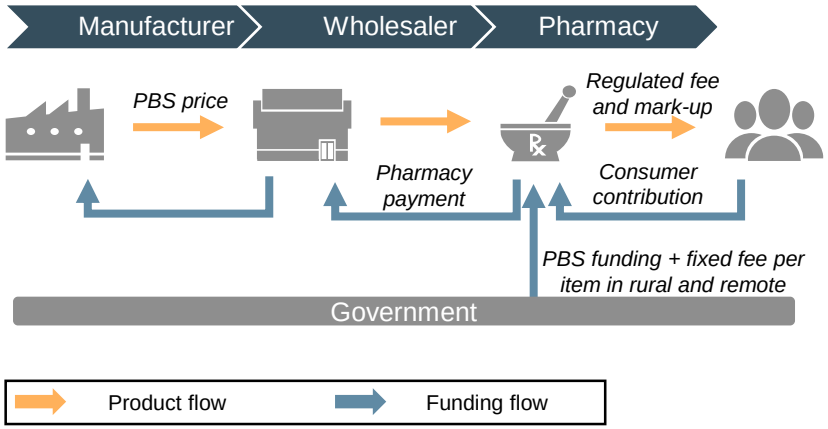
Stakeholder	Criteria	Greater than current funding	Less than current funding	Commentary
Consumer	Timely access			Wholesalers will respond to incentives to cherry-pick profitable product ranges and locations and may elect not to distribute unprofitable lines
	Cost to consumer			Consumers may not be able to access low volume or difficult to handle medications in a conveniently located pharmacy and as such may incur addition cost or inconvenience
	Appropriate standards			The model will likely see a greater prevalence of short-line wholesalers who are not subject to the same standards as full-line wholesalers
Government and taxpayer	Cost to government			The cost to government may be reduced, depending on fee structure. The administrative burden and cost will increase
	Quality use of medicines			No direct impact
Industry	Viable industry			No direct impact

L.E.K.

The fee to rural and remote pharmacy model is inefficient and results in higher cost to government, pharmacy and consumers

2 D

Supply chain



Description of model

- Rural and remote pharmacies are paid a fixed fee by government to compensate for the increased cost of delivery, with fees to vary based on location
- Each pharmacy negotiates with wholesalers to deliver products

Key risks and benefits associated with model

- Wholesalers will be incentivised to build dominant positions in regional areas to maximise return on fixed cost infrastructure, reducing competition in the longer term. Pharmacists would not have sufficient power to negotiate optimal outcomes, likely increasing costs to government

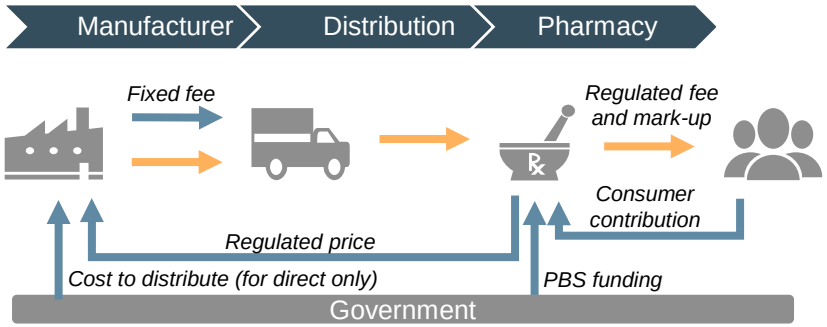
Stakeholder	Criteria		Commentary
Consumer	Timely access		There is a risk that pharmacies may negotiate fewer deliveries and keep part of the delivery fee, jeopardising timely access
	Cost to consumer		Pharmacists are likely to pass on increased costs to consumers on below co-payment items
	Appropriate standards		No direct impact
Government and taxpayer	Cost to government		There will be an increased cost to government as this model shifts negotiation for delivery to rural and remote areas to a fragmented buyer base
	Quality use of medicines		There may be a negative impact on access to the full range of PBS medicines for rural and remote consumers
Industry	Viable industry		Rural and remote pharmacists will not have sufficient power to negotiate optimal outcomes, likely increasing costs to each pharmacy

L.E.K.

Manufacturer distribution models increase government buying power with manufacturers, but risk the inefficient delivery of PBS products

2 E

Supply chain



Description of model

- Manufacturer would contract directly with wholesalers or distributors for the distribution of products
- Government can reimburse the wholesaler indirectly by incorporating the cost to distribute into the PBS price or directly by providing mark-up to the manufacturer

Key risks and benefits associated with model

- The requirement to distribute medicines may increase barriers to entry for smaller manufacturers and compromise consumer access to innovative products or lower price generics
- Without a CSO, under the direct model, power would become concentrated with manufacturers
- Pharmacies will experience a greater administrative burden as they need to engage multiple distributors/wholesalers to access the full range of PBS products
- The administrative burden to government and manufacturers to negotiate distribution costs on an ongoing basis by products would be significant

Stakeholder	Criteria	Direct	Indirect	Commentary
Consumer	Timely access			Not all manufacturers will be able to efficiently distribute their full range of PBS products to all Australians
	Cost to consumer			No impact to consumer
	Appropriate standards			Full-line wholesalers currently have to meet the standards of the Code of Good Wholesaling Practice and are subject to independent audits. Similar regulations would need to be introduced to ensure that
Government and taxpayer	Cost to government			Manufacturers will likely sacrifice margin to secure a PBS listing putting the Government in a strong negotiating position under the indirect model It is impractical to estimate the cost of distributing products over a long time frame with certainty. Costs would need to be revisited and renegotiated with government at regular intervals which would be costly to administer for all products on the PBS
	Quality use of medicines			The range of medicines available in Australia will reduce as smaller manufacturers with innovative or generic products may not be willing to enter the market
Industry	Viable industry			The requirement to distribute medicines may increase barriers to entry for smaller manufacturers that offer innovative products or lower price generics, negatively impacting the viability of the industry Pharmacies will need to deal with multiple suppliers, and as such administrative burden is likely to increase

Lessons from overseas markets: The UK Office of Fair Trading has concerns that the Direct to Pharmacy model has a negative impact on pharmacies

2 E

Summary

Manufacturers, with sufficient scale, prefer a Direct to Pharmacy (DTP) model for a number of reasons:

- To prevent counterfeit medicines from entering the supply chain
- To limit parallel trade
- Manufacturers can keep a larger margin by offering lower discounts than those traditionally offered by wholesalers

Pharmacies and wholesalers argue this model is not in the consumers' and customers' best interests

- Pharmacists estimate that higher prices to pharmacies could potentially add hundreds of millions of pounds to NHS costs
- Lack of back-up supply options and fewer deliveries per manufacturer and order quotas may limit access to drugs
- Pharmacies will bear extra administration burden
  - an Office of Fair Trading survey found that 20% of pharmacies will need to spend >2 hours per week on each new DTP account opened
- The Office of Fair Trading has concluded that DTP may have negative impacts on pharmacy services but no extra regulation has emerged to date. It remains an issue under review due to pharmacy and wholesaler concern

Evolution of DTP in the UK

2006
2007, Pfizer chooses Alliance as sole distributor
2007, High court overturns interim injunction appeal from full-line wholesalers against Pfizer's DTP arrangement, despite estimates that Pfizer's move will remove 18 wholesalers from the supply chain

2008
2008, AstraZeneca and GSK begin reduced wholesaling arrangement (RWA), with AAH and Alliance wholesalers

2009, Eli Lilly chooses RWA model, with AAH and Phoenix wholesalers

2010
2010, 10% of distribution in the UK through DTP model and 15% by RWA
2010, Pfizer pharmacy survey reveals 74% of pharmacies are unhappy with DTP arrangements
2010, Pfizer renews Alliance distributor contract

2012
2012, c.90% of UK pharmacies dissatisfied with DTP and c,91% dissatisfied with RWA
2012-13, Astellas Pharma and Sucampo begin RWA model, with Alliance as their logistic provider

2014
2014, GSK begins DTP distribution, with AAH as its logistic provider

Source: Office of Fair Trading; Irish Pharmacy Union; Pharmtech; Alliance Healthcare; Farmeconomia 2012

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A change to wholesale and distribution funding levels and mechanisms is required to ensure a sustainable industry and achieve the goals of the NMP

1

Funding levels

Continued investment and innovation depends on funding levels whereby wholesalers are confident they can achieve a threshold return on capital for often longer term investments

2

Community service obligation

The CSO Pool as a funding structure should be retained and paired with an indexation mechanism because it is more effective and efficient in achieving NMP outcomes than alternative models. Indexation will allow wholesaler funding to keep pace with inflation and growth in volumes

3

Mark-up structure

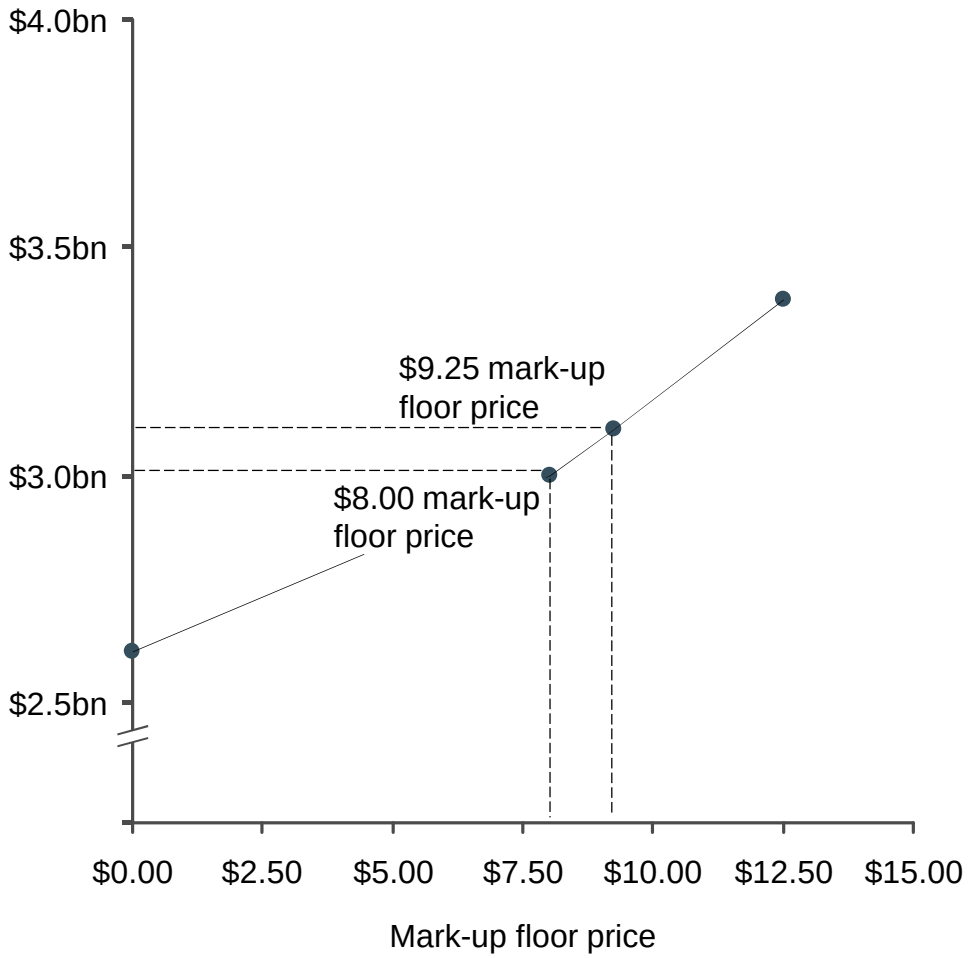
To avoid an expected collapse in funding, the current mark-up structure needs to be revised to include a floor to adapt to the cost of distributing low priced PBS items. The funding structure for high cost drugs must be altered to appropriately manage risk and remunerate supply chain participants

A mark-up floor price of $8.00 to $9.25 will deliver sustainable funding for wholesalers in the range $3.0bn to $3.1bn

3

Wholesaler PBS funding, by mark-up floor price*

Billions of Australian dollars



- A benefit of a mark-up floor is greater confidence in continued wholesaler viability and willingness to invest in improving service quality and efficiency
- Introduction of a mark-up floor price between $8.00 - $9.25 (equivalent to a per unit mark-up of $0.60 to $0.70) will provide total wholesaler funding of $3.0bn to $3.1bn, the funding range required to deliver a sustainable return on capital
- The introduction of a mark-up floor will bring the compensation model for wholesalers in line with that of pharmacists
  - since July 2016, pharmacists have received a minimum fee of $3.54 per item under the Administration, Handling and Infrastructure fee (AHI), which is indexed to the CPI
  - additionally, pharmacists receive a minimum dispensing fee of $7.02

Note: * Based on a margin ceiling of $930.06 and currently budgeted CSO
Source: Department of Health; PBS; ANAO; Verve Consulting; L.E.K. Analysis

L.E.K.

An alternate mechanism is required to compensate wholesalers for the costs of handling and distributing high value items

3

- The volume of high cost drugs dispensed through community pharmacy has increased from FY2010 to FY16. The growth in volume of high cost drugs expected to continue, given R&D trends
- Wholesalers incur extra inventory and handling costs for the supply of high cost drugs
  - For example, a write-off of Hepatitis C drug Ledipasvir + Sofosbuvir, valued at c.$22k, would be equivalent to the wholesaler mark-up earned for the distribution of c.314 equivalent units
- High cost, Hepatitis C products currently only recover half of their stockholding costs through the capped wholesaler mark-up of $69.94 (7.52% of $930.06), even before considering other associated distribution costs such logistics, secure storage and stock write-offs
- To ensure that the delivery of high cost medicines remains viable, a change in the current funding model – combined with a higher mark-up ceiling – must be considered to appropriately compensate wholesalers for distributing high cost medicines across Australia
- The NPSA will provide an addendum to this report outlining and assessing the alternative compensation structures for the wholesaling and distribution of high cost drugs

Source: PBS; L.E.K. analysis

In summary, a sustainable wholesaler funding model that effectively and efficiently delivers the NMP would be comprised of the following

Recommended Funding Quantum

- Achieving returns at or above the cost of capital is important to encourage ongoing investment in the sector, including investment in innovation to bring about efficiency gains. The level of funding required for wholesalers and distributors over the period FY2016-2020 to meet this threshold return on capital is equivalent to $3.0bn-$3.1bn
- The level of funding budgeted under the 6CPA, of $2.775bn plus patient below co-payment contributions of $0.2bn, would only deliver $3.0bn – the lower end of the required sustainable funding
- Moreover, when compared to the NPSA forecast of PBS expenditure and wholesaler funding that is likely to eventuate ($2.6bn), a funding shortfall of $0.4bn to 0.5bn will emerge if no changes are made to wholesaler funding

Recommended Funding Mechanism

CSO

- The CSO Funding Pool be retained as the most effective way to deliver the CSO
- The CSO pool should be indexed to ensure funding keeps pace with inflation and increasing volumes
- The CSO Funding Pool should be expanded to include s100 products distributed to community pharmacy

Mark-up

- Holding constant the mark-up percentage of 7.52%, the introduction of a mark-up floor price of $8.00 - $9.25 (equivalent to a unit mark-up of $0.60 - $0.70) will provide sustainable compensation to wholesalers and will recognise the significant decline in PBS prices. A mark-up floor of $8.00 - $9.25 will deliver funding of $3.0bn-$3.1bn
- The current mark-up ceiling does not adequately compensate wholesalers for the costs related to the holding and distribution of high cost drugs. An alternate mechanism for compensation should be considered. The NPSA will provide an addendum to this report outlining and assessing the alternatives

Agenda

- Executive summary
- Context and introduction
- Pharmaceutical wholesale market overview and history
- Changing regulatory landscape and impact on wholesale sustainability
- Proposed sustainable funding model
- **Appendix**

L.E.K.

Glossary

Term	Definition
3PL provider	Third party logistics provider
AHI fee	Administration, Handling and Infrastructure fee
Ex-manufacturer price	Government approved PBS product price sold by the manufacturer
Code of Good Wholesaling Practice	Standards of safe and effective distribution practice that apply to medicinal products and devices
Cold chain	Temperature controlled distribution
CPA	Community Pharmacy Agreement. Each five year agreement commits remuneration for pharmacies and wholesalers, provision of pharmacy services and regulations of the pharmaceutical industry
CSO	Community Service Obligation. A set of guidelines which ensure timely access to PBS medicines for all consumers across Australia
Generic	Off-patent medicine
GMP	Good Manufacturing Practice
HSD	Highly specialised drug. Medicines for the specialised treatment of chronic conditions
Listed brand	A PBS approved brand of medicine
Margin	The difference between gross sales and cost of goods sold. Margin rate calculated as a proportion of gross sales

Term	Definition
Mark-up	The difference between gross sales and cost of goods sold. Mark-up rate calculated as a proportion of the cost of goods sold
NMP	National Medicines Policy
OTC	Over-the-counter. Products sold in pharmacies that are not covered by the PBS
PBS	Pharmaceutical Benefits Scheme. A Government program that provides subsidised medicines to Australians
PBS code	Unique identifier for each PBS medicine, by name, form, strength and pack size
RPBS	Repatriation Pharmaceutical Benefits Scheme
Rural and remote	Regions outside of metro and suburban areas
RWA	Reduced wholesaling arrangement. An exclusive agreement between a manufacturer and selected wholesalers to distribute medicines
Safety Net	The threshold above which consumers no longer pay for PBS products
TGA	Therapeutic Goods Administration

Source: Department of Health; Pharmacy Guild of Australia; PBS

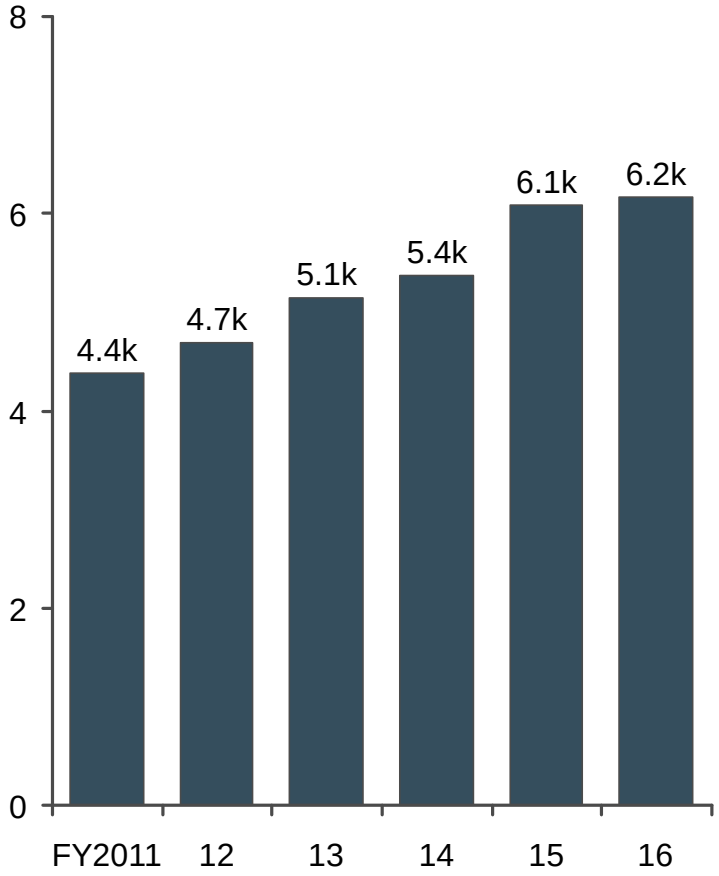
L.E.K. utilised data from member companies, as well as secondary data sources in developing this report

External sources	Company supplied information
• Department of Health Australia • Department of Human Services Australia • National Pharmaceutical Services Association Australia • Pharmaceutical Benefits Scheme publications • Verve Economics • Pharmacy Guild of Australia • Australian National Audit Office • Medicines Australia • Victoria University • UK Office of Fair Trading • Irish Pharmacy Union • Company websites • Broker reports • Press • Medici Capital	• API • Sigma • Symbion • NPD Data collected and analysed includes: • Volume and sales by product • Discount data • Capital and operating costs

The PBS reforms have generated savings through increased competition, with the resulting outcome of a c.1,800 increase in the number of SKUs wholesaled

Number of products listed on the PBS* (FY2011-16)

Thousands of unique PBS products



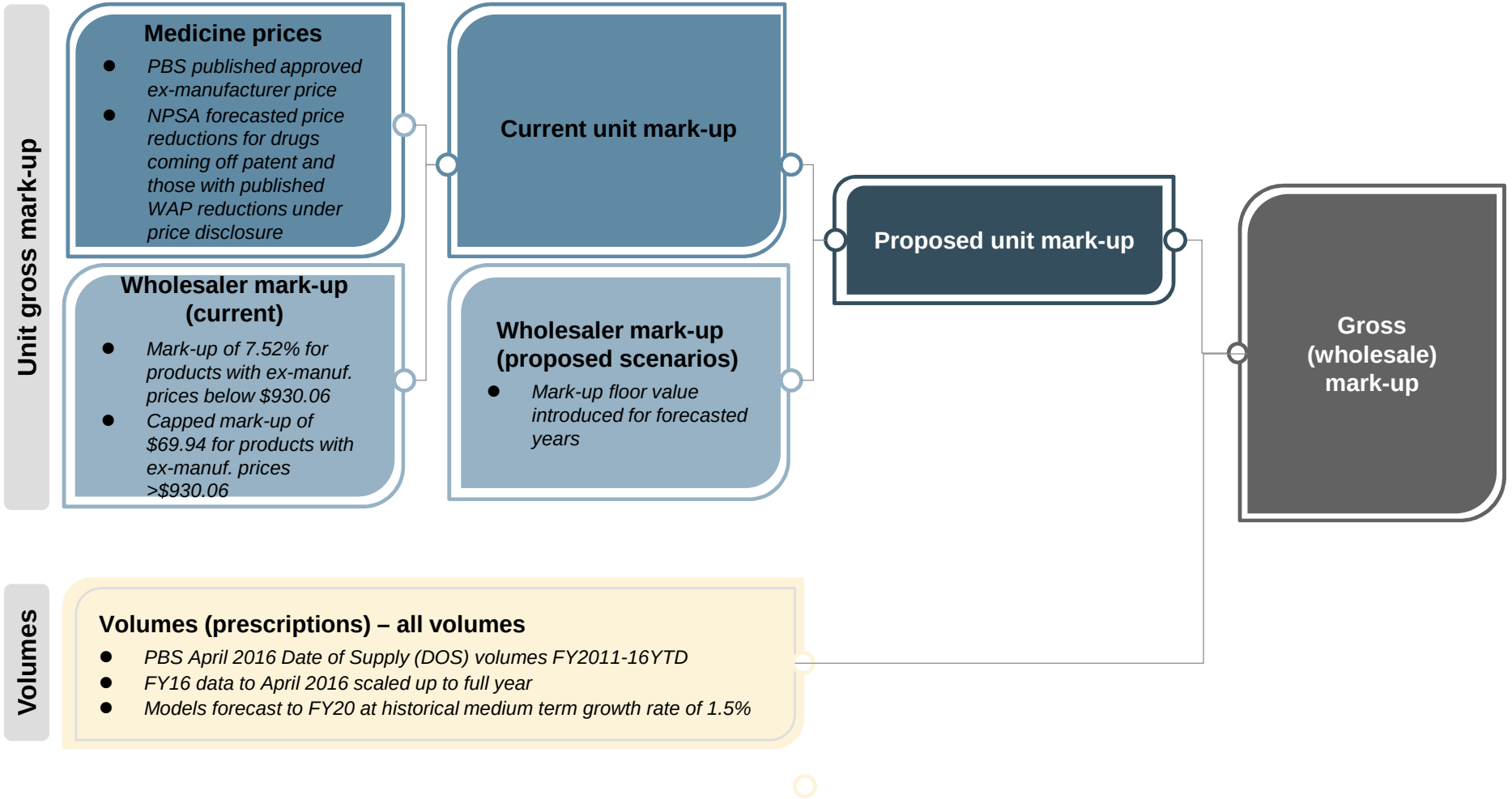
	Compound annual growth rate% (FY2011-16)
	7.1

- Price disclosure and premium dispensing initiatives for pharmacies have lead to a greater prevalence of generic brands
- The number of PBS listed stock keeping units (SKUs) has increased by c.41% since price disclosure measures were introduced
- For example, atorvastatin, the highest value PBS drug, was sold under the brand name Lipitor by Pfizer came off patent in Nov 2011
  - there are now 15 atorvastatin brands listed on the PBS

Note: * Number of unique PBS medicines by brand name, dosage and pack size as taken from annual published PBS products price lists
Source: PBS; L.E.K. analysis

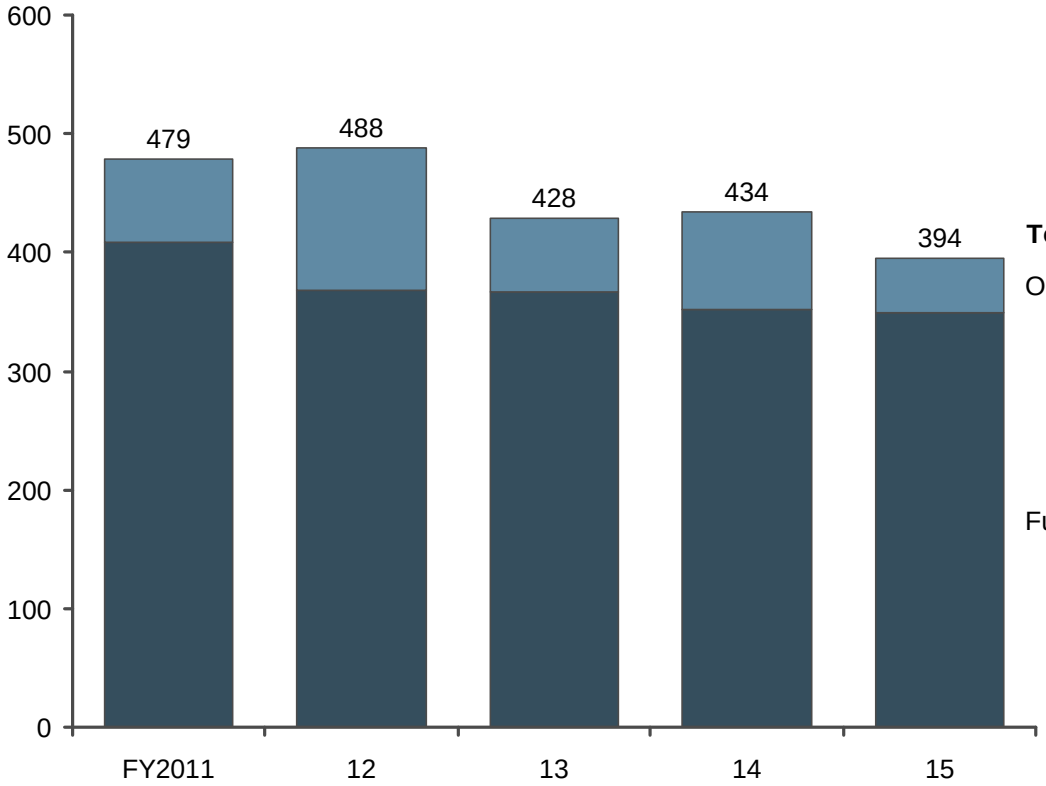
L.E.K.

A forecast of wholesale mark-up funding was developed for the purpose of this report



PBS wholesale mark-up is available to all distributers of PBS products. Approximately 83% of wholesale mark-up is attributable to full-line wholesalers

Gross wholesale mark-up, by wholesaler type (FY2011-15)
Millions of Australian dollars



	FY2011	12	13	14	15	Compound annual growth rate% (FY2011-15)
Total	479	488	428	434	394	**(3.8)**
Other wholesale mark-up						(8.3)
Full-line wholesale mark-up						(3.1)
Share of gross (wholesale) mark-up (%)	85	75	86	81	89	

Source: Australian Government, Department of Health; PBS; NPSA member company data; L.E.K. Analysis

L.E.K.