Report for Community Pharmacy Services Governance Group

Strategic think piece on pharmaceutical margins

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Sapere Research Group is one of the largest expert consulting firms in Australasia and a leader in provision of independent economic, forensic accounting and public policy services. Sapere provides independent expert testimony, strategic advisory services, data analytics and other advice to Australasia’s private sector corporate clients, major law firms, government agencies, and regulatory bodies.

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Disclaimer:
Sapere Research Group was commissioned by the Community Pharmacy Services Governance Group to develop a think piece that will help it consider the pharmaceutical – wholesale margins issue.

Both the Governance Group and the Taskforce are satisfied that the information provided has been taken into account within the Taskforce considerations.

The Report has provided information on the issue of margins for the Pharmaceutical Margin Taskforce and Governance Group to think through and does not reflect any government policy or strategic direction at this time.

Disclaimer: Strategic think piece on pharmaceutical margins – not Government policy or DHB direction.
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# Glossary

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<tbody>
<tr>
<td>6CPA</td>
<td>Sixth Community Pharmacy Agreement (Australia)</td>
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<td>AHI fee</td>
<td>Administration, Handling and Infrastructure fee</td>
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<tr>
<td>CADTH</td>
<td>Canadian Agency for Drugs and Technologies in Health (Canada)</td>
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<td>CPA</td>
<td>Community Pharmacy Agreement (Australia)</td>
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<td>CPSA</td>
<td>Community Pharmacy Services Agreement (NZ)</td>
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<td>CPSGG</td>
<td>Community Pharmacy Services Governance Group</td>
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<td>CSO</td>
<td>Community Service Obligation (Australia)</td>
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<td>DHB</td>
<td>District Health Board (New Zealand)</td>
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<td>DNG</td>
<td>Discount Not Given (UK)</td>
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<td>EAC</td>
<td>Estimated Acquisition Cost (USA)</td>
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<td>EPPB</td>
<td>Extemporaneously-Prepared Pharmaceutical Benefit (Australia)</td>
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<td>FDA</td>
<td>US Food and Drug Administration (USA)</td>
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<td>FUL</td>
<td>Federal Upper Limit (USA)</td>
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<td>GPO</td>
<td>Group Purchasing Organisation (Canada)</td>
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<td>HSSBC</td>
<td>Health Shared Services British Columbia (Canada)</td>
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<td>IPD</td>
<td>Independent Pharmacy Distributor (Canada)</td>
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<td>ISPOR</td>
<td>International Society for Pharmaeconomics and Outcomes Research</td>
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<tr>
<td>NHS</td>
<td>National Health Service (UK)</td>
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<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
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<td>OTC</td>
<td>Over-the-counter drugs</td>
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<td>PBAC</td>
<td>Pharmaceutical Benefits Advisory Committee (Australia)</td>
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<td>PBS</td>
<td>Pharmaceutical Benefits Scheme (Australia)</td>
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<tr>
<td>pCODR</td>
<td>Canadian Oncology Drug Review Process (Canada)</td>
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<td>pERC</td>
<td>CADTH pCODR Expert Review Committee (Canada)</td>
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<td>PHARMAC</td>
<td>Pharmaceutical Management Agency (New Zealand)</td>
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<td>PricewaterhouseCoopers</td>
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<td>Pharmacy Wholesalers (Bay of Plenty) Limited (NZ)</td>
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<td>RPPB</td>
<td>Ready-Prepared Pharmaceutical Benefit (Australia)</td>
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<td>SHI</td>
<td>Statutory Health Insurance (Germany)</td>
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<tr>
<th>Acronym</th>
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<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration (Australia)</td>
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<tr>
<td>U&amp;C price</td>
<td>Usual and customary price (USA)</td>
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<td>UK</td>
<td>United Kingdom</td>
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<tr>
<td>US</td>
<td>United States of America</td>
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<tr>
<td>VCU</td>
<td>Voluntary Compliance Undertaking (Canada)</td>
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<tr>
<td>vdek</td>
<td>Verband der Ersatzkassen e. V. (Germany)</td>
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<tr>
<td>VSWG</td>
<td>Vaccine Supply Working Group (Canada)</td>
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<tr>
<td>WAC</td>
<td>Wholesale Acquisition Cost (USA)</td>
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Executive summary

The purpose of this ‘think piece’ is to provide information to the Community Pharmacy Services Governance Group (CPSGG) to help it consider the pharmaceutical-wholesale margins issue. Margins have been a contentious issue within community pharmacy for a considerable period. The changes to the Community Pharmacy Services Agreement (CPSA) in 2012 seem to have exacerbated this issue.

The Government funded pharmaceutical margin is worth about $33 million per annum and is one component of the total reimbursement to pharmacy provided under the CPSA. The pharmaceutical margin is a payment towards what is described as the ‘procurement and stockholding’ costs for pharmaceuticals that are subsidised through the Pharmaceutical Schedule.

Funding for procurement and stockholding services comes from District Health Boards (DHBs) through a regulated formula under the CPSA. However, the actual charges and margins for these services are subject to commercial negotiation between wholesalers and pharmacies. This negotiated approach is unique to New Zealand and no other jurisdiction we reviewed had such an approach.

In this report we have looked at pharmaceutical supply chain logistic models in several other countries to ascertain whether there are alternative models that may be applicable to New Zealand. Our review of the supply chain model included the regulatory arrangements underpinning the pharmaceutical sector in each of the jurisdictions.

We also looked at e-government funding arrangements in some of the jurisdictions to see whether there were any approaches that may be applicable for consideration in New Zealand.

We looked at arrangements in Australia, Canada (British Columbia), United Kingdom (England, Scotland and Wales) and the United States. We also considered the pharmaceutical margins in Germany.

For the most part, the traditional pharmaceutical supply chain model operates in each of the jurisdictions we reviewed but changes are emerging that could disrupt this model.

Innovations in the pharmaceutical sector

The types of innovations that we have observed from our research include:

- Wholesale/distribution:
  - Tendering for wholesale/distribution services
  - Direct-to-pharmacy and exclusive distribution by manufactures
  - Government health agency provision of wholesale services.
- Pharmacy:
  - Pharmacy in supermarkets
  - Mail-order and online pharmacy
- Full-service pharmacies
- Dispensing GPs.

**Demand-side:**
- Combined purchasing by health agency buying groups
- Group purchasing organisation.

We considered whether these approaches would be applicable to New Zealand. We assessed these different approaches against a set of criteria that is based on achieving the long-term interest of consumers. The criteria include efficient pricing and investment signals, affordability, timeliness and reliability, sustainability, adaptability and innovation, transparency and minimising regulatory and administrative burden.

**Suggested way forward**

Innovations in the pharmaceutical supply chain are leading to disruption of the traditional – manufacturer- wholesaler/distributor – pharmacist model. Instead of being a linear supply chain from manufacturer through to pharmacy, the pharmaceutical sector can be viewed as becoming more of the series of ‘networks’ whereby greater collaboration is occurring among various parties. Innovations include the formation of buying groups as a way of improving purchasing power. Other channels such as dispensing GPs and online services may eventually better complement the main channels and provide an alternative to the traditional supply chain or networks.

We consider that there are a number of options for CPSGG to consider in helping to alleviate some of the problems surrounding the margins issue.

**In the shorter term:**

- De-linking the pharmacy mark-up from the price of medicines. This could be achieved by moving the form of margin to a more fixed approach rather than a percentage based approach or a mix of fixed and percentage-based margin. This may provide greater certainty about remuneration to the pharmacy and wholesaler sectors.

**In the longer term:**

- Tendering for wholesaler services. Tendering for wholesale-distribution services by an agency arrangements could be introduced in New Zealand whereby a government agency such as PHARMAC seeks tenders for the provision of wholesaler-distribution services to community pharmacies. The intention of this type of model is to create competitive tension between existing and potential new entrant distributors.
- Review of the pharmacy ownership restrictions. We consider that relaxation or removal of ownership restrictions would open up the pharmacy sector to more players, new business skills and in particular those with capital to inject into new innovations.
- Separating the wholesaler and pharmacy margin. Currently there is a lack of transparency about how much is being earned and a lack of certainty about what services the margin covers. We suggest reconsideration the margin approach to look at either separating or margin for the wholesalers and pharmacist or ways of achieving greater transparency, as occurs in other jurisdictions.
A summary of our analysis is summarised below.

**Innovations in wholesale and distribution sector**

**Tendering for wholesale/distribution services**

Tendering and contracting for wholesaling arrangements could be introduced in New Zealand whereby a government agency such as PHARMAC contracts for the provision of wholesale and distribution services to community pharmacies. The tender could specify the service requirements that would be factored into the wholesalers cost structure. There could be different type of tenders for different types of services and perhaps different regions or rural areas.

The intention of this type of model is to create competitive tension between incumbent and potential new entrant wholesaler-distributors. This competitive tension should result in greater efficiency as they seek to lower costs. The drive to lower costs may lead to greater innovation in wholesaling and distribution services.

The potential benefit of this contracting arrangement is to deliver continued innovation and improvement to wholesale-distribution services. Remuneration could be in the form of a margin, fixed fee for services or both. The funding for this type of approach fixed for the period of the contract.

The disadvantage of this option is that, in the short term, the incumbent wholesalers are probably the only credible participants – thereby limiting competition. It would also introduce greater administration and tender management costs for the agency undertaking the contract. And, the greater the number of contracts, the greater the administrative burden would be. This cost would need to be weighed up against benefits of creating a more contestable sector with the potential to lower costs, encourage innovation, and possibly attract new entrants.

**Direct-to-pharmacy distribution**

In the UK and Australia, the international manufacturer Pfizer operates an ‘exclusive’ direct-to-pharmacy distribution arrangement. It has been a significant disruption to the traditional distribution arrangement.

In the US, pharmacies predominately purchase their drugs from pharmaceutical wholesalers. However, large pharmacies, mail-order pharmacies and specialty pharmacies may also negotiate directly with manufacturers if they have the required infrastructure to distribute drugs without the involvement of a wholesaler.

We understand that there are no exclusive distribution arrangements in New Zealand at present. Even so, the potential for manufacturers to distribute their products directly and exclusively does create competitive tension (also referred to as contestability) in the wholesale sector. It provides an incentive for the incumbent wholesalers to ensure that they are meeting the service requirements of the manufacturers.

The downside of exclusive arrangements is that traditional distributors cannot supply the full range of government listed pharmaceutical products. This situation raises concerns about the availability and timeliness of delivery of drugs and a potential loss of economies of scale.
for delivery services. Concerns about this type of exclusive distribution arrangement were raised with regulators by wholesalers in Australia and UK and the time it was being introduced by Pfizer. The concerns included risk to timely delivery of Pfizer products and a more complex and expensive procurement environment.

**Government provision of wholesale services**

In British Columbia (Canada), government ministries, municipalities and publicly-funded agencies are supplied with pharmaceuticals through the government-owned Product Distribution Centre. The Product Distribution Centre operates as a full service dispensing pharmacy on a full cost-recovery, providing drug procurement, warehousing and distribution services.

The benefits of such an approach include the potential economies of scale and better purchasing power in negotiations with manufacturers.

This type of options may offer greater competition to the oligopoly structure that exists in the New Zealand pharmaceutical wholesale sector. The disadvantage is that such an approach would be a radical departure from the norm in New Zealand. It would require significant upfront capital expenditure to establish the warehouse and distribution infrastructure as well as ongoing running costs. These costs could be recouped from charging the users of the service.

**Innovations in the pharmacy sector**

**Pharmacy in supermarkets**

In the US, supermarkets have been gaining prescription market share. From 2012 to 2013, the number of prescriptions dispensed through supermarket pharmacies increased from 522 million to 536 million (2.7 per cent increase) which corresponds to an increase in market share of 0.3 per cent.¹

In New Zealand, legislation restricts the development of the ‘chain’ ownership model. However despite this, the supermarket chain Countdown launched its first pharmacies in 2012 in partnership with a registered pharmacist. There is nothing to prevent them entering into additional partnerships to increase the number of pharmacies.

In Australia, pharmacy location and ownership restrictions are in place. Even so, a discount pharmacy chain Chemist Warehouse in Australia has managed to operate a business model that is a supermarket within a pharmacy (as opposed to the prohibited pharmacy in a supermarket). The company is owned by pharmacists and has publically advocated for a relaxation of the ownership restriction rules in Australia.

Relaxation of ownership rules could lead to greater innovation in the pharmaceutical wholesaling and retailing sectors. For example, supermarkets have a well-established logistics supply chain and changes to New Zealand ownership rules to allow for pharmacies in supermarkets could result in greater competition and reductions in costs.

¹ Fein 2014a; IMS Institute of Healthcare Informatics 2014, p.49.
Mail-order and online services

Drug distribution via mail-order is legal in six European countries, including the United Kingdom (UK). In the UK these pharmacies are known as ‘National Health System (NHS) distance selling pharmacies’. They are not allowed to be on primary care premises with a registered patient list, and they must be able to provide pharmaceutical services to anyone in England without face-to-face contact. Distance selling pharmacies can organise repeat prescriptions on behalf of the patient from the doctor that can be delivered free of charge for registered patients.

In the United States, most Pharmacy Benefit Managers are third party administrators that manage pharmaceutical costs for health plans sponsors, such as self-insured employers, insurance companies, and health maintenance organisations. They run their own mail-order pharmacies, which enable them to reduce costs through efficiency gains achieved through using automated dispensing processes and increasing generic or therapeutic substitution.

In New Zealand there are a few mail order or online pharmacies that operate under the same legislation as community pharmacists. Physical copies of prescription must be received before a medication is dispensed which can then be courier to a patient’s home (at cost). Essentially it is a home delivery service.

Online and mail-ordering services are market-led initiatives facilitated by the internet and consumer preferences for online shopping. There is potential for online and mail-ordering services to result in consumers bypassing physical pharmacies.

Dispensing General Practitioners

In the UK, there were approximately 6,300 dispensing doctors operating out of 1,059 practices in 2014. Dispensing doctors are general practitioners who can dispense medicines to their patients if the patient meets the relevant criteria and wishes them to. It is a service that is generally used to ensure access to pharmaceuticals for patients in rural areas and those who may not otherwise have access to a community pharmacist.

Nearly 7 per cent of all prescribed medicines were dispensed by a doctor in the UK in 2014. However, this model is changing with an increase in the number of dispensing doctors coinciding with a decrease in dispensing practices as practice amalgamate and/or co-locate with pharmacies.

Greater use of dispensing GPs may be an option for bypassing physical pharmacies – especially in rural and remote areas.

Full-service pharmacies

2 Viewed at http://psnc.org.uk/contract-it/market-entry-regulations/distance-selling-pharmacies/
Another market initiative is the emergence of full-service pharmacy models. The full-service business model reflects a trend towards more health orientated service offering which differentiates itself on factors other than price. Services are aimed at enabling customers to manage some of their existing health conditions, and access preventative health services, from within the pharmacy network rather than through the traditional GP network. It is a model that contrasts with the discount pharmacy approach.

There is a suggestion that limiting ownership of pharmacies to registered pharmacists only is reducing innovation and entrepreneurship in the sector. In the long-term this is detrimental to the interest of consumers. We suggest that a review of ownership restrictions should be conducted to ensure that the industry is able to respond to consumer preferences.

**Innovations in the buyer/ demand-side**

Along with changes in the traditional supply-chain there have been major shifts occurring among the buyers of pharmaceutical products including by government agencies and consumers themselves.

The dominance and market power of the multi-national manufacturers and large scale national wholesalers, has given rise, in our view to the emergence of demand-side initiatives. We refer to the demand-side as buyers of pharmaceutical and other medical requirements. Individually, the buyer has limited ability to negotiate with large manufacturers or wholesalers. But combining the purchasing requirements of a large group of government agencies or hospitals can significantly increase purchasing power and counter the market power of the manufacturers and wholesalers.

**Combined purchasing by health authorities**

The province of British Columbia in Canada has been able to leverage buying power and increase process efficiency by managing its supply chain for pharmaceuticals through a single entity, Health Shared Services British Columbia (HSSBC). HSSBC is responsible for all purchasing, inventory, warehousing and delivery functions for British Columbia’s six health authorities.

The advantages of such an arrangement include better buying power in negotiating with manufacturers, better oversight, control and management of the hospital requirements.

**Group purchasing organisations**

In Canada, regional health authorities and hospitals usually purchase their drugs through Group Purchasing Organisation (GPOs). GPOs are governed by their member organisations, which are mainly hospitals, regional health authorities and other health care providers. Instead of each hospital signing its own contract with multiple different pharmaceutical manufacturers, GPOs purchase drugs in bulk on behalf of them. They gather information from their member hospitals about the amount of drugs each hospital needs, and then run a competitive tendering process.

The manufacturer with the lowest bid typically wins the entire contract. This enables regional health authorities and hospitals to obtain procurement efficiencies, including cost
reduction and increased access to healthcare goods and services.\textsuperscript{3} In the US, buying clubs use GPOs to procure better prices for medicines.

**healthAlliance**

In New Zealand, healthAlliance began providing procurement services nationally to all 20 district health boards in July 2014. Its aim is to generate savings for the health sector.

The healthAlliance model in New Zealand represents an innovative approach to help government agencies consolidate back room services and reduce costs. It has potential for use with community pharmaceuticals, but would require much broader distribution to a larger range of sites. The distribution of medicines for community use also presents additional logistics issues in that New Zealand legislation requires trained pharmacists to oversee the repackaging of medications into resalable quantities from the outer packs.

This new distribution approach helps to consolidate services and reduce costs. The creation of healthAlliance is consistent with the trends that are occurring in the US and Canada with government agencies and buying groups combining to increase their purchasing power.

**Options for addressing the margin issue**

The types of high-level options for funding wholesale and pharmacy services that have emerged from our scan of overseas approaches include:

**Separate mark-up arrangements for wholesale and pharmacy**

Under the German model the remuneration for wholesalers and pharmacists are separate. The margins have a hybrid flat and percentage based structure and the remuneration varies depending on the price of the product. The wholesaler margin is set at €0.70 plus 3.15 per cent of the manufacturer price per package, with an upper limit of maximum €37.80 per package. Pharmacists receive a 3 per cent margin and a fixed pharmacy fee of currently €8.35 plus a lump sum payment of €0.16 per package on pharmaceutical products.

In Australia, as in Germany, the wholesaler mark-up and pharmacy margin are separate and transparent. Under the latest Community Pharmacy Agreement, the wholesaler mark-up is in two forms. A 7.52 per cent margin for products that are at or below $930.06, and a flat margin of $69.94 for products that are priced above $930.06. As discussed in more detail below pharmacies earn a predominantly fixed administration, handling and infrastructure fee as well as a dispensing fee.

These types of models offer greater transparency and certainty in revenue for the wholesalers and pharmacists.

\textsuperscript{3} Born, K., Petch, J., & Dhall, I. 2012, Medication shortages: How Ontario came to rely on one manufacture. 19 April 2012. Toronto (ON), Canada: Healthy Debate.
Delink pharmacy remuneration from the price of medicines

For pharmacists in Australia, from 1 July 2015, a predominantly fixed administration, handling and infrastructure fee replaced the previous retail percentage-based mark-up on the price of the medicine. The reason for delinking the pharmacy mark-up from the price of medicines was due to the impact of medicine pricing reforms, such as price disclosure, that resulted in price reductions in medicines that flowed through to lower remuneration to pharmacy.

Fixed funding in UK

In the UK, community pharmacies receive a fixed amount of funding from the National Health Service. This is to cover essential and enhanced services and then there is a fixed pool of retained margins which is the pharmacy’s profit. The difference between the listed price and the cost that pharmacists can obtain the drugs for is their retained margin. Retained margins are set at an agreed level (8.6 per cent for 2014 in England and Wales) and 120 pharmacies are audited against this to ensure it is at an accurate reflection of the discounts being received.

The Department of Health can alter the price of drugs in the tariff (under category M) to ensure that the amount of margins to be paid falls within the fixed budget. Scotland undertakes spot checks. Direct-to-pharmacy arrangements are a risk to the NHS because if the margins the pharmacists receive are squeezed by these arrangements then the overall cost to the NHS is increased as they still need to meet their obligations under the funding framework.

Other payments

Other issues that can impact on stockholding and procurement costs are wastage through ‘broken bulk’, expired drugs and medicine recalls. This is discussed in Appendix 3.

Pharmacy ownership restrictions

There is a suggestion that limiting ownership of pharmacies to registered pharmacists is not in the interest of consumers. New Zealand and Australia have similar arrangements whereby a pharmacist must have majority interest in a pharmacy and the number of pharmacies that can be owner by a pharmacist are limited (five in New Zealand). The Productivity Commission in Australia found that excluding corporations from owning pharmacy businesses reduced innovation and entrepreneurship in the sector. Further, it limited the scope to leverage specialised management skills and expertise to that could reduce costs and improve services.  

In our view, these findings can be extended to the situation in New Zealand. We suggest that a review of ownership restrictions should be conducted to ensure that the industry is able to respond to changing consumer preferences. Given that two of the wholesalers in New Zealand are owned by co-operative of pharmacists, a review of pharmacy ownership restrictions may also have flow-on effects to the wholesale-distribution sector.

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1. Introduction

1.1 Purpose

Sapere Research Group (Sapere) was engaged by the Community Pharmacy Services Group (CPSGG) to prepare a ‘think piece’ on pharmaceutical margins to provide input into the development of a preferred options model for consultation in a discussion document.

The scope of the research is to:

1. Identify if there are other industries/supply-chain/logistic models which should be considered as inputs into developing options for addressing the pharmaceutical margins issue currently facing the New Zealand health sector.
2. Identify a broad range of options for addressing the margin issue. The focus should be on how the current funding formula should be modified to address some of the issues raised in the Deloitte report.5

Our research draws on examples in other relevant industries to identify an alternative set of supply-chain and distribution/logistic models for distributing pharmaceuticals in New Zealand. We have compared the relative strengths and weaknesses of these models for application to distributing pharmaceuticals in New Zealand.

1.2 Our approach undertaking this project

This research intends to explore ways to improve the pharmaceutical supply chain. Our approach in undertaking this project included:

1. defining the current pharmaceutical supply chain in New Zealand
2. undertaking a literature review of supply chain models including innovations that are emerging
3. undertaking research into supply chain in other countries
4. undertaking research into government funding arrangements of distributors and wholesalers in other countries
5. conducting interviews with agencies involved in the pharmaceutical supply chain, and
6. developing a range of options, including out-of-the-box options, for addressing these issues.

Information was gathered by drawing on inputs from other industries, supply chains and logistic models that are relevant to the New Zealand pharmaceutical industry, namely in the

United Kingdom, Australia, Canada, the United States of America and Germany. The analysis of each model included:

- a description of the industry/supply-chain/logistic models,
- the form of government regulatory arrangements, and
- the margins earned by each of the supply chain component.

In addition, our understanding of these industries, supply chains and logistic models was underpinned by a range of stakeholder consultation with relevant stakeholders in New Zealand and overseas.\(^6\) Issues of supply management were also discussed with relevant experts.

By comparing the relative strengths and weaknesses of supply chains and logistic models in other jurisdictions and industries, a set of options was developed to address the issues around pharmaceutical margins in New Zealand.

### 1.3 Structure of this report

This report is structured as follows:

- Executive summary
- Section 1: Introduction
- Section 2: Pharmaceutical supply chain and margins in New Zealand
- Section 3: Alternative pharmaceutical supply chain models
- Section 4: Supply chain trends and innovations
- Section 5: Alternative funding arrangements
- Section 6: Strengths and weaknesses of alternative approaches.

The appendices contain more detailed information about each of the jurisdictions reviewed and a list organisations and experts we interviewed as part of our research.

\(^6\) A list of the organisations interviewed can be found in Appendix 6.
2. Pharmaceutical supply chain and margins in New Zealand

The New Zealand medicines strategy, Medicines New Zealand (the Strategy) provides the overarching framework to govern the regulation, procurement, management and use of medicines in New Zealand.

The three core outcomes for the medicines system are access, optimal use, quality, safety and efficacy. Access refers to ensuring New Zealanders have access to the medicines they need, regardless of their individual ability to pay, and within the government funding provided. Optimal use refers to choices about medicines, the ways the system delivers medicines and the ways individuals use medicines result in optimal outcomes. Quality, safety and efficacy refer to ensuring medicines are safe, of high quality, and are effective.

An implementation plan, Implementing Medicines New Zealand (the Plan) sets out the changes required to deliver on the Strategy. This Plan provides a high-level framework for organisations to consider when planning their work programmes and delivering services to New Zealanders. Initiatives underway include work with the Pharmacy Steering Group to develop a road map for pharmacy.7

2.1 Existing supply chain and margin arrangements

2.1.1 Pharmaceutical Management Agency

The Pharmaceutical Management Agency (PHARMAC) is the government agency that agrees which medicines receive a government subsidy, and negotiates the price with the manufacturer. A terms and supply agreement is then signed between the parties which lays out the agreed maximum drug cost, for which particular application and in what formulation. This then informs the publicly available pharmaceutical schedule which forms the basis of negotiations between manufacturers and New Zealand wholesalers. The funding for these subsidies is provided by the DHBs through an agreed community pharmaceutical budget.

The budget for medicines that is managed by PHARMAC is set each year by the Minister of Health, and includes funding for medicines dispensed in the community, and for cancer medicines that are used in DHB hospitals. For community medicines, DHBs reimburse community pharmacists for dispensing prescribed medicines and PHARMAC works on their behalf to manage the spending.8

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2.1.2 Wholesalers

In New Zealand, there are two national wholesalers that pharmacists can order from, as well as regional one or part-service ones. The two national wholesalers are:

- CDC Pharmaceutical Limited - a pharmacy owned cooperative, and
- Pharmacy (Retailing) (commonly known as ProPharma) is part of the EBOS Group a publicly listed company.

In August 2014, CDC Pharmaceutical and Pharmacy Wholesalers (Central) Limited (PWL Central) received clearance from the Commerce Commission to merge their wholesaling businesses. The merged business is a wholesaler of pharmaceutical, over-the-counter and veterinary products. At this time the merger was being considered CDC primarily wholesaled pharmaceuticals in the South Island and in Wellington from its warehouses in Dunedin, Christchurch and Wellington. PWL Central primarily wholesaled pharmaceuticals in the central North Island from its warehouses in New Plymouth, Wanganui and Napier.

The merged CDC Pharmaceutical business is a co-operative company and its existing shareholders are pharmacists (and some hospitals which were PWL Central shareholders). The shareholders are also CDC’s main customers.\(^9\)

Pharmacy Retailing (NZ) Limited, most commonly referred to as ProPharma is part of EBOS Group Limited. EBOS Group Limited is listed on the New Zealand Stock Exchange and is prominent within the healthcare sector, providing various logistics and wholesaling services across Australasia. Pharmacy Retailing (NZ) Limited wholesales pharmaceutical products using three brands. These are: \(^10\)

- ProPharma - operates eight warehouses and is the only provider that currently supplies pharmacies in every region of New Zealand
- Pharmacy Wholesalers Russell - operates one warehouse in West Auckland and focuses on supplying pharmacies in the upper North Island, and
- Onelink - operates from warehouses in Dunedin, Hamilton and Auckland and is focused on wholesaling pharmaceutical products to hospitals. (We discuss the Onelink model in more detail in section 3.4.4).

We note that in total there are 18 warehouses servicing New Zealand pharmacies. It is not within the scope of this report to assess whether this is an efficient number or not. Instead, our main objective is to look at ways of providing incentives for wholesalers to operate more efficiently.

Pharmacy Wholesalers (Bay of Plenty) Limited (PWL BOP) is a regional wholesaler which services areas north of Taupo. PWL BOP is a co-operative company whose pharmacist


shareholders are its main customers. PWL BOP currently has one warehouse in Tauranga from which it primarily supplies customers in the Waikato, Bay of Plenty and Auckland regions.

Prescription pharmaceuticals account for around 85 per cent of a pharmaceutical wholesalers business.11

2.1.3 Community pharmacy

In New Zealand, there are 960 community pharmacies responsible for dispensing the majority of prescription medicines to patients. Community pharmacists are funded to do this through the Community Pharmacy Services Agreement (CPSA) with their respective District Health Boards (DHBs).

For dispensing prescription medicines pharmacies are reimbursed:

- A handling fee of $1
- $4.38 for an initial item (Core and LTC)
- $3 per repeat multiplied by RVU (Core and LTC)

For procurement and stockholding of medicines pharmacies are reimbursed:

- List price of pharmaceutical
- A procurement margin towards the procurement and stockholding costs for the Pharmaceutical, being either:
  - A margin of 4% for pharmaceuticals less than $150.00; or
  - A margin of 5% for pharmaceuticals equal to or greater than $150.00 as specified in the Pharmaceutical Schedule (this includes special foods)

The wholesalers purchase the drugs at the schedule list price from the manufacturers, and may offer the pharmacists discounts for terms of trade such as prompt payment discount (which with one company can range from 2.5 – 6.7 per cent) and margins of 10.4 per cent on the manufacturing cost of rebatable ethicals that cost more than $5 and less than $150. Pharmaceuticals that cost under $5 are often at cost plus 10 per cent, which means they can cost more than their reimbursement price.

In addition, for pharmacies who belong to a cooperative (CDC and PWL BOP) and their members will receive a rebate annually which will be the wholesaler’s margin or profit.

The margin is stipulated under the CPSA as “a contribution to procurement and stockholding costs for the pharmaceutical”. As the Deloitte report noted what constitutes “stockholding and procurement costs” can be interpreted in various ways, but could include all cold chain storage, the stockholding requirements under the CPSA, wastage, expiry and

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Disclaimer: Strategic think piece on pharmaceutical margins – not Government policy or DHB direction.
recalls. Usually the cost of the pharmaceutical is covered during a recall but not the pharmacist’s time in returning the stock and contacting patients. In New Zealand in the last year for example there were 18 medicine recalls.\textsuperscript{12}

In the UK certain products are exempt from the discount deduction process (these are called the ‘discount not given’ (DNG) list such as controlled drugs or cold-chain items, and there is a separate reimbursement process for ‘broken bulk’\textsuperscript{13}.

The CPSA stipulates that 90 per cent of prescription items should be available to the patient within one hour of the prescription being presented at the pharmacy, 99 per cent by the end of the next business day and 100 per cent within two business days. This means that pharmacies must maintain an adequate level of stock to meet this requirement.

Some DHBs have chosen to contract for direct distribution to patients for bulky items such as special foods. Home delivery of some pharmaceuticals results in bypassing pharmacies and the wholesale chain. In addition, PHARMAC is currently involved in the direct-to-patient distribution of a small group of medicines (interferon beta, glatiramer, dasatinib, Glivec brand of imatinib) that are approved through special access panels. This mechanism also has the effect of not moving these products through the supply chain.\textsuperscript{14}

In considering the pharmaceutical supply chain, it is important to realise that while part of the community pharmacist’s role is to dispense the medications to patients, their role also includes the education and support of people with medications. This is the fundamental shift that has been attempted with the new community pharmacy contract to shift away from pill counting and increased volumes as income generation, and towards service delivery and efficient and effective use of medicines.

The concerns surrounding the pharmaceutical arrangements in New Zealand are set out in the section 2.2.

### 2.2 The margin problem in New Zealand

The government funded pharmaceutical margin is about $33 million per annum and is one component of the total reimbursement provided under the Community Pharmaceutical Services Agreement. The margin is a payment towards what is described as the ‘procurement and stockholding’ costs for pharmaceuticals that are subsidised through the Pharmaceutical Schedule.

Funding for procurement and stockholding services comes from DHBs through a ‘regulated’ formula. However, the actual charges for services are subject to commercial negotiation between wholesalers and pharmacies.

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\textsuperscript{13} In the UK pharmacists may claim ‘broken bulk’ for certain pharmaceuticals that come in large outer packs once in a six month period, see the UK section for more detail.

\textsuperscript{14} Information received from CPSGGG.
We understand that there is an increasing view in the sector that the current margin funding model is no longer fit-for-purpose.

The 2015 Deloitte report found that the drug margin totaled around 4.2 per cent. Of this, wholesalers’ average margin was around 3.5 per cent (net of discounts) on top of the gross drug price negotiated by PHARMAC with the manufacturers. Thereby if you deduct the 3.5 per cent wholesaler margin from the 4.2 per cent gross drug margin, leaves an average margin for pharmacy of 0.7 per cent.

A consistent theme found by Deloitte was that there was an increased volume of medicines being delivered through Community Pharmacy while the cost of medicines and therefore PHARMAC spend was reducing. Reduction in spend, as mentioned, leads to a reduction in margin to wholesalers and pharmacy.

An issue for wholesalers and pharmacy is that these increased volumes and inflation over the period have increased supply-chain costs whilst funding received from the pharmaceutical margin has decreased. Pharmacy is prohibited from on-charging patients from the increasing costs charged by third parties.

Deloitte found that this reduction in margin, and associated reduction in income, is a source of considerable uncertainty for both wholesalers and pharmacy.

In particular, the pharmacy net share of the pharmaceutical margin is small and declining due to wholesalers increasingly seeking to pass through rising costs associated with distribution. As volumes increase the costs of distribution, particularly transport and cold-chain related costs. This has placed pressure on wholesalers. Pharmacy is particularly squeezed on margin when urgent medicines are required and not available from their usual wholesaler. If urgent medicines are not available from their usual wholesaler the pharmacy is forced, under the requirements of the CPSA to order from another wholesaler and therefore does not receive any wholesaler discounts. In these instances the wholesaler margin may significantly exceed the pharmaceutical margin.

Other issues that emerged from the Deloitte research include:

• high degree of concern in the sector that the current funding for pharmaceutical margins is unsustainable,
• lack of clarity over what the drug margin is intended to cover. In particular around supply chain activities stop and when dispensing activities commence,
• the number of community pharmacies is currently too high in some areas,
• small rural pharmacies may face higher risks and costs related to procurement and stock-holding, and
• not confident that the current mechanism encourages innovation in the distribution of medicines.
There are no restrictions on who is given a pharmacy contract as long as they have a pharmacy licence which stipulates that the majority ownership share of a pharmacy must be held by a registered pharmacist. There are also restrictions on the number of pharmacies a company or individual can own (five) and there are restrictions on the involvement of an authorised prescriber.

While there can be some tweaking of the margins and percentages as part of the next CPSA, the problem appears to be one of the contracting environment. The contracting with the wholesalers sits with the individual community pharmacy. There are 2-3 wholesalers and around 960 pharmacies. This sets up a situation of many pharmacies negotiating with an ‘oligopoly’ market structure.

The question arises as to how much negotiating power pharmacies have relative to wholesalers. The situation is different for vertically integrated organisations compared to independent pharmacies. An organisation with many pharmacy stores may have greater negotiating power than a smaller pharmacy on its own.

It is important to note however that one of the two major wholesales is a cooperative already. Therefore those pharmacies that are members will benefit from annual rebates and benefit from the margin percentage as well.

In the short term, tinkering with percentages may be one solution but in this research is focused on considering whether in the longer term are there other options?

As a result of the issues that have emerged, DHBs are interested in considering alternative approaches to the funding of the pharmaceutical margins for community pharmacy and wholesalers.

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3. **Alternative pharmaceutical supply chain models**

The pharmaceutical industry supply chain at its base level consists of three parts, the manufacturer (which will include research and development and production of drugs), the wholesaler and distributor (wholesaler) and the community pharmacist. These three sectors are involved in the delivery of the product to the patient.

We have looked at the supply chain of pharmaceuticals in other countries. We are particularly focusing on the arrangements involving the wholesaler and pharmacist.

Unlike other commercial products, the pharmaceutical supply chain is complex due to the regulatory environments that it must adhere to within different countries. Regulations cover the approval for new medicines, costs, method of supply, marketing and the associated clinical profession of pharmacists. This may be a factor as to why the supply chain has not been as exploited as in other industries.

A report by PricewaterhouseCoopers (PwC) in 2011 identified the need for pharmaceutical companies to redevelop the supply chain based on a number of pending factors at that time such as patent expiries, advances in technology and medicines, and new models of care.\(^{16}\)

PwC argued that these changes mean that pharmaceutical companies need to extract maximum value out of the supply chain, for example through new developed drugs being transported in separate components and compounded on location, a stronger focus on community based healthcare rather than hospitals, and the support of emerging technologies such as virtual monitoring and nano-technology.

Some of these changes may already be evident in the shift in the last few years towards direct-to-pharmacy distribution methods. While this method may bypass additional handling by wholesalers it does not benefit the pharmacy as it means it is an additional party required to purchase specific drugs from, increasing the transactional costs for the pharmacist.

Community pharmacists are well placed to be members of community based health care teams, supporting patient’s self-management and monitoring. However, while the community pharmacist’s service role is expanding, there is still the issue of how the current business model inhibits innovation in the distribution aspect of medicines. An expanding service role may support more opportunity to engage and support patients, it is also a stock holding business which requires customers to come to the store to potentially buy other goods.

3.1 Traditional pharmaceutical supply chain

The typical pharmacy supply chain is depicted in Figure 1 below. According to the World Health Organisation, the ten largest pharmaceutical companies control one third of the global market. Six of these companies are located in the US and four in Europe. In most Western countries, there is regulation that governs the process to introduce new medicines in a country, for the price of medicines as well as for the distribution of medicines through approved dispensing clinicians, such as pharmacists or dispensing doctors.

The agreed price for pharmaceuticals usually takes into account the need for pharmaceutical companies to make a profit in recognition of high research and development (R&D) costs, as well as ensuring the viability of this industry as an employer. However, there is a much publicised debate about the profits that pharmaceutical companies make, and the proportion of costs on R&D versus marketing.\(^\text{17}\) Pfizer spent nearly double on marketing than it did on R&D in 2013 and made a 43 per cent profit margin.

Governments commonly agree with the manufacturers the prices that they will pay for drugs and what those drugs can be used for. Wholesalers will negotiate this price with manufacturers and receive discounts based on agreed terms of sale. In turn, community pharmacies will purchase from the wholesaler and also receive discounts for agreed terms of sale. Where there is a publicly funded healthcare system, governments will often agree those pharmaceuticals that can be used for certain conditions and agree the amount they will pay for those drugs.

The traditional pharmaceutical supply chain is shown in Figure 1 below.

**Figure 1: Pharmaceutical supply chain**

![Pharmaceutical supply chain diagram](source: PwC (2011).)

However, pharmaceutical distribution has been changing in recent years and much of this appears to centre on by-passing third party wholesaler-distributors. These trends have potential to disrupt the traditional supply chain model.

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3.2 Wholesale and distribution

3.2.1 Direct-to-pharmacy

In Europe, the industry has been dominated by horizontal and vertical integration, as large retail chains merge and then dominate the distribution channels to become major market players. This has also impacted on the traditional model of distribution from manufacturers to wholesalers to retailers, with some manufacturers agreeing sole distribution channels for their products, such as direct-to-pharmacy distribution methods.

Direct-to-pharmacy supply chain was of such a concern that the Office of Fair Trading (UK) produced a report on it in 2007, to help inform the PPRS. The outcome of this report was that the Office of Fair Trading could see both advantages and disadvantages to direct-to-pharmacy channels.

One the one hand, the choice of some major manufacturers to adopt a direct-to-pharmacy distribution model was seen as a risk to the provision of medicines. The model is depicted in Figure 4 below.
The NHS guarantees a level of funding to community pharmacy under its funding framework. This funding is offset by the ‘profit’ that pharmacies can make through effective purchasing of medicines, in effect the discounts it receives through wholesalers. If manufacturers select a single channel of distribution, this creates a monopoly for that provider, negating the need for discounts or competition under favourable terms of service. In 75 per cent of prescriptions, pharmacists have no choice over the selected drug, and so have to deal with certain providers to obtain the necessary product.

**Figure 3: Direct-to-pharmacy and the traditional wholesale model (UK)**

![Diagram showing DTP and the traditional wholesale model](source)


The Office of Fair Trading did also recognise that there could be efficiencies for consumers with the reduction in the risk of counterfeits products being distributed.

### 3.2.2 Exclusive distribution

In Australia, the most significant recent development in the distribution component of the supply chain was Pfizer’s decision in February 2011 to institute exclusive distribution arrangements with all retail pharmacies. The agreement gives all community pharmacies across Australia the ability to order the full range of Pfizer prescription medicines. The arrangement represents bypassing the traditional Community Service Obligation (CSO) wholesalers entirely. A representation of the supply chain is presented in Figure 4 below.

Pfizer operates in accordance with confidential service standards agreed with the Pharmacy Guild of Australia—an agreement which is both separate and distinct from the standards under which CSO wholesalers operate. Since the Pfizer Direct model applies only to Pfizer medicines and does not comply with the CSO standards, neither Pfizer Direct nor DHL
receive funding from the CSO Funding Pool. In order to recover and reduce their costs, therefore, a range of additional delivery charges are applied.\(^\text{18}\) At the time, Pfizer stated that, that the move reflected increasing strain on its business model from the Pharmaceutical Benefit Scheme reform (price reductions), as well as the looming expiry of a number of patents for Pfizer medicines, including Lipitor in 2012.\(^\text{19}\)

Pfizer’s distribution model includes operating a sales team and an exclusive logistics partnership with DHL. Pfizer also operates ‘Pfizer Direct’ which is an online ordering service for pharmacists. Pharmacists can order through their Pfizer representative, via the web, point of sale system, phone or fax. Pfizer Australia states that it is delivering to all pharmacies in Australia regardless of location.\(^\text{20}\)

In September 2013, DHL launched The Cool Green Cell, a temperature-controlled packaging solution specifically designed for pharmaceutical and medical products.\(^\text{21}\)

**Figure 4: Pharmaceutical supply chain in Australia with Pfizer exclusive distribution**

Source: Deloitte Access Economics (2011, p. 9)

The direct-to-pharmacy arrangement has raised a number of concerns in the industry including the viability of the CSO wholesaler model in Australia, risk to timely delivery of Pfizer PBS products and a more complex and expensive procurement environment.\(^\text{22}\)

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Disclaimer: Strategic think piece on pharmaceutical margins – not Government policy or DHB direction.
Notwithstanding the CSO distribution arrangements, wholesale bypass (where manufacturers seek to bypass the wholesaler in favour of direct distribution channels) has been a feature of the pharmacy industry in Australia for a number of years. Over-the-counter pharmaceutical manufacturers such as Glaxo-Smith Kline, Sanofi, Merck and Roche all engage in limited direct distribution to retail pharmacies.

### 3.2.3 Government operated facilities

British Columbia in Canada operates a full-service inventory management and distribution facility established for the use by government ministries, municipalities, the broader public sector and publicly-funded agencies. The Product Distribution Centre operates as a full service dispensing pharmacy that provides drug procurement, warehousing and distribution services.\(^\text{23}\)

The Production Distribution Centre provides a range of consulting services, including drug information research, assistance in the development of drug distribution policies and procedures, and drug formulary; and assistance in the establishment and customisation of treatment protocols.\(^\text{24}\)

In addition it provides an inventory management and distribution facility established for a range of other products used by government agencies including pharmaceutical products, industrial cleaning and medical supplies. This type of model offers a one-stop shop for a range of products for hospitals and other government facilities.

The Centre operates on a full cost-recovery basis with fiscal annual recoveries that range between $30 to $35 million (Canadian dollars).

### 3.3 Pharmacy sector

#### 3.3.1 Mail and online ordering

Drug distribution via mail order is legal in six European countries, including the United Kingdom\(^\text{25}\), and is governed by the *Pharmaceutical and Local Pharmaceutical Services Regulations 2013*. These pharmacies are known as ‘NHS distance selling pharmacies’.\(^\text{26}\) NHS distance selling pharmacies are required to register to be on the Pharmaceutical List as a distance selling pharmacy. They are not allowed to be on primary care premises with a registered patient list, and they must be able to provide pharmaceutical services to anyone in England. In addition, they must be able to provide essential services without face-to-face contact.\(^\text{27}\)

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\(^{23}\) Source: [http://www.pss.gov.bc.ca/pdc/home.html](http://www.pss.gov.bc.ca/pdc/home.html)

\(^{24}\) Source: [http://www.pss.gov.bc.ca/pdc/home.html](http://www.pss.gov.bc.ca/pdc/home.html)

\(^{25}\) In addition to the United Kingdom, drug distribution via mail order is legal in Denmark, Germany, the Netherlands, Sweden and Switzerland.


Distance selling pharmacies can organise repeat prescriptions on behalf of the patient from
the doctor that can be delivered free of charge for registered patients.

In the United States, most Pharmacy Benefit Managers are third party administrators that
manage pharmaceutical costs for health plans sponsors, such as self-insured employers,
insurance companies, and health maintenance organisations. They run their own mail-order
pharmacies, which enable them to reduce costs through efficiency gains achieved through
using automated dispensing processes and increasing generic or therapeutic substitution.

Mail-order or internet pharmacies do exist in New Zealand. However, they are generally an
extension of community pharmacy practice and are just an alternate delivery mechanism
rather than the UK ‘distance pharmacies’. New Zealand legislation requires the signed
physical copy of the prescription for the medicine to be dispensed apart from certain
circumstances. Therefore, internet pharmacies require the prescription to be posted to them
before they dispense the medication, which they will do so by courier to the patient’s home.
This service is really a home delivery service and costs the patient the standard co-payment
plus a courier delivery fee of $3.

In Australia, the discount chain pharmacy, Chemist Warehouse, is offering online ordering
of prescription drugs.

3.3.2 Pharmacies and supermarkets

In the US, supermarkets have been gaining prescription market share. From 2012 to 2013,
the number of prescriptions dispensed through supermarket pharmacies increased from 522
million to 536 million (2.7 per cent increase) which corresponds to an increase in market
share of 0.3 per cent.28

In Australia, pharmacy location and ownership restrictions are in place. Even so, Chemist
Warehouse in Australia has managed to operate a business model that can be described as a
supermarket within a pharmacy (as opposed to the prohibited pharmacy in a supermarket).
Chemist Warehouse operates a chain of discount pharmacies owned by a group of
pharmacists. The company has publically advocated for a relaxation of the ownership
restriction rules in Australia.

In New Zealand, legislation restricts the development of the ‘chain’ ownership model.
However despite this, the supermarket chain Countdown launched its first pharmacies in
2012 in partnership with a registered pharmacist. There is nothing to prevent them entering
into additional partnerships to increase the number of pharmacies.

In New Zealand, there are also other pharmacies that choose to site themselves next to
particular retailers, for example, discount chain the Warehouse, to attract a particular client
group. There are also ‘umbrella’ organisations such as Green Cross (owner of Unichem and
Life pharmacy brands) that represent 300 pharmacies and have equity shares in 70
pharmacies.

3.3.3 Dispensing clinicians

In the UK, there were approximately 6,300 dispensing doctors operating out of 1,059 practices in 2014. Dispensing doctors are general practitioners who can dispense medicines to their patients if the patient meets the relevant criteria and wishes them to. It is a service that is generally used to ensure access to pharmaceuticals for patients in rural areas and those who may not otherwise have access to a community pharmacist. Nearly 7 per cent of all prescribed medicines were dispensed by a doctor in the UK in 2014. However, this model is changing with an increase in the number of dispensing doctors coinciding with a decrease in dispensing practices as practice amalgamate and/or co-locate with pharmacies.

One in ten Scottish practices dispenses medicines however this practice is considered as a requirement by the NHS Board where no pharmaceutical services exist and is not considered the provision of pharmaceutical services per say. This means that the doctors are providing an essential service but there is a push to support more community pharmacies to establish themselves where there are no pharmacies. Scotland still adheres to the essential small pharmacies payment system which was ceased in England and Wales in 2006.

It is an important distinction how these two governments view community pharmacies and pharmacists. England has deemed that there is no difference between the service that can be offered by a GP with authority to dispense, whereas Scotland have declared that the service provided through this arrangement is not the same as community pharmacy.

3.3.4 In-pharmacy health services

In 2013, Western Australia’s largest health insurer HBF acquired the Friendlies Chemist franchise in Perth. It was looking to expand its franchise to 60 stores.

Under the franchise agreement, the Friendlies franchisees will pay for building consulting rooms which will be sued to provide new services.

It has been described as part of HBF’s “transition from a health insurer to health partner”, the acquisition will enable HBF members to manage some of their existing health conditions, and access preventative health services, from within the pharmacy network rather than through the traditional GP network.

The range of services offered at the pharmacies will include flu vaccinations, cholesterol, heart and blood pressure checks, nutrition advice, blood glucose monitoring, and quite smoking programmes. The services will be available to the community at a fee. HBF members will receive a reduced, subsidised or free service. 29

The HBF business model reflects a trend towards more health orientated service offering which differentiates itself on factors other than price. It is a model that contrasts with the discount pharmacy approach.

3.4 Demand-side initiatives

3.4.1 Combined agency buying group

The province of British Columbia in Canada has been able to leverage buying power and increase process efficiency by managing its supply chain for pharmaceuticals through a single entity, Health Shared Services British Columbia (HSSBC).\(^{30}\)

HSSBC was created in March 2010 and is governed by a management board that is made up of the CEOs from the six health authorities, the Chief Operating Office of the Ministry of Health and two external members. The HSSBC Management Board has a system-wide planning perspective and provides strategic guidance as it relates to the provision of shared services to the health authorities across the province.

The purpose of shared services is to enable the health authorities to be more effective and efficient by integrating common non-clinical service delivery. HSSBC is responsible for all purchasing, inventory, warehousing and delivery functions for British Columbia’s six health authorities.

The supply chain process includes creating a request for supplies, submitting the order to a supplier/wholesaler, receiving the product at a regional warehouse delivering to the end user, and paying the supplier/distributor. The warehouses are automated and installed with carousels.

Contracts ranging from CAD$20 to $100 million (Canadian dollars) and contracts for high value and critical drugs are directly managed by HSSBC. Contract management for lesser value generics and drugs that are not considered critical is outsourced to Group Purchasing Organisations (GPOs).\(^{31}\) We discuss GPOs below.

As a not-for-profit organisation, HSSBC is funded by the six participating health authorities to perform these services. Any savings realised are distributed back to the health authorities for reinvestment in patient care.

We note that New Zealand has a similar model whereby procurement for the 20 DHBs is managed through a single entity, healthAlliance.

3.4.2 Group Purchasing Organisations

In Canada, hospital drug formularies are under provincial purview. Regional health authorities and hospitals do not normally purchase drugs directly. Hospitals may negotiate their supplies of drugs directly with manufacturers and/or independent pharmacy distributors they usually purchase their drugs through Group Purchasing Organisation (GPOs).

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30 Namely the Provincial Health Services Authority, Interior Health, Fraser Health, the Vancouver Coastal Health Authority, the Vancouver Island Health Authority and Northern Health

31 Discussion with HSSBC representative on 29 July 2015.
GPOs are governed by their member organisations, which are mainly hospitals, regional health authorities and other health care providers. Instead of each hospital signing its own contract with multiple different pharmaceutical manufacturers, GPOs purchase drugs in bulk on behalf of them. They gather information from their member hospitals about the amount of drugs each hospital needs, and then run a competitive tendering process.

The manufacturer with the lowest bid typically wins the entire contract. This enables regional health authorities and hospitals to obtain procurement efficiencies, including cost reduction and increased access to healthcare goods and services.32

In 2008, the Competition Bureau noted that although ‘competitive tendering has the potential to provide large cost savings to public plans in Canada, (...) a frequently expressed concern (...) is that it could lead to shortages when winning bidders are unable to meet demand’.33 A recent report from the House of Commons found that the practice of GPOs of sole-sourcing drug supplies increases the vulnerability of the drug supply chain and the likelihood of drug shortages.34

We understand that HSSBC uses GPOs for purchasing lower value generics.35

3.4.3 State buying clubs

A number of states in the US have established State Drug Discount Programmes, sometimes termed ‘Rx Buying Clubs’ or ‘Discount Cards’. Rx Buying Clubs organises their members’ collective buying power, i.e. the large-volume purchasing power of the states, to negotiate discounts on a wide range of prescription drugs and generics. Pharmaceuticals are distributed through participating pharmacies. Participants typically pay the resulting discounted price at the pharmacy counter.

Buying clubs typically contract with Pharmaceutical Benefit Managers (PBMs), which in turn handle the price negotiations with the drug suppliers.36 Up to 2014, 27 states have created or authorised Rx Buying Clubs that offer drug discounts for eligible or enrolled residents, from which 16 are currently in operation.37 Some states charge a small fee to cover pharmacists’ professional services and the administration of the programmes, which ranges from USD $20 to USD $35. Fees may be waived for low-income members.

32 Born, K., Petch, J., & Dhalla, I. 2012, Medication shortages: How Ontario came to rely on one manufacture. 19 April 2012. Toronto (ON), Canada: Healthy Debate.
35 Discussion with HSSBC representative on 29 July 2015.

A complete list of Rx Buying Clubs in the United States can be found at http://www.staterxplans.us/
Pharmaceuticals are distributed through participating pharmacies. Participants typically pay the resulting discounted price at the pharmacy counter.

### 3.4.4 Combined support services – healthAlliance

A procurement model has recently emerged in New Zealand health that helps to consolidate services and reduce costs.

HealthAlliance is a non-profit organisation formed in 2000 through a joint venture between Waitemata and Counties Manukau DHBs to provide key non-clinical business services. On 1 July 2014, healthAlliance began providing a centre-led service delivering agreed procurement needs to the 20 DHBs throughout the country. This involves managing contracts for the provision of a range of services including imaging (Cardiology & Radiology); laboratory; surgical; and medical. Work is currently underway to synchronise the supplies and order methods. As a first step it is rolling out an oracle system to support national procurement (three years from 2016). However the current operations in the Northern Region support supply chain for 10 hospital locations, and a multitude of different locations, Auckland City Hospital for example has a 250 different store room locations.

The DHBs have a similar issue to community pharmacies in that they need a large varying amount of stock available however it is unlikely to be used very often or in huge volumes. HealthAlliance has varying relationships and stock holding options employed.

Therefore there are a few options:

- **Inventory management.** Storage bins in warehouse have triggers set so when an agreed minimum amount of stock is reached the stock is counted and if no order is currently in the system then one is placed. As stock levels are all pre-agreed there is no need for a purchase order and approval process, order goes straight to supplier.

- **Consignment stock.** This is essentially suppliers’ stockholding within the DHB. The stock remains the property of the supplier and it is regularly monitored and the DHB is charged for what they use. This is a shared risk arrangement as it reduces the suppliers need for storage but equally means that the supplier has value locked in stock in numerous locations.

- **Third party logistics model.** Utilising a third party to provide supplies from a variety for sources such as OneLink directly into the DHBs.

The largest issue for this supply chain is the huge variation in stock and the number of suppliers, both nationally and internationally. The latter option removes some of those layers for healthAlliance, and for the DHBs to reduce the number of deliveries and handling of supplies through their loading docks.

OneLink is a specialist healthcare supply chain ‘partner’. It is the largest supply chain partner into private hospitals, offering nationwide delivery of hospital pharmaceuticals and medical consumables to the DHBs, and even home delivery for ACC clients. It works in partnership with the DHBs and have an open book policy, while healthAlliance holds the governance or contractual side of the relationship. As discussed in later sections, this approach of establishing a combined procurement agency is consistent trends in other countries.

This type of model has potential to be used for procurement of pharmaceutical products.

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Disclaimer: Strategic think piece on pharmaceutical margins – not Government policy or DHB direction.
4. Supply chain trends and innovations

We have prepared a high level scan of innovations occurring in supply chains more generally. This has been prepared as background information to assist in understanding trends in pharmaceuticals.

4.1 Relationship-based innovation

4.1.1 Customer relationship management

Traditionally, customer service provided by manufacturers and retailers followed a standardised approach where the same services were provided for all customers. They now increasingly move towards the creation of multiple, differentiated supply chain configurations to focus on certain customer segments. This is commonly achieved through the use of call-centres, B2B databases and social media in combination with Customer Relation Management (CRM) software, which analyses the information to optimise inventory and stock by location.

The latest trend goes towards CRM software delivered via the internet and accessed through a web browser, where businesses pay a subscription fee to the software provider instead of purchasing and installing the software on a local computer.

4.1.2 Supply chain collaborations

Manufacturers and retailers are moving increasingly towards developing collaborative relationships with suppliers and customers in order to increase in-stock fill rates and reduce lead times. These collaborative relationships are characterised through collaboration commitments, the establishment of shared goals and integrated information sharing.

As Valadares de Oliveira et al. (2011) point out, ‘the development of new governance structures in automotive industries can be taken as an example of such efforts to enhance collaborative practices. (…) New relationship structures have altered old governance forms between automakers and suppliers in segmentation regimes, putting pressure on first-tier suppliers to take on new responsibilities in manufacturing, logistics and product development’.

References:
38 University of Tennessee Global Supply Chain Institute 2013, Game-changing Trends in Supply Chain. First Annual Report by the Supply Chain Management Faculty at the University of Tennessee. Spring 2013, p. 3.
4.1.3 Transformational agile supply chain strategies
In contrast to more traditional, experienced-based supply chain strategies, agile transitional strategies aim to increase the agility of supply chains to respond or adapt to changes, opportunities or threats through coordinated operations with suppliers and customers.40

4.2 Process-based innovation

4.2.1 Process integration
More and more companies align functional silos along the supply chain (purchasing, planning, manufacturing/operations and logistics) into an integrated, performance-targeted business process.

4.2.2 Relative value for customers
Manufacturers and retailers increasingly move towards enhancing the overall performance of their supply chains by improving or introducing new performance measurement and goal setting systems. This includes the introduction of cross-functional accountability, the establishment of driver-based supplier and customer segmented metrics, and the definition of appropriate cross-functional goals.

4.2.3 End-casting
Firms increasingly integrate demand management into forecasting processes to ‘sense and respond’ to dynamic and evolving customer or consumer behaviours.41 Data is mined through multiple sources, statistically analysed for historical demand patterns and integrated into the forecasting process to create a baseline forecast. This forecast is then adjusted through the sales and marketing team based on their insights in chaining demand patterns, new product introductions, new market entries, or pricing actions.

John Deere, a global manufacturer of agricultural and construction equipment, has successfully integrated demand management into its forecasting processes, which led to improvements in cost, working capital and product availability.42

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40 University of Tennessee Global Supply Chain Institute 2013, Game-changing Trends in Supply Chain, First Annual Report by the Supply Chain Management Faculty at the University of Tennessee. Spring 2013, p. 15.
41 University of Tennessee Global Supply Chain Institute 2013, Game-changing Trends in Supply Chain, First Annual Report by the Supply Chain Management Faculty at the University of Tennessee. Spring 2013, p. 32.
42 University of Tennessee Global Supply Chain Institute 2013, Game-changing Trends in Supply Chain, First Annual Report by the Supply Chain Management Faculty at the University of Tennessee. Spring 2013, pp.33-35.

Disclaimer: Strategic think piece on pharmaceutical margins – not Government policy or DHB direction.
4.3 Knowledge-based innovation

4.3.1 Knowledge-based learning

Most firms with extensive supply chains have moved towards developing talent for key supply chain process roles through creating specific professional development plans for supply chain manager, and integrating these managers into their executive teams.

4.3.2 Virtual integration and information sharing

Developments in information systems and information technologies have been facilitating the integration of relationships along supply chains.

The availability of real-time information, the internet as medium to access and transmit among supply chain partners, sourcing of ‘big data’ from multiple sources, and the systematic and automated analysis of this data through SCM systems are allowing the virtual integration of the entire supply chain. This virtual integration is also referred to in the literature as e-SCM.\(^{43}\)

Virtual integration implies the development of well-defined outsourcing strategies to optimise the leverage of third party expertise. Effective virtual integration requires the establishment and management of upstream and downstream relationships across different geographical locations to mitigate the risk of increasing labour costs and supply chain disruptions.

As the University of Tennessee notes in its 2013 white paper, ‘in line with this trend, most major retailers in North America have started sharing data with partners, including BJ, Costco, CVS, Dollar General, Family Dollar, Food Lion, HEB, Home Depot, Kmart, Kroger, Lowes, Meijer, Petco, Petsmart, Publix, RiteAid, Safeway, Sam’s Club, SuperValue, Target, Walgreens, and Walmart’.\(^{44}\)

4.3.3 Value-based management approaches

Firms increasingly recognise the relationship between their supply chains and shareholder value, and the potential of supply chain excellence as major driver for working capital and cash flow improvements and, as a consequence, economic profit. This is reflected in the implementation of value-based management (VBM) approaches.

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\(^{44}\) University of Tennessee Global Supply Chain Institute 2013, Game-changing Trends in Supply Chain. First Annual Report by the Supply Chain Management Faculty at the University of Tennessee. Spring 2013, p. 47.
4.4 Piggy-back distribution

4.4.1 ‘Piggy back’ distribution

It has been said that ‘government monopoly over the medicine supply chain de-incentivises innovative models’\(^{45}\). The private sector is often the best place to look for innovation, Coca-Cola is a global brand which has one of the most successful supply chains in the world.

A UK charity approached Coca-Cola to ‘piggy back’ on their distribution chain to support the delivery of potentially life-saving anti-diarrhoea kits to remote African villages by using an innovative packaging design which utilised empty space in cola crates to deliver the kits to the villages. However advice from Coca-Cola was to establish what the value chain of the product was, how those distributing the product could receive a small margin and was actually a better way to get the product to where it needed to go and to be valued.

**Figure 5: Cola life award winning packaging, but margins were the answer**

![Cola life award winning packaging](http://www.bbc.com/news/magazine-23348408)

An innovative packaging design utilises empty space in cola crates. This initiative supported the distribution of life-saving anti-diarrhoea kits to remote African villages in the same way Coca-Cola does. Advice from the expert supply chain was that the logistics of getting the product to the villages was not as important as developing a value chain for it to ensure the product got to where it was needed and that it was valued. The product is now sold rather than given away but that has still seen an increase of utilisation from 1 to 45 per cent.

Based on the above example, for a radically different approach to the distribution of pharmaceutical products – in particular to remote areas in New Zealand – it may be plausible for some type of pharmaceutical products to piggyback on existing retail logistical supply chains. This may be an option for existing wholesalers to consider in the future.

4.5 Cisco Systems

Cisco Systems is a California-based designer and manufacturer of networking equipment. Cisco acquires companies who have leading technology and integrates them rapidly with its system.

Cisco’s Internet-based business model has been instrumental in its ability to quadruple in size from 1994 to 1998 ($1.3 billion to over $8 billion), hire approximately 1,000 new employees.

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per quarter while increasing their productivity and save $560 million annually in business expenses.

Over 80% of Cisco’s customer business is performed over the Internet. Cisco sells network solutions to its customers and not just components. This requires coordination of hardware, software, and service components in its sales. The ability to provide these services and integrate many new businesses is enabled by Cisco’s single-enterprise system.

This system provides the backbone for all activities. It connects customers and employees with chip manufacturers, component distributors, contract manufacturers, logistics companies, and systems integrators. These participants can perform like one company because they all rely on the same Web-based data sources. All its suppliers see the same demand and do not rely on their own forecasts based on information flowing from multiple points in the supply chain. Cisco also built a dynamic replenishment system to help reduce supplier inventory.\(^\text{46}\)

The Cisco Systems is one example of where the internet has facilitated closer collaboration between participants on the demand-side and supply-side. This appears to have assisted with improving inventory management. In our view, it is not hard to imagine that an internet based shared portal may have the potential for use within the pharmaceutical supply-chain to improve ordering practises and inventory management.

5. Alternative funding arrangements

We have defined the margin problem as being one related to contracting and negotiations between wholesalers and pharmacists. In this section we summarise the funding arrangements in other jurisdictions that may provide alternative approaches for consideration in New Zealand.

5.1 Separate mark-up arrangements for wholesale and pharmacy

Under the German model the remuneration for wholesalers and pharmacists are separate. The margins have a hybrid flat and percentage based structure and the remuneration varies depending on the price of the product. The wholesaler margin is set at €0.70 plus 3.15 per cent of the manufacturer price per package, with an upper limit of maximum €37.80 per package. Pharmacists receive a 3 per cent margin and a fixed pharmacy fee of currently €8.35 plus a lump sum payment of €0.16 per package on pharmaceutical products. However, pharmacists that are not grouped in reference prices groups have to grant a range of mandatory discounts that are deducted from the pharmacists reimbursement claim against public health insurance funds.

In Australia, the wholesaler mark-up and the payments made to pharmacies are separate. The regulated margins are set out in the Community Service Pharmacy Agreement.

5.2 Delink pharmacy remuneration from the price of medicines

For pharmacists in Australia, from 1 July 2015, a predominantly fixed Administration, Handling and Infrastructure (AHI) fee replaced the previous retail percentage-based mark-up on the price of the medicine. The reason for delinking the pharmacy mark-up from the price of medicines was because of the impact of pricing policies, such as price disclosure that resulted in price reductions impacted the remuneration provided to pharmacy. The AHI fee is in additional to dispensing fee that is also paid to pharmacists.

The Australia Government is intent on reviewing the remuneration arrangements in Australia. The scope of the review is set out in the 6th Community Pharmacy Agreement and is presented in Appendix 1. The matters being considered in Australia are relevant to the issues in New Zealand.

5.3 Retained margins in UK

In the UK, community pharmacies receive funding from the National Health Service (NHS). This is to cover essential and enhanced services, and there is a fixed pool of retained margins which is the pharmacy’s profit.
The pool is a fixed amount (£800 million for 2014/15). The difference between the drug tariff listed price and the cost that pharmacists can obtain the drugs for is their retained margin. Retained margins are set at an agreed level (8.6 per cent for 2014 in England and Wales) and 120 pharmacies are audited against this to ensure it is an accurate reflection of the discounts being received, the NHS claw back anything above this. Scotland undertakes spot checks.

5.4 Community service obligation arrangements

In Australia a Community Service Obligation (CSO) Funding Pool was established in recognition of the additional costs faced by some pharmaceutical wholesalers in providing the full range of PBS medicines to pharmacies. Every five years, the Australian Government Department of Health requests tenders for wholesaling operations that will meet community service obligations (CSO). The Government makes a community service obligation payment directly to the selected CSO wholesalers. This payment is in addition to the Government funded wholesaler mark-up.

This type of model may be an alternative to paying a higher margin to wholesalers. The benefit of such a model is that the payment is made directly to the wholesaler who is incurring the cost of supplying pharmacies.

This type of government contracting arrangement could be extended to New Zealand whereby the Government seeks tenders for the provision of distribution services to community pharmacies. The CSO wholesalers would receive a fixed fee in addition to any mark-up. The distribution service could be broken up into components – say on a regional basis.

The intention of this type of model is to create competitive tension between existing and potential new entrant wholesalers. This competitive tension, in theory, should result in greater efficiency as wholesalers seek to lower costs. The drive to lower costs may lead to greater innovation in distribution services.

The disadvantage of this option is that, in the short term, the incumbent wholesalers are probably the only credible wholesalers – thereby limiting competition.

5.5 Other payments

Other issues that can impact on stockholding and procurement costs are wastage through ‘broken bulk’, expired drugs and medicine recalls. In the UK pharmacists may claim ‘broken bulk’ for certain pharmaceuticals that come in large outer packs once in a six month period, and there are certain drugs such as cold chain and controlled drugs that are exempted from discounts.

Table 1 on the next page summaries the key characteristics of New Zealand and international pharmaceutical supply chains.
### Table 1: Comparison of international pharmaceutical supply chains

<table>
<thead>
<tr>
<th></th>
<th>New Zealand</th>
<th>UK</th>
<th>AUS</th>
<th>Canada</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No. of pharmacies</strong></td>
<td>960</td>
<td>11,647 England</td>
<td>5,500</td>
<td>9,558 community pharmacies</td>
<td>61,668</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>285 in patient hospital pharmacies</td>
<td></td>
</tr>
<tr>
<td><strong>No. of wholesalers</strong></td>
<td>2</td>
<td></td>
<td></td>
<td>207</td>
<td>3 market-dominating wholesalers generating about 85% to 90% of all revenues from drug distribution.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>≈50 wholesalers in total.</td>
</tr>
<tr>
<td><strong>Drug pricing</strong></td>
<td>Pharmaceutical schedule – terms of supply contract</td>
<td>Pharmaceutical Price Regulation Scheme (PPRS) – voluntary agreement</td>
<td>Government negotiates price of medicine with manufacturers listed on the Pharmaceutical Benefits Scheme (PBS).</td>
<td>Prices are based on a percentage of the brand name price in some provinces, while other provinces use a maximum-reimbursable-cost approach. Prices for patented drugs are regulated through PMPRB. Prices for generic drugs are determined through invoice price and net pharmacy price.</td>
<td>Manufacturers set baseline price (Wholesale Acquisition Cost – WAC) for wholesalers.</td>
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<td></td>
<td>New Zealand</td>
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<tr>
<td>Wholesale margin</td>
<td>12.5% manufacturer’s discount on list price to wholesalers</td>
<td>7.52% margin where the price is up to and including $930.06, and $69.94 per dispense, where the price is above $930.06.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Pharmacy margin</td>
<td>Drugs that cost less than $5 are not receiving any rebate from wholesalers, they are typically cost plus 10 percent 4% &lt; $150; 5% &gt; $150; On PHARMAC list price</td>
<td>10.5% discount from wholesalers to pharmacies $800M purchase profit</td>
<td>New Administration, Handling and Infrastructure (AHI) fee: $3.49 per dispense for branded pack less than $180. $3.49 per dispense for branded pack between $180 - $2,089.71, plus 3.5% of the amount by which the price to pharmacists exceeds $180. $70.00 per dispense for branded pack above $2,089.71</td>
<td>Pharmacies receive mark-ups at 7-10% of the drug’s invoice price in most provinces. Pharmacies receive dispensing fees which vary from province to province.</td>
<td></td>
</tr>
<tr>
<td>Govt. subsidy</td>
<td>Govt pays subsidised cost of medicines negotiated by PHARMAC</td>
<td>Govt. pays medicines list price minus claw back</td>
<td>PBS medicines are subsidised by the Government. Government makes total CSO payment of $195,000,000 to CSO wholesalers.</td>
<td>National Government provides drug coverage for eligible groups. Each provincial government provides drug coverage through public drug plans</td>
<td></td>
</tr>
<tr>
<td></td>
<td>New Zealand</td>
<td>UK</td>
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</tr>
<tr>
<td><strong>Co-payment</strong></td>
<td>Co-payment only applies to government funded items.</td>
<td>90p per item</td>
<td>General - $37.70; Concessional $6.10.</td>
<td></td>
<td>$10</td>
</tr>
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<td></td>
<td>$5 co-payment is for non-hospital items (funded PHO prescriber medicines).</td>
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<tr>
<td></td>
<td>The $5 co-payment is per item.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Innovation</strong></td>
<td>As with intent of CPSA moving away from more medicines = more money.</td>
<td>Optimisation – selecting most clinically effective for overall better outcome to achieve efficiencies</td>
<td>Government - pricing reforms. Impending review of industry regulation. Industry – direct to pharmacy.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Rural or small pharmacy support arrangements</strong></td>
<td>Local Pharmaceutical Services (Essential Small Pharmacies) Directions 2005 Scheme – ceased March 2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

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47 Included as feedback shows that rural or smaller pharmacies in terms of dispensing volumes may be disproportionately affected by funding issue which threatens their viability and the supply of medicine to the local population.

Disclaimer: Strategic think piece on pharmaceutical margins – not Government policy or DHB direction.
6. Strengths and weaknesses of alternative approaches

Research into international jurisdictions has revealed a number of innovations in pharmaceutical supply chains. These supply chains have emerged under different regulatory arrangements and the strengths and weakness of the different approaches depend very much on the environment in which they have emerged.

We observe that government intervention in the pharmacy sector increasingly appears to be stifling incentives to innovate and adapt to changing consumer preferences.

6.1 Assessment criteria

In considering the range of alternative options we have thought about what would be an appropriate basis for assessing the strengths and weaknesses of the alternative models. We propose that the primary goal of any change to regulatory arrangements, especially any potential radical changes, should be based on considering what is in the long-term interest of consumers.

As such we have drawn on provisions in the Commerce Act 1986 which has at its core the objective of encouraging competition for the long-term benefit of consumers. The pharmaceutical sector can be characterised as being heavily regulated with significant government intervention for pricing, cost subsidisation, ownership and locational restrictions. It is an industry that has legislated barriers to entry.

Part 4 of the Commerce Act, provides for the regulation of the price and quality of goods or services in markets where there is little or no competition and little or no likelihood of a substantial increase in competition. While we acknowledge that there is competition in the pharmacy and scope for competition in the distribution sector, there are barriers such as ownership restrictions that inhibit full competition in pharmacy.

The purpose of Part 4 is:

\[\text{[...]}\] to promote the long-term benefit of consumers in markets [referred to in section 52] by promoting outcomes that are consistent with outcomes produced in competitive markets such that suppliers of regulated goods or services—

(a) have incentives to innovate and to invest, including in replacement, upgraded, and new assets; and

(b) have incentives to improve efficiency and provide services at a quality that reflects consumer demands; and

48 Section 52, Commerce Act 1986.
49 Section 52A, Commerce Act 1986.
(c) share with consumers the benefits of efficiency gains in the supply of the regulated goods or services, including through lower prices; and

(d) are limited in their ability to extract excessive profits.

We consider that the purpose statement set out in Part 4 presents a good starting point for the assessment of options relating to the regulated pharmaceutical sector. We have used the purpose statement to develop a list of criteria for assessing alternative supply chain and logistic models. These include:

1. Efficient pricing and investment signals
2. Affordability for consumers and government
3. Timeliness and reliability
4. Sustainability in the long term
5. Adaptability and innovation
6. Transparency
7. Minimise regulatory and administrative burden on the industry and government.

We used this list to compare the strengths and weaknesses of the various options.

6.2 Assessing the supply chain options

In our research of supply options we have found a number of initiatives in the manufacturing, wholesaler and pharmacy sectors. These initiatives are on the supply side as well as on the demand side.

We consider that demand-side initiatives have emerged as a way of countering, to some extent, the negotiating power of the manufacturers and the wholesalers. The range of initiatives have been both market and government agency driven.

The types of initiatives that have occurred include:

- Wholesale/distribution:
  - Tendering for wholesale/distribution
  - Direct-to-pharmacy and exclusive distribution by manufacturing
- Pharmacy:
  - Expanded service pharmacies
  - Pharmacy in supermarkets
  - Mail-order and online pharmacy
  - Dispensing GPs.
6.3 Wholesaling and distribution

6.3.1 Tendering for distribution services

Every five years, the Australian Government Department of Health, invites wholesalers to tender for wholesaling operations that will meet its set community service obligations (CSO). The Government makes a community service obligation payment directly to the selected CSO wholesalers. This payment is in addition to the Government funded wholesaler mark-up.

Tendering for wholesaling arrangements could be introduced in New Zealand whereby a government agency such as PHARMAC seeks tenders for the provision of distribution services to community pharmacies.

Remuneration could be in the form of a margin, fixed fee for services or both. There could be different type of tenders for different types of services and perhaps different regions or rural areas.

The intention of this type of model is to create competitive tension between existing and potential new entrant wholesalers. This competitive tension, in theory, should result in greater efficiency as wholesalers seek to lower costs. The drive to lower costs may lead to greater innovation in distribution services. The tender could specify the service requirements which would be factored into the wholesalers cost structure. The potential is to deliver continued innovation and improvement to wholesale services. This funding for this type of approach fixed for the period of the contract.

The disadvantage of this option is that, in the short term, the incumbent wholesalers are probably the only credible wholesalers – thereby limiting competition. It would also introduce greater administration and tender management costs for PHARMAC. The greater the number of contracts, the greater the administrative burden on PHARMAC. This cost would need to be weighed up against benefits of creating a more contestable sector with the potential to lower costs, encourage innovation, and possibly attract new entrants.

6.3.2 Direct-to-pharmacy and exclusive distribution

The direct-to-pharmacy and exclusive distribution models have been market driven initiatives. Government reforms to drive down the prices of medicines in countries such as Australia and the UK have led to at least one manufacturer adjusting its distribution approach.

In the case of Pfizer, the move to exclusive distribution was seen as a way to improve operating efficiencies in response to a reduction in prices it received for products that came off patent. In the UK and Australia concerns were raised about the impact on the exclusive distribution arrangements on the industry. The exclusive arrangements mean that traditional wholesalers could no longer supply to full range of government listed pharmaceutical products. This raises concerns about the availability and timeliness of delivery of drugs, especially to rural or remote areas. This model may also involve a loss of economies of scale for delivery services. These costs may be passed onto the pharmacy – and the consumer.
There is, however, a trade-off between timeliness and cost of delivery. The delivery of single-dose medication or small scale order could be seen costly. Therefore the exclusive distribution approach of passing on costs to pharmacy may improve ordering practices in order to reduce delivery charges imposed by Pfizer.

The potential for manufacturers to distribute their products directly and exclusively does create competitive tension (also referred to as contestability) in the wholesale sector. It provides an incentive for the incumbent wholesalers to ensure that they are meeting the service requirements of the manufacturers. However, concerns have been raised that the reliability and timeliness of supplies maybe be jeopardised with a more decentralised logistics chain. A more decentralised approach may also reduce economies of scale and thus increase costs to pharmacy.

We understand that there are no exclusive distribution arrangements in New Zealand at present.

6.3.3 Government ownership of warehouse and distribution facilities

British Columbia’s Product Distribution Centre (PDC) provides an inventory management and distribution facility established for a range of products used by government agencies including pharmaceutical products, industrial cleaning and medical supplies. It operates as a full service dispensing pharmacy that provides drug procurement, warehousing and distribution services.\(^5\)

This type of model would offer a one-stop shop for a range of products for hospitals and other government facilities. The benefits of such an approach include the potential economies of scale, better purchasing power and perhaps lower costs.

The benefits of adopting such a scheme in New Zealand is the potential to offer greater competition to the oligopoly structure that exists in the New Zealand pharmaceutical distribution sector.

The disadvantage is that it would require a significant amount of up-front investment for the facilities and ongoing administration of the service. It would be a radical departure from the norm in New Zealand.

However as discussed in previously, in New Zealand the 20 DHBs have outsourced procurement and distribution to healthAlliance. In in turn, healthAlliance partners with other companies to deliver hospital pharmaceuticals and medical consumables. They are currently working on a system to streamline the number of deliveries into the DHBs. To extend this further to deliver to a large number of disparate pharmacies would be a move from the business model and instead may be an opportunity or a 4PL; an independent wholesaler.

\(^5\) Source: [http://www.pss.gov.bc.ca/pdc/home.html](http://www.pss.gov.bc.ca/pdc/home.html)
6.4 Pharmacy sector

There are two main types of business models that are emerging as consumers preferences change. One type is for large, high volume, lower margin pharmacies offering deep price discounts. We consider that discount pharmacies, online pharmacy and pharmacy within supermarkets fit into this category.

The second model type is for high service pharmacies that offer a range of services including personal health advice and health testing services in addition to retailing of medicines and other health products.\(^{51}\)

6.4.1 Supermarkets and discount pharmacies

In the US, supermarkets have been gaining prescription market share. From 2012 to 2013, the number of prescriptions dispensed through supermarket pharmacies increased from 522 million to 536 million (2.7 per cent increase) which corresponds to an increase in market share of 0.3 per cent.\(^{52}\)

In Australia, pharmacy location and ownership restrictions are in place. Even so, Chemist Warehouse in Australia has managed to operate a business model that is a supermarket within a pharmacy (as opposed to the prohibited pharmacy in a supermarket). Chemist Warehouse operates a chain of discount pharmacies (owned by a group of pharmacists). The company has publically advocated for a relaxation of the ownership restriction rules in Australia.

In New Zealand, legislation restricts the development of the ‘chain’ ownership model. However despite this, the supermarket chain Countdown launched its first pharmacies in 2012 in partnership with a registered pharmacist. There is nothing to prevent them entering into additional partnerships to increase the number of pharmacies.

There are also other pharmacies that choose to site themselves next to particular retailers, for example discount chain the Warehouse, to attract a particular client group. There are also ‘umbrella’ organisations such as Green Cross (owner of Unichem and Life pharmacy brands) that represent 300 pharmacies and have equity shares in 70 pharmacies.

Relaxation of ownership rules could lead to greater innovation in the pharmaceutical wholesaling and retailing sectors. For example, supermarkets have a well-established logistics supply chain and changes to New Zealand ownership rules to allow for pharmacies in supermarkets could result in greater competition and reductions in costs.

6.4.2 Mail-order and online services

Drug distribution via mail-order is legal in six European countries, including the United Kingdom (UK). In the UK these pharmacies are known as ‘National Health System (NHS)
distance selling pharmacies’. They are not allowed to be on primary care premises with a registered patient list, and they must be able to provide pharmaceutical services to anyone in England without face-to-face contact. Distance selling pharmacies can organise repeat prescriptions on behalf of the patient from the doctor that can be delivered free of charge for registered patients.

In the United States, most Pharmacy Benefit Managers are third party administrators that manage pharmaceutical costs for health plans sponsors, such as self-insured employers, insurance companies, and health maintenance organisations. They run their own mail-order pharmacies, which enable them to reduce costs through efficiency gains achieved through using automated dispensing processes and increasing generic or therapeutic substitution.

In New Zealand there are a few mail order or online pharmacies’ that operate under the same legislation as community pharmacists. Physical copies of prescription must be received before a medication is dispensed which can then be courier to a patient’s home (at cost). Essentially it is a home delivery service.

Some pharmacies in Australia such as Chemist Warehouse have recently started to operate online mail ordering services.

Online and mail-ordering services are market-led initiatives facilitated by the internet and consumer preferences for online shopping. There is potential for online and mail-ordering services to result in consumers bypassing pharmacies.

### 6.4.3 Dispensing General Practitioners

In the UK, there were approximately 6,300 dispensing doctors operating out of 1,059 practices in 2014. Dispensing doctors are general practitioners who can dispense medicines to their patients if the patient meets the relevant criteria and wishes them to. It is a service that is generally used to ensure access to pharmaceuticals for patients in rural areas and those who may not otherwise have access to a community pharmacist.

Nearly 7 per cent of all prescribed medicines were dispensed by a doctor in the UK in 2014. However, this model is changing with an increase in the number of dispensing doctors coinciding with a decrease in dispensing practices as practice amalgamate and/ or co-locate with pharmacies.

For New Zealand a greater use of dispensing GPs may be an option for bypassing physical pharmacies – especially in rural and remote areas.

### 6.4.4 Full-service pharmacies

Another market initiative is the emergence of full-service pharmacy models. The full-service business model reflects a trend towards more health orientated service offering which differentiates itself on factors other than price. Services are aimed at enabling customers to manage some of their existing health conditions, and access preventative health services.

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Disclaimer: Strategic think piece on pharmaceutical margins – not Government policy or DHB direction.
from within the pharmacy network rather than through the traditional GP network. It is a model that contrasts with the discount pharmacy approach.

This type of model would require significant capital to establish and is probably not within the financial capability of many sole operator pharmacist. Therefore this type of model is likely to be hindered by the ownership restrictions.

There is a suggestion that limiting ownership of pharmacies to registered pharmacists is not in the interest of consumers. The Productivity Commission in Australia found that excluding corporations from owning pharmacy businesses reduced innovation and entrepreneurship in the sector. And limited the scope to leverage specialised management skills and expertise to that could reduce costs and improve services.54

We suggest that a review of ownership restrictions should be undertaken at some stage to ensure that the industry is able to respond to consumer preferences. Given that two of the wholesalers in New Zealand are owned by co-operative of pharmacists (CDC Pharmaceutical and PWL BOP), the concerns raised by the Productivity Commission about the pharmacy sector are also likely to apply to the wholesale sector.

6.5 Demand side initiatives

The dominance and market power of the multi-national manufacturers and large scale national wholesalers, has given rise, in our view to the emergence of demand-side initiatives. We refer to the demand-side as buyers of pharmaceutical and other medical requirements. Individually, the buyer has limited ability to negotiate with large manufacturers or wholesalers. But combining the purchasing requirements of a large group of government agencies or hospitals can significantly increase purchasing power and counter the market power of the manufacturers and wholesalers.

6.5.1 Combined agency buying group

Health Shared Services British Columbia (HSSBC) in Canada operates a joint buying group which has responsibility for all purchasing, inventory, warehousing and delivery functions for British Columbia’s six health authorities.

The advantage of this model is that the combined requirement of the six health boards is able to leverage buying power from manufacturers. It is also able to increase process efficiency by managing its supply chain for pharmaceuticals through HSSBC.

This type of model has potential to leverage buying power and increase process efficiency by managing supply chain for pharmaceuticals through a single entity. The purpose of shared services is to enable the health authorities to be more effective and efficient by integrating common non-clinical service delivery. HSSBC is responsible for all purchasing, inventory, warehousing and delivery functions for British Columbia’s six health authorities.

The advantages of such an arrangement include better buying power in negotiating with manufacturers, better oversight, control and management of the hospital requirements.55

6.5.2 Group buying organisation

In Canada, hospitals usually purchase their drugs through Group Purchasing Organisation (GPOs). GPOs provide better purchasing power and so can negotiate better prices for the member hospitals. As discussed above, we understand that HSSBC uses GPOs to procure generics for contract values that are for less than $20 million (Canadian dollars).

6.5.3 HealthAlliance

In New Zealand, a combined agency buying group has been established

The healthAlliance model represents an innovative approach to help government agencies consolidate back room services and reduce costs. It has potential for use with community pharmaceuticals, but they require much broader distribution to a larger range of sites. The distribution of medicines for community use also presents additional logistics issue in that New Zealand legislation requires, and would require trained pharmacists to oversee the repackaging of medications into resalable quantities from the outer packs.

This new distribution approach helps to consolidate services and reduce costs. It’s establishment is consistent with the trends that are occurring in the US and Canada with government agencies and buying groups combining to increase their purchasing power.

6.6 Reforms to location and ownership

Government intervention in pharmacy ownership interferes with normal commercial operations and decision-making. Government intervention creates an ‘artificial’ environment that can lead to unintended outcomes. There is scope for reducing the level of government intervention in the pharmacy sector by removing ownership restrictions.

The Productivity Commission in Australia found that restrictions on retail pharmacy location and ownership are more about protecting the vested interests of incumbent pharmacists than about promoting consumers’ interests and maximising benefits for society as a whole. The Commission found that removing location and ownership restrictions would give Australian pharmacists the opportunity and incentive to adjust to developments such as online purchasing and co-locating in supermarkets.

We consider that in the longer term, removal of ownership restrictions should be considered as a way to open up the pharmacy sector to more players and in particular those with capital to inject into the sector. This may also have flow on effects for the wholesale sector given that two of the wholesalers are owned through pharmacy co-operatives.

55 This was the view presented by the Director, Clinical Sourcing; Pharmacy, Acute Surgical & Medicine.

Disclaimer: Strategic think piece on pharmaceutical margins – not Government policy or DHB direction.
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Disclaimer: Strategic think piece on pharmaceutical margins – not Government policy or DHB direction.
Appendix 1– Australia

The supply of medicines in Australia is underpinned by the National Medicines Policy which is a ‘cooperative endeavour to bring about better health outcomes for all Australians, focusing especially on people’s access to, and wise use of, medicines’\textsuperscript{56}

One of the main components of the National Medicines Policy relates to timely access to the medicines that Australians need at a cost individuals and the community can afford.\textsuperscript{57}

To meet this objective, the Australian Government is heavily involved in setting standards for the timely supply and delivery of medicines and subsidising the cost of accessing medicines. The Australian subsidises the provision of listed medicines through the Pharmaceutical Benefits Scheme (PBS), providing funding for Community Service Obligation (CSO) wholesalers and paying fees for services provided by pharmacies.

The remuneration structure for the dispensing of medicines and health services is largely fixed by a five year Community Pharmacy Agreement negotiated between the Government and the Pharmacy Guild of Australia. The Sixth Community Pharmacy Agreement (6CPA) will commence on 1 July 2015.

These supply chain and government funding arrangements are set out in the following sections.

Overview of the Australian pharmaceutical supply chain

In Australia, medicines are distributed through a supply chain that starts with manufacturing of medicines either locally or overseas. The medicines are packaged, labelled and, for the most part, sent to wholesalers for distribution to pharmacies for dispensing. There are some exceptions to the traditional supply chain model these are discussed in the following sections.

Key government bodies involved in the regulating prescription medicines in Australia include:

- The Therapeutic Goods Administration assesses new drugs for safety, quality and efficacy, before they can be supplied on the Australian market.
- The Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations and gives advice to the Minister about which drugs and medicines should be made


\textsuperscript{57} The other components of the National Medicines Policy are medicines meeting appropriate standards of quality, safety and efficacy; quality use of medicines; and maintaining a responsible and viable medicines industry.
available as pharmaceutical benefits. No new drug may be made available as a pharmaceutical benefit unless recommended by the PBAC.

- The Australian Government Department of Health is responsible for health policy and is responsible for negotiating the Community Pharmacy Agreement with the Pharmacy Guild of Australia. Price negotiations with the responsible person for new or changed listings are undertaken by the Pricing Section on behalf of the Minister, following a positive PBAC recommendation.  

- The Australian Government Department of Human Services administers the PBS and processes pharmacists' claims and reimburse them for the medicines they supply.

Manufacturing

Suppliers of prescription medicines in Australia are typically global companies supplying their drugs to worldwide markets. The majority of prescription medicines used in Australia are manufactured overseas.

The pharmaceuticals industry receives significant financial support from the Australian Government through the sales of medicines listed in the Pharmaceutical Benefits Scheme (PBS). There are around 140 separate firms listed as suppliers to the PBS. The Government Pharmaceutical Benefits expenditure was around $9.0 billion in 2012/13.

Under the PBS, the government subsidises the cost of medicine for most medical conditions. Most of the listed medicines are dispensed by pharmacists. Some medicines are dangerous to administer and need medical supervision (such as chemotherapy drugs) and are only accessible at specialised medical services, usually hospitals. There are currently 6,600 medicines listed on the PBS.

The PBS Schedule lists all of the medicines available to be dispensed to patients at a Government-subsidised price. The Pharmaceutical Benefits Scheme is managed by the Department of Health and administered by Department of Human Services.

From 1 July 2015, under the 6CPA, Pharmaceutical Benefits Scheme (PBS) price changes will occur six times a year (compared to three times a year under the previous CPA). This measure expands the number of times a new generic brand can be listed per year.

The listing of the first generic brand of a medicine triggers a statutory price reduction of 16 per cent. The changes will allow some, first to market, generic brands of medicines to list and trigger statutory price reductions earlier than currently possible, resulting in reduced...
prices for medicines flowing to both the consumer and the Government earlier and more frequently.\(^{61}\)

During 2012/13, the largest firm by PBS sales was AstraZeneca. Its sales represented 12.4 per cent of the value of total sales made to the PBS. The top 10 suppliers by sales contributed more than 67 per cent of the value of total sales made to the PBS.

Alphapharm (Mylan N.V, a global pharmaceutical company) has been developing and making generic medicines in Australia for more than 30 years. It is the largest firm by number of prescriptions on the PBS, accounting for 13 per cent of all prescriptions dispensed under the PBS. The top 10 firms by the number of prescriptions account for a total of just over 73 per cent of total prescriptions written.

**Price disclosure**

In 2007, a ‘price disclosure’ regime was introduced to apply to cheaper generic drugs sold after a medicine comes off patent. The new regime meant that pharmaceutical companies making new brands listed after August 1, 2007 had to provide data to the Department of Health about the volume and price of certain medicines sold to wholesalers and pharmacists. The government could then use this data to determine whether the PBS dispensed price should be reduced.

Originally, this form of price disclosure collected data over cycles of 23 or 27 months in length (depending on the start date), which meant that price reductions could take over two years to flow through. The disclosure cycle periods have gradually been reducing in length.

From 1 July 2015, under the 6CPA PBS price changes will occur six times a year.\(^{62}\)

The wholesaling and distribution of medicines is described in the next section.

**Wholesale and distribution**

Wholesale and distribution is an important conduit between the 140 or so manufacturers and the 5,000 community pharmacies. In Australia, there are three main approaches to wholesaling and distributing PBS medicines. PBS medicines are distributed through:

- Community Service Obligation (CSO) wholesalers (also known as ‘full-line’ wholesalers),
- Direct-to-pharmacy distribution, and
- Exclusive distribution.

Exclusive distribution is a relatively new initiative in the distribution sector in Australia.

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\(^{61}\) Australian Government Department of Health.

\(^{62}\) Clause 4.3 6CPA.
Community Service Obligation wholesalers

Universal access to medicines under the National Medicines Policy requires government intervention in the supply chain. In 2006, a Community Service Obligation (CSO) Funding Pool was established to support the wholesaling and distribution of the full range of PBS medicines to pharmacies regardless of location within a 24 hours period.

The logistical challenges for Australia can be demonstrated by comparing the number of pharmacies relative to geographic area. Australia has one community pharmacy per 1,500 square kilometres. To put this into context, in Germany it is estimated that there is one pharmacy per 23 square kilometres and in the UK one pharmacy per six square kilometres. This indicates a higher wholesale and distribution cost structure in Australia compared to Germany and the UK.

Around 3,600 of the PBS medicines are stocked by CSO wholesalers, with others being largely generic substitutes and sourced from manufacturers when a request is placed by pharmacy. On average, pharmacies stock between 300 and 500 medicines in their dispensaries, relying on CSO wholesalers for the supply of infrequently required medicines.

Under CSO arrangements, payments are provided directly to eligible wholesalers (CSO wholesalers) who supply the full range of PBS medicines to any pharmacy, usually within 24 hours, and that meet compliance requirements and service standards. The CSO payments are over and above those made directly to pharmacists to cover the costs of supply from the wholesaler.

Data from NPSA indicates that, in the absence of exclusive distribution, around 50 per cent of PBS listed medicines stocked by CSO wholesalers are unprofitable to deliver. The data suggests that 90 per cent of drugs on the PBS account for less than 10 per cent of sales; and are ordered as single doses on average less than once per pharmacy per week. Around 60 per cent of PBS medicines stocked by CSO wholesalers are ordered less than once per pharmacy per month and 240 of these have not been ordered in a 12 month period.

The CSO wholesalers currently eligible under the CSO Funding Pool are:

- Australian Pharmaceutical Industries Ltd (National Distributor)
- Sigma Pharmaceuticals Limited (National Distributor)

66 API has a relationship with more than 4000 independent pharmacies. The services include wholesale product delivery, retail services, marketing programs and business advisory services. API also owns and operates the Priceline retail store brand that is a leading health and beauty brand in Australia. As viewed at http://www.api.net.au/aboutus.asp
67 Sigma is a leading Australian full line wholesale and distribution business to pharmacy. In addition, Sigma owns the largest pharmacy-led network in Australia, with over 1,200 branded and independent pharmacies in its network, including Amcal, Amcal Max, Guardian, Pharmasave, Chemist King and Discount Drug Stores. As viewed at http://sigrasco.com.au/about/the-company

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• Symbion Pharmacy Services Pty Ltd (National Distributor)\textsuperscript{68} and
• National Pharmacies Distribution (NPD) (State Distributor).\textsuperscript{69}

Most of Australia’s PBS medicines are distributed through CSO wholesalers. Community pharmacists generally maintain at least two accounts with CSO wholesaler to ensure timely back up arrangements.\textsuperscript{70} Around 70 per cent of medicines supplies for hospitals are supplied through the CSO wholesalers.\textsuperscript{71}

There is significant vertical integration between the CSO wholesalers and pharmacies in Australia. Australian Pharmaceutical Industries also owns and operates the Priceline retail store brand which retails health and beauty products and with pharmacies located within (some but not all) stores. Sigma owns largest pharmacy-led network in Australia, with over 1,200 branded and independent pharmacies including Amcal, Amcal Max, Guardian, Pharmasave, Chemist King and Discount Drug Store. (It sold its generic drug manufacturing business in 2010).

There are two forms of government funding for wholesalers:

• a wholesalers margin:
  – 7.52 per cent margin where the Ex-Manufacturer Price is up to and including $930.06, and
  – $69.94 per dispense, where the price is above $930.06.
• A Community Service Obligation is paid to the CSO wholesalers. From 1 July 2015 to 30 June 2020, the value of the CSO will be up to $195,220,000 per year.

The intention is that CSO wholesalers: will supply PBS medicines under the CSO arrangements at the ‘price to pharmacists’ plus the ‘wholesale mark-up’.

The CSO wholesaler may not impose new or additional fees for the supply of PBS medicines under the CSO arrangements that were not specifically allowed for under the CSO arrangements as at 1 July 2015. New or additional fees may be charged for the supply of PBS medicines that are requested by the pharmacy in a manner inconsistent with the CSO arrangements.

In 2015/16, the Government intends to undertake a formal process to appoint CSO wholesalers during. Wholesalers will be required to satisfy CSO eligibility requirements, as determined by the Commonwealth, and as set out in the documentation released by the

\textsuperscript{68} Symbion is a national wholesaler of healthcare services and products with over 3,500 pharmacy customers across Australia. The company has 12 warehouses located around Australia which coordinate daily deliveries and house 15,000 product lines from 550 manufacturing partners. As viewed at \url{http://www.symbion.com.au/about-us/}

\textsuperscript{69} NPD is an accredited CSO Distributor for South Australia and Victoria. As viewed at \url{http://www.npdistribution.com.au/}


Commonwealth when calling for such applications.\textsuperscript{72} This Government goes through this process every five years.

**Direct-to-pharmacy (wholesaler by-pass)**

Notwithstanding the CSO distribution arrangements, wholesale bypass (whereby manufacturers seek to bypass the wholesaler in favour of direct distribution channels) has been a feature of the pharmacy industry for a number of years.

Over-the-counter pharmaceutical manufacturers such as Glaxo-Smith Kline, Sanofi, Merck and Roche all engage in limited direct distribution to retail pharmacies. The type of direct to pharmacy supply arrangements have mostly been for infrequent bulk deliveries and not on-demand deliveries.\textsuperscript{73}

**Exclusive distribution**

The most significant recent development in the distribution component of the supply chain was Pfizer’s decision in February 2011 to institute exclusive distribution arrangements with all retail pharmacies. The agreement gives all community pharmacies across Australia the ability to order the full range of Pfizer prescription medicines directly from the Pfizer.

At the time, Pfizer stated that, that the move reflected increasing strain on its business model from PBS reform, as well as the looming expiry of a number of patents for Pfizer medicines, including Lipitor in 2012.\textsuperscript{74}

Pfizer’s distribution model includes operating a sales team and an exclusive logistics partnership with DHL. Pfizer operates ‘Pfizer Direct which is an online ordering service for pharmacists’. Pharmacists can order through their Pfizer representative, via the web, point of sale system, phone or fax. Pfizer Australia states that it is delivering to all pharmacies in Australia regardless of location.\textsuperscript{75}

In September 2013, DHL launched The Cool Green Cell, a temperature-controlled packaging solution specifically designed for pharmaceutical and medical products.\textsuperscript{76}

The exclusive distribution arrangement by-passes the CSO wholesalers entirely and as such the CSO wholesalers can no longer distribute the full range of PBS medicines. A diagram comparing the traditional and exclusive supply chains is presented in Figure 6 below.

\textsuperscript{72} Refer to clause 5.1.3 of the 6th Community Pharmacy Agreement.


\textsuperscript{75} Source: \url{http://www.pfizerdirect.com.au/faq.aspx}

\textsuperscript{76} Source: \url{http://www.tandlnews.com.au/2014/02/27/article/pfizer-re-signs-dhl/}
Figure 6: Comparison of traditional and exclusive supply chains


Pfizer distribution arrangements operate in accordance with confidential service standards agreed with the Pharmacy Guild of Australia. It is separate and distinct from the standards under which CSO wholesalers operate. Pfizer does not receive CSO funding and as such charges pharmacies a range of additional delivery charges.\(^{77}\)

While at the time, there was a concern that other manufacturers would follow suit this has not occurred to date in Australia.

The arrangement has raised a number of concerns in the industry including the viability of the CSO wholesaler model in Australia, risk to timely delivery of Pfizer PBS products and a more complex and expensive procurement environment.\(^{78}\)

Community pharmacy

As of June 2014, there were around 5,500 retail pharmacies approved to supply PBS medications in Australia.\(^{79}\) About 210 million prescriptions were covered by the PBS in 2013/14, at a cost to the Government of almost $9.15 billion. The Australian Government funded 83 per cent of the total cost of PBS prescriptions that year with direct patient co-

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\(^{79}\) Some hospitals and doctors can also supply PBS medicines, although reimbursement arrangements differ for these providers.
payments funding the remainder.\textsuperscript{80} Australian Government expenditure on the PBS has grown by 4.3 per cent per year in nominal terms over the past decade.\textsuperscript{81}

Pharmacies in Australia are remunerated to support access to, and the quality use of, Pharmaceutical Benefit Scheme (PBS) medicines in accordance with a five year Community Pharmacy Agreement (CPA) negotiated between the government and the Pharmacy Guild of Australia.

The Sixth Community Pharmacy Agreement (6CPA) commenced on 1 July 2015 and expires on 30 June 2020. The 6CPA contains a number of new measures aimed at reducing pharmaceutical costs to the Government.

When a pharmacist supplies a medicine that attracts an Australian Government benefit, the pharmacist is paid the PBS-dispersed price of the medicine, less any patient contribution.

The PBS-dispersed price consists of\textsuperscript{82}

\begin{itemize}
\item the cost to the pharmacist
\item an Administration, Handling and Infrastructure (AHI) fee
\item dispensing fees, and
\item any other fees the pharmacist is entitled to.
\end{itemize}

The cost to the pharmacist is made up of the manufacturer’s price plus wholesale/distributor mark-up.

The remunerations for pharmacy under the 6CPA includes:

\begin{itemize}
\item new AHI fee that replaces the former pharmacy mark-up and represents a significant change to the basis upon which community pharmacies are remunerated. The new AHI fee de-links pharmacy remuneration from medicine pricing. From 1 July 2015 the administration, handling and infrastructure fee consists of:
  \begin{itemize}
  \item For a pack quantity of a listed brand with a price to pharmacists less than $180 is $3.49 per dispense\textsuperscript{83}
  \item For a pack quantity of a listed brand with a price to pharmacists from $180 to $2,089.71 - $3.49, plus 3.5% of the amount by which the price to pharmacists exceeds $180, per dispense
  \item For a pack quantity of a listed brand with a price to pharmacists more than $2,089.71 - $70.00 per dispense.
  \end{itemize}
\end{itemize}

\textsuperscript{80} Australian Government Department of Health 2014f.

\textsuperscript{81} Productivity Commission 2015, Efficiency in Health, Commission Research Paper, Canberra., April 2015, p. 56.


\textsuperscript{83} Per dispense means per listed PBS item maximum quantity (MQ) supplied. Fee is calculated from the per pack price with AHI applied for maximum quantity, proportionate to the number of packs required for maximum quantity, and will be adjusted if less or more than the maximum quantity is supplied. See [http://www.pbs.gov.au/general/pbs-access-sustainability/fact-sheet-ahi-fee-1-july-2015.pdf](http://www.pbs.gov.au/general/pbs-access-sustainability/fact-sheet-ahi-fee-1-july-2015.pdf)
• dispensing fee (for RPPBs84) is $6.93 per dispense.
• dispensing fee (for EPPBs85) - dispensing fee for RPPBs, plus $2.04, per dispense.
• dangerous drug fee (for RPPBs) - $2.91 per dangerous drug dispensed.

While for some medicines the AHI fee paid by the Commonwealth will be higher than the previous pharmacy mark-up, for other medicines it will be lower.86 The AHI Fee, dispensing fee for RPPBs and dangerous drug fee for RPPBs will each be subject to price indexation.

Under the previous CPA, the pharmacy margins were set at a sliding scale of between 4 per cent and 15 per cent of the ‘Approved Price to Pharmacist’. The Government states that the delinking of remuneration from the price of a medicine under the AHI fee will allow changes to pricing policy, while not having significant impact on pharmacy remuneration.87 The AHI fee and de-linking pharmacy remuneration from medicine pricing is intended to support the sustainability of the community pharmacy sector while removing a barrier to future PBS reform.88

Australian Government payments to pharmacists are based on the dispensed price, but the actual wholesale cost of a PBS medicine dispensed via a retail pharmacy may differ from the determined wholesale cost (that is, the approved ex-manufacturer price plus mark-up). Pharmacies are able to negotiate with manufacturers for lower prices and take the difference as profit.

Discounting by manufacturers is most common when there are multiple generic versions of medicines in the market after a medicine comes off patent. With multiple suppliers of the same drug, pharmacists are able to leverage competitive pressure to obtain price discounts. However, the PBS Price does not change. Pharmacists are remunerated by the government at the PBS price, despite the actual price to the pharmacist being, in many cases, substantially less. This results in a windfall which the industry calls ‘trading terms’ income.89

**Emerging trend of discount retailers**

Further disruption in the pharmaceutical sector, is the emergence of ‘big box’ discounters and in particular a chain known as Chemist Warehouse. Since 2000, Chemist Warehouse has grown to become Australia’s 13th largest retailer with a turnover of $2.7 billion and 260 stores nationally. The chain is owned by a collective of pharmacists.90

In a tightly regulated industry that has legal barriers to entry and has prevented supermarkets opening up pharmacies within their stores, Chemist Warehouse has effectively achieved the

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84 Ready-Prepared Pharmaceutical Benefit or RPPB means a brand of a pharmaceutical item included in an operative determination in place under subsection 85(6) of the Act.
85 Extemporaneously-Prepared Pharmaceutical Benefit or EPPB means a pharmaceutical benefit that is not a Ready-Prepared Pharmaceutical Benefit.
88 Clause 3.4 6CPA.
same thing, albeit as ‘supermarkets within pharmacies’ rather than ‘pharmacies within supermarkets’. It sells a large range of

The Chemist Warehouse business model focuses on providing price competition and volume sales. In a recent submission, it stated that it is able to significantly reduce retail prices because of scale economics, purchasing power and business philosophy of remaining tightly focused on cost control.

As a result, it is able to offer many PBS medicines at below the PBS co-payment threshold price, resulting in lower prices for consumers and savings for the Government. Chemist Warehouse estimated that it provided savings of about $15 million to the Government through discounting of PBS medicines in 2010/11.91

Chemist Warehouse operates a mail order service for prescription drugs. It operates chemistwarehouse.com and epharmacy.com.au, the number one and number two Australian pharmacy websites by traffic and transactions. It offers both the listed brand and a generic option.

Chemist Warehouse has advocated the removal of restrictions on ownership (five pharmacies in any one state) and location92 claiming that they prevent Chemist Warehouse from bringing affordable medicines to new communities often most in need of services. Further that these rules represent a distortion of the market and barriers to entry that are anti-competitive; artificially constrain consumer choice; inflate prices; prevent entrepreneur innovation; create unnecessary costs for tax payers; encourage and protect lazy and out-dated business practices, and prevent some communities, particularly in new estates, from gaining access to services in a timely manner.93

In-pharmacy health services expanding
In 2013, Western Australia’s largest health insurer HBF acquired the Friendlies Chemist franchise in Perth. It was looking to expand its franchise to 60 stores.

Under the franchise agreement, the Friendlies franchisees will pay for building consulting rooms which will be sued to provide new services.

It has been described as part of HBF’s “transition from a health insurer to health partner”, the acquisition will enable HBF members to manage some of their existing health conditions, and access preventative health services, from within the pharmacy network rather than through the traditional GP network.

The range of services offered at the pharmacies will include flu vaccinations, cholesterol, heart and blood pressure checks, nutrition advice, blood glucose monitoring, and quite

92 Before a pharmacy can be established in a newly established community, it must demonstrate, in writing, to the Government that there is a large supermarket and a prescribing doctor within 1km, and no existing pharmacy within 1.5km.
smoking programmes. The services will be available to the community at a fee. HBF members will receive a reduced, subsidised or free service. 94

The HBF business model reflects a trend towards more health orientated service offering which differentiates itself on factors other than price. It is a model that contrasts with the discount pharmacy approach discussed in section 0.

Australian Government review

The Australia Government has committed to reviewing pharmacy remuneration and regulation. The scope of the review is set out in the 6CPA and repeated below in Box 1.

The review is likely to be of interest to CPSGG.

Box 1 Comprehensive review of pharmacy remuneration and regulation

<table>
<thead>
<tr>
<th>8. Comprehensive review of pharmacy remuneration and regulation</th>
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<tbody>
<tr>
<td>8.1 The Commonwealth will appoint a panel of three eminent independent reviewers to conduct a comprehensive review of matters including:</td>
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<tr>
<td>8.1.1 remuneration for supplying government subsidised medicines; and</td>
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<tr>
<td>8.1.2 rules about the location of pharmacies.</td>
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<tr>
<td>8.2 The comprehensive review will be based on specific terms of reference determined by the Minister. The Minister will determine the terms of reference for the comprehensive review after consultation with the Guild. It is anticipated that the review:</td>
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<td>8.2.1 will consider:</td>
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<td>(a) the Location Rules, and their role in supporting access to PBS medicines;</td>
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<td>(b) remuneration of community pharmacy, both in terms of the level of funding and how it is provided to pharmacies for the dispensing of PBS medicines; and</td>
</tr>
<tr>
<td>(c) PBS supply chain arrangements, such as the logistics and distribution of medicines, including their regulatory requirements and cost to the Commonwealth and the Australian community, including how the matters set out in clauses 8.2.1(a), 8.2.1(b) and 8.2.1(c) contribute to patient health outcomes and improve the quality use of medicines; and</td>
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<tr>
<td>8.2.2 provide recommendations as to:</td>
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<tr>
<td>(a) how to promote the most effective models for facilitating access to PBS medicines for consumers; and</td>
</tr>
<tr>
<td>(b) any regulatory changes that may be required to promote high standards of</td>
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8.3 It is intended that the comprehensive review will commence on or about 1 September 2015 and will deliver its final report by 1 March 2017.

8.4 The basis of community pharmacy remuneration specified in Table 3 and the PFDI will not be changed during the Term based on the outcomes of the comprehensive review.

8.5 The Location Rules will not be changed during the Term based on the outcomes of the comprehensive review or otherwise, except with the express written agreement of the parties.

8.6 Changes to arrangements with the wholesale distributors of pharmaceuticals based on the outcomes of the comprehensive review may be agreed between the Commonwealth and the relevant wholesalers during the Term.

8.7 The Guild undertakes to provide its full support to the comprehensive review, including by:

8.7.1 providing such Information within its possession or control as is requested by the reviewers; and

8.7.2 taking all reasonable steps to ensure that its members provide such Information within their possession or control as is requested from them by the reviewers, provided that the Guild or its members (as applicable depending on who is being asked to provide the Information) have no legitimate obligation of confidence to a third party in respect of such Information. Nothing in this clause 8.7 requires the Guild or its members to provide Information that they are not lawfully entitled to disclose under the Australian Privacy Principles set out in the Privacy Act 1988 (Cth).

Australian Productivity Review

Earlier in 2015, the Australian Productivity Commission released a research paper that focused on improving efficiency in the health sector. The Commission’s purview included the pharmacy sector and in particular the State legislation restricting pharmacy ownership to registered pharmacists and limitations to the number of pharmacies a single pharmacist can own (five per state); as well as the Australian Government regulation of the location of retail pharmacies approved to dispense subsidised medicines under the Pharmaceutical Benefits Scheme.

The Commission commented that rules about pharmacy ownership hurt consumers by reducing innovation and entrepreneurship in the sector. Excluding corporations (such as supermarkets and general retail outlets) and non-pharmacists from owning pharmacy businesses limits the scope to leverage specialised management skills and expertise that could
reduce costs and improve service quality. This together with limits on the number of separate businesses a pharmacist may own, stifles opportunities to reduce costs and prices though economies of scale and scope across a broader range of service offerings.\textsuperscript{95}

The Commission noted that in competitive markets without location restrictions, firms are able to open or relocate where the commercial opportunities are greatest. The Commission’s concerns about the location rules applying to pharmacy included that limiting the number of pharmacies that can open in a given area results in reducing accessibility and convenience for consumers. The location rules can prevent a pharmacy opening in a high-demand area if another pharmacy is already present, or from co-locating with another business (such as a supermarket) where this improves convenience for consumers.

Further, it makes it harder for consumers to compare price and service offerings across pharmacies. This acts to reduce the competitive pressure on pharmacies to reduce prices or increase service offerings (including opening hours).

It was noted that ongoing developments in technology, including the internet, are shaping consumers’ expectations about how medicines can be bought. It mooted that consumers will increasingly question why they cannot purchase pharmaceuticals in supermarkets (dispensed by a qualified pharmacist) or fill prescriptions online. The Commission found that removing location and ownership restrictions would give Australian pharmacists the opportunity and incentive to adjust to developments such as online purchasing and co-locating in supermarkets.

Overall, the Commission found that restrictions on retail pharmacy location and ownership are more about protecting the vested interests of incumbent pharmacists than about promoting consumers’ interests and maximising benefits for society as a whole. The Commission recommended that these existing ownership and location rules be reviewed.

\textsuperscript{95} Productivity Commission 2015, Efficiency in Health, Commission Research Paper, Canberra, April 2015, p. 52.
Appendix 2—Canada

Canada does not have a national strategy for the purchase, reimbursement and distribution of pharmaceuticals. Eligibility of drugs for public reimbursement, for example, is decided province by province, hospital by hospital and, in some cases, separately for diseases. This has led to a relatively complex, decentralised pharmaceutical supply chain with multiple players and overlapping responsibilities.

Overview of the Canadian pharmaceutical supply chain

Canada’s pharmaceutical supply chain includes multiple government agencies, drug manufacturers, bulk purchasers and wholesalers, hospitals, community pharmacies and health care practitioners. An illustration of pharmaceutical distribution and reimbursement in Canada is provided in Figure 7. A brief description of each player’s role within supply chain is provided below.

• Health Canada, as the federal regulator, is responsible for the approval of drugs and issuing marketing authorisations.
• The Canadian Agency for Drugs and Technologies in Health (CADTH) conducts the Common Drug Review (CDR) process and the pan-Canadian Oncology Drug Review Process (pCODR). It evaluates approved drugs and recommends drugs eligible for reimbursement through participating public drug plans.
• The Patented Medicine Prices Review Board regulates prices for patented medicines.
• Each provincial and territorial government maintains its own public drug plan and makes arrangements with pharmaceutical bulk purchasers and wholesalers (also called Independent Pharmacy Distributors, or IPDs) for the supply of drugs.
• Pharmaceutical bulk purchasers and wholesalers in turn negotiate contracts with the manufacturers, including penalties or contingencies for non-delivery.
• Hospital drug formularies are under provincial purview. Hospitals purchase drugs through Group Purchase Organisations (GPOs), which in turn purchase drugs in bulk directly from manufacturers through a competitive tender process.
• Pharmacies deliver the drugs to patients.

96 International Society for Pharmacoeconomics and Outcomes Research 2011.
Figure 7: Pharmaceutical distribution and reimbursement in Canada

![Diagram of pharmaceutical distribution and reimbursement in Canada]

**Source:** House of Commons (2012, p.1).

**Manufacturing**

Once a drug has received marketing approval by HC, manufacturers are free to sell the approved drug and enter into contracts for supply.

Canada’s drug manufacturing sector employed approximately 26,300 people in 2014. The sector consists of two major types of manufacturers: Subsidiaries of multinational brand-name drug producers and the largely Canadian-owned generic drug producers. Pharmaceutical manufacturing is primarily concentrated in the provinces of Ontario (approximately 55 per cent of the sector’s total direct employment) and Quebec (30 per cent).97

According to Industry Canada (IC), annual domestic pharmaceutical manufacturing production is valued at CAD $7.7 billion (≈NZD $23.75 billion).98

Brand-name products account for 77 per cent of Canadian sales and 34 per cent of prescriptions.99 US pharmaceutical manufacturers Johnson & Johnson (9.6 per cent market share) and Pfizer (6.5 per cent) are the largest brand-name manufacturers in Canada, followed by the domestically owned and controlled manufacturer Apotex (5.4 per cent).100

Canada’s generic pharmaceutical industry, represented through the Canadian Generic Pharmaceutical Association, accounts for 23 per cent of sales and 66 per cent of prescriptions.101 The market consists of over 15 suppliers of generic drugs, with 13 companies having manufacturing facilities in Canada. Apotex is the largest manufacturer of

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97 Morgan et al. 2010, p.3.
98 Industry Canada 2015c.
99 Industry Canada 2015c
100 Industry Canada 2015c
101 Industry Canada 2015c; Canadian Generic Pharmaceutical Association 2015b, 2015c.
generic drugs in Canada, followed by Teva Canada Ltd. (formerly Novopharm) and Mylan (formerly Genpharm).102

**Distribution of pharmaceuticals**

**Wholesalers and Independent Pharmacy Distributors**
Most prescription drugs in Canada are distributed to hospitals and retail pharmacies through wholesalers and so called Independent Pharmacy Distributors (IPDs).103 Prescription drugs may also be distributed to the retail pharmacy level by self-distributing pharmacy chains or through direct supply by manufacturers.104

Pharmaceutical wholesalers and self-distributing pharmacy chains are responsible for approximately 95 per cent of pharmaceuticals distributed to community and hospital pharmacies (indirect distribution). The remaining 5 per cent are dispensed directly from manufacturers to pharmacies and hospitals.105

Pharmaceutical manufacturers, distributors of pharmaceuticals, wholesalers and self-distributing pharmacy chains are represented through Canadian Association for Pharmacy Distribution Management, which claims to manage the pharmaceutical supply chain in Canada.106

Industry Canada (IC) lists 207 pharmaceutical wholesalers and distributors in Canada, from which 111 are specifically classified as pharmaceuticals and pharmacy supplies wholesalers and distributors.107 The sector employs approximately 26,300 people.108

McKesson Canada in Edmonton (AB) is the largest pharmacy distributor, followed by Amerisource Bergen Canada in Calgary (AB) and Kohl & Frisch Limited in Vaughan (ON).

According to Statistics Canada, sales of pharmaceuticals and pharmacy supplies wholesalers and distributors in Canada amounted to approximately CAD $43.5 billion in 2012, with total operating revenues of CAD $45.1 billion.109 The pre-tax profit margin in the Pharmaceuticals and Pharmacy Supplies Wholesalers industry was 5.0 per cent.110

**Group Purchasing Organisations**
Hospital drug formularies are under provincial purview. Regional Health Authorities (RHAs) and hospitals do not normally purchase drugs directly. While some hospitals may

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102 Canadian Generic Pharmaceutical Association 2015a; Competition Bureau 2007, p.9.
103 OECD 2014a, p.4.
104 Only 9.2 per cent of drug distribution occurs directly from manufacturers to retail (Ibid.).
106 Canadian Association for Pharmacy Distribution Management (2015). A full list of members is available at [http://www.capdm.ca/capdm-members](http://www.capdm.ca/capdm-members)
107 Industry Canada 2015a.
110 Industry Canada 2015b.
negotiate their supplies of drugs directly with manufacturers or IDPs, they usually purchase their drugs through Group Purchasing Organisation (GPOs).

GPOs are governed by their member organisations, which are mainly hospitals, RHAs and other health care providers. Instead of each hospital signing its own contracts with multiple different pharmaceutical manufacturers, GPOs purchase drugs in bulk on behalf of them. They gather information from their member hospitals about the amount of drugs each hospital needs, and then run a competitive tendering process. The manufacturer with the lowest bid typically wins the entire contract. This enables RHAs and hospitals to obtain procurement efficiencies, including cost reduction and increased access to healthcare goods and services.\(^{111}\) The three largest GPOs in Canada are Medbuy in London (ON), HealthPro in Toronto (ON) and Sigma Santé in Montreal in Quebec (QC).

GPOs are able to achieve cost reductions through buying in bulk. However, due to the aggressive negotiating on prices, this often leads to only one or a few manufacturers being willing to supply the GPOs with the required drugs at the negotiated price. Consequently, many GPOs rely on a single supplier for their drugs. In Ontario, for example, the supply two largest GPOs Medbuy and HealthPRO rely on only one pharmaceutical manufacturer (Sandoz) for the supply of a dozen drugs.\(^{112}\)

In 2008, the Competition Bureau noted that although ‘competitive tendering has the potential to provide large cost savings to public plans in Canada, (…) a frequently expressed concern (…) is that it could lead to shortages when winning bidders are unable to meet demand’.\(^ {113}\) A recent report from the House of Commons found that the practice of GPOs of sole-sourcing drug supplies increases the vulnerability of the drug supply chain and the likelihood of drug shortages.\(^ {114}\)

**Pharmacies**

As of January 2015, national statistics list 9,558 community pharmacies and 285 in-patient hospital pharmacies in Canada, with the majority being located in the provinces of Ontario (3,871) Quebec (1,864), British Columbia (1,231) and Alberta (1,105).\(^ {115}\)

Pharmacies are regulated on a provincial and territorial level. Each provincial and territorial regulatory authority is directly responsible for granting pharmacist licenses, assessing the competency of pharmacists and ensuring public safety.

National leadership in pharmacy regulatory practices is provided through the National Association of Pharmacy Regulatory Authorities, a voluntary association of all provincial and

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\(^{115}\) National Association of Pharmacy Regulatory Authorities 2015; Canadian Pharmacists Association 2015a.
territorial pharmacy regulatory bodies and the Canadian Forces Pharmacy Services.\textsuperscript{116} National Association of Pharmacy Regulatory Authorities develops national guidelines, standards and frameworks to harmonise the regulation of pharmacies and maintains and administers the National Drug Schedules (NDS), which provide guidance on the placement of drugs for provincial and territorial pharmacy regulatory bodies.\textsuperscript{117}

\section*{Drug pricing and reimbursement}

Pharmaceuticals are the second largest component of health care expenditures in Canada, representing around 16 per cent of total expenditures. According to the Canadian Institute for Health Information’s National health expenditure report, Canada spend CAD $33.3 billion on drugs in 2012. Expenditures for 2014 were forecasted at CAD $33.9 billion.\textsuperscript{118} Governments account for 42 per cent of drug expenditures and private payers for the remaining 58 per cent.\textsuperscript{119}

Pricing and reimbursement of drugs is controlled through the Patented Medicine Prices Review Board, the Canadian Agency for Drugs and Technologies in Health (CADTH) through its Common Drug Review (CDR), and through the 17 federal, provincial and territorial public drug plans. As a consequence, drug manufacturers have to obtain approval from 19 different bodies for the price of a new drug.\textsuperscript{120}

\subsection*{Price regulation of patented medicines}

Pricing approval for patented medicines is regulated by the federal government, through the Patented Medicine Prices Review Board (PMPRB). When new patented medicines are introduced to the market, the PMPRB sets a maximum introductory price set for these medicines. PMPRB also limits the rate of rise of prices to the inflation rate.

Prices for patented medicines are regulated at the ‘factory gate’, i.e. the price at which patent holders or their licensees sell patented medicines to bulk purchasers and wholesalers, hospitals and pharmacies. Consequently, the PMPRB has no jurisdiction to regulate prices that bulk purchasers and wholesalers charge to pharmacies, prices that are charged to consumers, or prices negotiated with the federal, provincial or territorial drug plans.\textsuperscript{121}

Patentees are required to submit specified pricing information at introduction of the medicine and on a semi-annual basis to the PMPRB. The Board then undertakes a review of this information to categorise the medicine based on the level of therapeutic improvement: breakthrough, substantial improvement, moderate improvement, or slight or no improvement. A price test determines if the price of the medicine is considered excessive.

\textsuperscript{116} National Association of Pharmacy Regulatory Authorities 2012.
\textsuperscript{117} National Association of Pharmacy Regulatory Authorities 2012.
\textsuperscript{118} Canadian Institute of Health Information 2014, p.13.
\textsuperscript{119} Industry Canada 2015c.
\textsuperscript{120} Bonner & Daley 2010, p.17.
\textsuperscript{121} Patented Medicine Prices Review Board 2015a, 2015b.
In the event of pricing being found to be excessive, the PMPRB may negotiate a voluntary compliance undertaking with the patentee to reduce the price of that medicine or another patented medicine, order a repayment of excess revenues, or do both at the same time.\(^\text{122}\)

**Pricing for generic drugs**

Once a drug comes off patent, generic versions of the drug may be submitted to Health Canada for approval. Once approved through HC, there are two pricing systems for determining the price of the drug that are regulated provincially: One for hospital pricing and another for retail pharmacy pricing.\(^\text{123}\)

**Hospital pricing**

Drugs for hospitals are purchased in bulk by Group Purchasing Organisation (GPOs) through tendering processes. These processes are subject to provincial regulations on internal trade and competitive bidding.

**Retail pharmacy pricing**

Pricing for generic drugs for retail pharmacies are determined by the invoice prices (i.e. the amounts typically reimbursed by public and private drug plans) and the net pharmacy prices (i.e. the price paid by the pharmacy net of any off invoice rebates and discounts). These prices are set by drug manufacturers. In most provinces, manufacturers compete to have their product stocked by pharmacies by offering rebates off invoice prices. Although the Competition Bureau notes in its report that ‘it has not been possible to obtain detailed evidence regarding the size of these rebates’, the rebates are estimated ‘to be 40 per cent of the price the pharmacy is invoiced’.\(^\text{124}\)

Provincial legislation may dictate restrictions on the prices charged for generic products listed on their formularies. British Columbia, for example, uses a pricing model called reference-based pricing to set the price of drugs in certain classes, while Ontario requires that the price of generics must be no more than 25 per cent of the price of the brand name pharmaceutical equivalent.\(^\text{125}\) In Quebec and Ontario, granting of rebates to pharmacies is prohibited by law.\(^\text{126}\)

**Trends and innovation in pharmaceutical supply chain management**

**British Columbia**

The fact that most Canadian provinces lack buying power in times of rising pharmaceutical costs by purchasing drugs in isolation from each other has been seen as one of the major issues of the Canadian health system by contemporary literature. The province of British

\(^{122}\) Patented Medicine Prices Review Board 2015b; Bonner & Daley 2010, p.18.


\(^{126}\) In Ontario, the Ontario Transparent Drug System for Patients Act from 2006 prohibits the granting of rebates to pharmacies. The Act however allows professional allowances, capped at 20 per cent of pharmacies’ cost for drugs dispensed under the Ontario Drug Benefit programs, as a possible alternative to rebates (Ibid.)
Columbia (B.C.) has been quite innovative in addressing this issue through a combination of public drug plan reforms and several initiatives aimed at increasing efficiencies along the pharmaceutical supply chain.

**Fair PharmaCare**

In 2003, B.C. moved from an age-based coverage of prescription drugs to an income-based drug plan through the introduction of Fair PharmaCare.

Fair PharmaCare offers coverage of prescription drugs based on annual net income. Families with an annual net income of at least CAD $30,000 pay the full amount of the cost of prescription drugs until the reach the income-tested deductible, after which PharmaCare pays 70 per cent of the cost for the remainder of the year. If costs of prescription drugs reach the maximum of 4 per cent of the annual net family income, PharmaCare covers 100 per cent of eligible drug costs for the rest of the year.127

Most B.C. residents are covered by the Fair PharmaCare, which is the largest of the drug coverage plans under the B.C. PharmaCare program.

**Joint purchasing initiatives**

In addition to its public drug plan reforms, B.C. has been able to leverage buying power and increase process efficiency by managing its supply chain for pharmaceuticals through a single entity, Health Shared Services British Columbia (HSSBC).128 HSSBC was created in March 2010 and is governed by a management board that is made up of the CEOs from the six health authorities, the Chief Operating Office of the Ministry of Health and two external members. The Health Shared Services BC Management Board has a system-wide planning perspective and provides strategic guidance as it relates to the provision of shared services to the health authorities across the province.

The purpose of shared services is to enable the health authorities to be more effective and efficient by integrating common non-clinical service delivery. HSSBC is responsible for all purchasing, inventory, warehousing and delivery functions for BC’s six health authorities. The supply chain process includes creating a request for supplies, submitting the order to a supplier/distributor, receiving the product at a regional warehouse delivering to the end user, and paying the supplier/distributor. The warehouses are automated and installed with carousels.

Contracts ranging from CAD $20 to $100 million and contracts for high value and critical drugs are directly managed by HSSBC. Contract management for lesser value generics and drugs that are not considered critical is outsourced to Group Purchasing Organisations (GPOs).129

As a not-for-profit organisation, HSSBC is funded by the six participating health authorities to perform these services. Any savings realised are distributed back to the health authorities for reinvestment in patient care.

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127 Health Council Canada 2013, p.4.
128 Namely the Provincial Health Services Authority, Interior Health, Fraser Health, the Vancouver Costal Health Authority, the Vancouver Island Health Authority and Northern Health
129 Information sourced from an interview by Sapere with HSSBC representative on 29 July 2015.
The advantages of such an arrangement is better buying power in negotiating with manufacturers, better oversight, control and management of the hospital requirements.

Buying power has also been combined on the cross-provincial level. In 2009, HSSBC and Alberta Health Services signed a joint bulk purchasing agreement to consolidate their procurement of drugs, supplies, and equipment used in hospitals. The agreement combines purchases for the two provinces through a contract with HealthPRO, a group purchasing organisation (GPO) owned by participating health agencies. The Saskatchewan and Winnipeg Regional Health Authorities have recently joined the agreement.\textsuperscript{130}

**Government-owned distribution facilities**

British Columbia also operates the Product Distribution Centre a full-service inventory management and distribution facility established for the use by government ministries, municipalities, the broader public sector and publicly-funded agencies. The Product Distribution Centre operates as a full service dispensing pharmacy that provides drug procurement, warehousing and distribution services.\textsuperscript{131}

The Production Distribution Centre provides a range of consulting services, including drug information research, assistance in the development of drug distribution policies and procedures, and drug formulary; and assistance in the establishment and customisation of treatment protocols.\textsuperscript{132}

The Centre operates on a full cost-recovery basis with fiscal annual recoveries that range between CAD $30 to $35 million.

**National government agencies**

**Key organisations**

**Health Canada**

Production, import, export, transport and sale of drugs are regulated under the *Food and Drugs Act 1985*.\textsuperscript{133} The *Act* authorises Health Canada as the federal regulator to assess the safety, efficacy and quality of drugs. Health Canada approves drugs that ‘have an acceptable risk/benefit profile’ and enforces regulatory requirements of approved drugs, such as labelling, packaging, importing and manufacturing practices.\textsuperscript{134} Health Canada also manages the Drug Product Database (DPD), which contains product specific information for all drugs approved for use.\textsuperscript{135} Drugs that have not been issued a marketing authorisation by Health Canada – known as Notice of Compliance or ‘Notice of Compliance with

\footnotesize{\textsuperscript{130} Health Council Canada 2013, pp.4-5.
\textsuperscript{131} As viewed at \url{http://www.pss.gov.bc.ca/pdc/home.html}
\textsuperscript{132} As viewed at \url{http://www.pss.gov.bc.ca/pdc/home.html}
\textsuperscript{133} Health Canada pursues its regulatory mandate under the *Food and Drug Regulations* (C.R.C., c. 870).
\textsuperscript{135} Health Canada 2015.}
Conditions’ – cannot be sold in Canada. Health Canada is not involved in the regulation of drug prices.136

**Canadian Agency for Drugs and Technologies in Health**

Once a drug has been approved for sale by Health Canada, the publicly funded drug plans of each province and territory assess whether the drug is eligible for public reimbursement. Since 2003, this assessment process is called Common Drug Review, and is undertaken by the Canadian Agency for Drugs and Technologies in Health (CADTH), an independent not-for-profit organisation funded by federal, provincial and territorial governments.137 Under CADTH’s mandate, the Common Drug Review process accepts drug submissions from manufacturers and evaluates clinical, economic, and patient evidence on drugs.138 The Canadian Expert Drug Advisory Committee, which is composed of drug therapy and evaluation experts, then makes reimbursement recommendations to the participating public drug plans to support their formulary listing decisions.139

CADTH is also in charge of the pan-Canadian Oncology Drug Review Process (pCODR), which reviews all oncology whether they are eligible for public reimbursement.140 Each participating province and territory decides whether or not to reimburse an oncology drug based on recommendations by the CADTH pCODR Expert Review Committee (pERC) and other factors such as their program mandates, jurisdictional priorities, and budget impact.141

**Patented Medicine Prices Review Board**

The Patented Medicine Prices Review Board is an independent quasi-judicial body that was established in 1987 under the *Patent Act* that regulates prices for all prescription and non-prescription patented drugs sold in Canada.142 The Board:

- reviews the prices that the holders of the patent charge for the patented medicines at the ‘factory gate’;
- establishes a maximum price that can be charged for patented medicines;
- orders price reductions and/or the offset of excess revenues if the price of a patented medicine is considered too excessive; and
- provides transparency in the market through an annual report to the federal parliament on trends in pharmaceutical sales and pricing for all patented medicines as well as annual research and development expenditures of patent-holding drug manufacturer.143

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137 The Common Drug Review process includes six federal, nine provincial and three territorial drug plan, with the exception of Quebec. In Quebec, approved drugs are assessed through the Conseil du médicament.
138 CADTH 2015b.
139 ISPOR 2011.
140 Participating provinces and territories include Manitoba, Saskatchewan, British Columbia, Alberta, Nova Scotia, Newfoundland, Prince Edward Island, and New Brunswick.
141 CADTH 2015a.
142 Patented Medicine Prices Review Board 2015a; ISPOR 2011.
143 Patented medicines include prescription and over-the-counter drugs, vaccines, biologics and veterinary drugs.
PMPRB does not have jurisdiction over the prices of non-patented drugs, such as generics, prices charged by wholesalers or pharmacies or over pharmacists’ professional fees.

**Other departments**

Other federal departments that play a role in the pharmaceutical supply chain – in the event of drug shortages – are the Public Health Agency of Canada and Public Works and Government Services Canada.

PHAC maintains a limited stock of select drugs in the National Emergency Stockpile System to enable emergency access to provinces and territories in the event of drug shortages, a mass casualty event or pandemic.\(^{144}\) The agency is also part of the Vaccine Supply Working Group (VSWG) which monitors the supply and prices of vaccines and develops principles, guidelines and strategies for addressing vaccine supply and quality issues.\(^{145}\)

Public Works and Government Services Canada manages the Federal/Provincial/Territorial Bulk Purchasing Program to assure a safe supply of vaccines for Canadians. Contracting decisions are overseen by the VSWG.\(^{146}\)

**Provincial and territorial governments**

In Canada, funding, managing and delivering health care – including prescription drug coverage – is primary responsibility of the provinces and territories, guided by the provisions of the *Canada Health Act 1984*.

Each of Canada’s 10 provinces and 3 territories manages its own publicly funded drug plan, defines which new and generic drugs are eligible for reimbursement, and under which conditions, and negotiates contracts with bulk purchasers and wholesalers to purchase drugs.

Before 2003, each jurisdiction would conduct its own drug review and decide independently if a drug is reimbursed through the publicly funded drug plan. With the introduction of the Common Drug Review process in 2003, the 18 independent review processes that existed in different jurisdictions in Canada have been replaced.\(^{147}\)

**Rapid Review Process – Ontario**

Although the province of Ontario participates in the Common Drug Review and the pCODR processes, a drug may also qualify for the Ontario Ministry of Health and Long-Term Care’s Rapid Review Process. This is the case if evidence is submitted showing that the new drug ‘will either fill a significant unmet medical need or that listing will result in significant savings for the drug plan or the Province’.\(^{148}\) Submissions can be made before the drug receives the Notice of Compliance by Health Canada, but not earlier than 90 days

\(^{143}\) Patented Medicine Prices Review Board 2015a; Bonner & Daley 2010, p. 17.

\(^{144}\) PHAC 2012.

\(^{145}\) Health Canada 2014; Alberta Health 2014.

\(^{146}\) Health Canada 2014; Alberta Health 2014.

\(^{147}\) CADTH 2015b.

\(^{148}\) ISPOR 2011.
before the expected NOC. The decision on whether the drug is included in the public drug plan is made by the Assistant Deputy Minister and Executive Officer, Ontario Public Drug Programs.  

**Conseil du médicament – Quebec**

In Quebec, approved drugs are assessed through the Conseil du medicament. Similar to the CADTH, the Conseil du médicament accepts submissions from manufacturers and makes recommendations for drugs that are eligible for reimbursement through the provincial public drug plan. Final listing decisions are made by the Ministry of Health and Social Services Quebec through the Minister of Health.

**Funding**

Canada has a publicly funded universal medicare system. However, this system – with some exceptions for drugs administered in hospitals and for certain populations – does not cover prescription drugs. The majority of the population (about 66 – 68 per cent) obtains drug coverage through private health insurance plans, either individually or through their employers.

**Public drug plans**

Public funding of prescription drugs is primarily operated on a provincial and territorial basis. Each province and territory maintains its own public drug plan to provide coverage for residents who choose to join the plan or are not able to afford private insurance. Formularies and prices differ from province to province. Under the terms of the Canada Health Act, all drugs administered in hospitals are fully funded by the public health care system for all Canadians with no co-payments.

Hospital drug formularies are under provincial purview. Hospital Pharmacy and Therapeutics Committees make decisions about which new drugs should be added to their formularies. Global hospital budgets are set by the provincial governments through their Ministries of Health.

The Canadian Government assists in funding provincial and territorial health care insurance programmes. In addition, the Government provides prescription drug coverage for members of eligible groups, such as First Nations and Inuit, inmates in federal penitentiaries, members of the Royal Canadian Mounted Police, members of the military and veterans, through its Federal Public Drug Benefit Programs. According to the OECD,

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149 Ministry of Health and Long-Term Care 2014; 2007; ISPOR 2011.
150 Régime Public D’Assurance Médicaments – Public Drug Insurance Program
151 Ministry of Health and Social Services Quebec 2015.
152 Morgan et al. 2015, p. 491; O’Brady et al. 2015, p.224.
153 ISPOR 2011; Kratzer et al. 2013, p.3.
154 British Columbia, for example, uses a pricing model called reference-based pricing to set the price of drugs in certain classes.

Disclaimer: Strategic think piece on pharmaceutical margins – not Government policy or DHB direction.
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approximately 10 million Canadians are covered by publicly funded drug plans, 9 million through the provincial and territorial plans and 1 million through the Federal Public Drug Benefit Programs.\textsuperscript{156}

\textsuperscript{156} Paris & Docteur 2007, p.17.
Appendix 3 – United Kingdom

The model of funding and distribution for pharmaceuticals in the United Kingdom (UK) varies between each country. This section will outline the model in England and then how Scotland and Wales vary from this.

Funding flows

The English and Welsh community pharmacy funding models are not dissimilar to that of New Zealand. The funding is comprised of a fixed amount to cover service fees which are constituted of essential (or core) services and advanced (specific) services, and a ‘flexible pool’ of retained margins.

Figure 8: Pharmacy funding flows – England and Wales

For the purposes of this report we are interested in the retained margins aspect of the funding flow. The retained margin is the difference between the price the pharmacy pays for the medicine and the price reimbursed by the NHS. This is the pharmacy’s profit.

The Scottish funding system is similar to that of England, however it consists of core service funding (or global sum), a margin sharing arrangement and additional funding elements. For the purposes of this report we are interested in the margin sharing arrangement.

Below is a table of the margins over the last few years
Spot checks are undertaken to ensure the level of margins achieved on both generic and proprietary pharmaceuticals.

**Margin between Government and manufacturer**

The prices of branded prescription medicines supplied to the National Health Service (NHS) by the pharmaceutical industry are indirectly controlled through the Pharmaceutical Price Regulation Scheme (PPRS). It is a voluntary agreement negotiated between the UK Government and Northern Ireland, represented by the Department of Health, and the pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry. The Department of Health includes the Health Departments of England, Wales, Scotland and Northern Ireland.

The PPRS controls the profits that pharmaceutical companies are allowed to make through their trade with the NHS, whilst recognising that the industry needs to earn enough money to enable it to develop and market new and improved medicines. The PPRS applies to all licensed, branded medicines sold to the NHS (community and hospitals). It does not cover generic medicines nor over-the-counter medicines sold to the general public. Price information is also provided in the British National Formulary.\(^{157}\)

Scheme M is a voluntary agreement between generic manufacturers and the government that agrees the price that the government will reimburse for generic medicines. This scheme is labelled as category M in the Drug Tariff for England and Wales that is published monthly. The Drug Tariff contains information regarding the prescribing, dispensing and reimbursement of medicines and appliances on primary care NHS prescriptions. The reimbursement price that the government will pay for generic medicines is agreed based on a volume weighted average price charged by the manufacturers.\(^{158}\) Scotland exited from the

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\(^{158}\) For more detail refer to Scheme M download available at; [http://psnc.org.uk/funding-and-statistics/funding-distribution/retained-margin-category-m/](http://psnc.org.uk/funding-and-statistics/funding-distribution/retained-margin-category-m/)
scheme in 2011/12 and has its own drug tariff\(^{159}\) which contains all the generic pricing under section 7.

**Margin between wholesaler and pharmacy**

The margins charged between the wholesaler and the pharmacies are covered under scheme W. This scheme is focused on the sharing of data between the wholesaler and government that supports the category M pricing process. The reimbursement price within the tariff can be altered on a monthly basis to match expected demand on the retained margins funding pool.

To avoid pharmacies having to submit individual discounts received for the drugs it has purchased, a standard ‘discount deduction’ is allocated against medicines which is currently assumed to be 8.6 per cent. This is set from data submitted quarterly by the manufacturers and wholesalers.

A margins survey is undertaken annually which audits 120 community pharmacies to verify the purchase prices and quantities of drugs. The difference between these amounts is then clawed back.

Scotland sets its own drug tariff costs and applies spot checks to ensure the margins are being allocated correctly.

In England, £800 million pounds of the £2.8 billion national funding framework are allocated under this revenue stream (referred to as the retained profit margin) in 2014/15.

The 2014/15 payment has been calculated to be worth 3.3 pence on each professional fee. This would equate to £2,000 GBP for a pharmacy dispensing approximately 7,000 items per month.

Certain products are exempt from the discount deduction process (these are called the DNG list ‘discount not given’) such as controlled drugs or cold-chain items.

There are alternate mechanisms of getting the product to the patients that bypasses both wholesaler and/or the pharmacy. These are ‘Direct-to-Pharmacy’; model whereby manufacturers operate with a single distributor which can bypass usual wholesalers, and/or manufacturers and DHBs distributing some medicines straight to patients such as special foods or special authority prescriptions.

**Distribution**

As well as the community pharmacy model of distributing drugs to patients, there are other options such as mail order or dispensing doctors.

The UK model also has other factors for consideration when looking at the margins issue, one is that there is additional funding or payment available for broken bulk packs, and there are also ‘dispensing doctors’ that are used.

Broken bulk
‘Broken bulk’ payments apply to certain categories of medicines where the complete pack can be claimed for even if a lesser amount is dispensed, if it is unlikely they will dispense the rest in a six month period. This can only be claimed once for a particular medicine in a six month period; any subsequent dispensing within that time is presumed to have been made from the same broken pack. This is to encourage pharmacists to fulfil their contracting obligations and dispense where it may have a financial disadvantage for them to do so;

“Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the Terms of Service), contractors are required to fulfil all prescriptions for medicines with reasonable promptness. The ‘Standards of conduct, ethics and performance’ issued by General Pharmaceutical Council (GPhC) in September 2010 also states that a pharmacist must make sure that their professional judgement is not affected by “personal or organisational interests, incentives, targets or similar measures.”

Dispensing doctors
In the UK there were approximately 6,300 dispensing doctors operating out of 1,059 practices in 2014. Dispensing doctors are general practitioners who can dispense medicines to their patients if the patient meets the relevant criteria and wishes them to. It is a service that is generally used to ensure access to pharmaceuticals for patients in rural areas and those who may not otherwise have access to a community pharmacist. Nearly 7% of all prescribed medicines were dispensed by a doctor in the UK in 2014. However this model is changing with an increase in the number of dispensing doctors coinciding with a decrease in dispensing practices as practice amalgamate and/ or col-locate with pharmacies.

One in ten Scottish practices dispenses medicines however this practice is considered as a requirement by the NHS Board where no pharmaceutical services exist and is not considered the provision of pharmaceutical services per say. This means that the doctors are providing an essential service but there is a push to support more community pharmacies to establish themselves where there are no pharmacies. Scotland still adheres to the essential small pharmacies payment system which was ceased in England and Wales in 2006.
Appendix 4 – United States

Overview of the US pharmaceutical supply chain

The key agencies involved in the pharmaceutical sector in the US include:

• The U.S. Food and Drug Administration (FDA), as the federal regulator, monitors the safety, effectiveness, quality, and security of drugs and vaccines. Within the FDA, the Center for Drug Evaluation and Research evaluates and approves New Drug Applications to ensure that drugs marketed in the United States are safe and effective.\(^{160}\)

• Pharmaceutical manufacturers conduct research and clinical trials to receive approval for sale by the FDA. Once approved, manufacturers produce drugs and distribute them to pharmaceutical wholesalers and self-warehousing chain pharmacies.

• Wholesaler and self-warehousing chain pharmacies in term distribute drugs to hospitals and retail, mail-order and other types of pharmacies. From here, drugs are delivered to the consumer.

• Pharmacy Benefits Managers (PBMs) manage the pharmacy benefit component of health care plans. Manufacturers also negotiate payments with PBMs.

An illustration of pharmaceutical distribution and reimbursement in the US is provided in Figure 10. A brief description of each player’s role within supply chain is provided below.

Figure 10: Pharmaceutical distribution and reimbursement in the US

Source: Fein 2014b, p.7.

\(^{160}\) FDA 2014a; 2015a.
Pharmaceutical manufacturing
Pharmaceutical manufacturers produce branded and generic pharmaceuticals which they distribute particularly to wholesalers and self-warehousing chain pharmacies. Direct sales to hospitals, retail and mail order pharmacies, and physician are relatively limited and not common.161

The US pharmaceutical manufacturing sector is dominated by a few large, multinational firms. Six of the world’s 10 largest pharmaceutical companies are based in the US, the other four in Europe.162

Pharmaceutical Research and Manufacturers of America is the peak industry association representing the pharmaceutical industry in the United States.163

Distribution of pharmaceuticals
Distribution of pharmaceuticals in the US is based on a centralised distribution model, whereby prescription drugs are packaged and sent from central warehouse locations instead of pharmacies.

A 2005 report described the US pharmaceutical supply chain as follows:

Pharmaceuticals originate in manufacturing sites; are transferred to wholesale distributors; stocked at retail, mail-order, and other types of pharmacies; subject to price negotiations and processed through quality and utilization management screens by pharmacy benefit management companies (PBMs); dispensed by pharmacies; and ultimately delivered to and taken by patients.164

Wholesalers
Once approved through the FDA, drugs are distributed by pharmaceutical manufacturers through wholesalers and self-warehousing chain pharmacies. These in term distribute pharmaceuticals to hospitals, retail and mail-order pharmacies and other medical facilities.

In addition, wholesalers and self-warehousing chain pharmacies provide complementing services around the distribution of drugs, such as repackaging of pharmaceuticals, disease management services and drug buy-back programmes. Large wholesalers also contract with smaller retail and independent pharmacy chains that lack of bargaining power to negotiate contracts with manufacturers on their behalf.

Following a period of consolidation in the last 30 years, the number of wholesale distributors declining from approximately 200 in 1975 to fewer than 50 in 2000.165 Today, the three largest wholesalers McKesson, Cardinal Health and AmerisourceBergen generate about 85

162 Source: http://www.who.int/trade/glossary/story073/en/
163 Pharmaceutical Research and Manufacturers of America 2015.
165 OECD 2014b, p.3; Health Strategies Consultancy LLC 2005, p. 9.
per cent to 90 per cent of all revenues from drug distribution in the United States.\textsuperscript{166} In addition to nationally operating wholesalers, there are a number of smaller regional and specialised companies that are licensed as wholesalers operate in the US market.

Pharmacies
Multiple types of pharmacies operate in the US, including independent pharmacies, chain pharmacies, pharmacies in supermarkets and other retail outlets, mail-order pharmacies (typically operated by PBMs), long-term care pharmacies (which provide packaging and other services to long-term care facilities and similar settings), and specialty pharmacies.\textsuperscript{167} Most US consumers obtain their prescription medications at retail pharmacies.

In 2015, there were 61,668 pharmacies in the US, including chain pharmacies (38,076), independent pharmacies (21,285), government-owned pharmacies (1,207), franchise pharmacies (607), pharmacies owned by health maintenance organisations (325) and pharmacies owned by universities or schools (168).\textsuperscript{168} The largest national pharmacy chain is Walgreens in Deerfield (IL), followed by the CVS Corporation in Woonsocket (RI) and Walmart Stores Inc. in Bentonville (AR).\textsuperscript{169}

US pharmacies predominately purchase their drugs from pharmaceutical wholesalers. However, large pharmacies, mail-order pharmacies and specialty pharmacies may source their supply directly from manufacturers if they have the required infrastructure (warehouse facilities, distribution vehicles, inventory systems).\textsuperscript{170}

Pharmacies negotiate with manufacturers or wholesalers for discounts and rebates based on volume sales or market share. In addition, they negotiate directly with PBMs for inclusion in their Pharmacy Networks to provide pharmacy services to members of the health plans administered by the PBMs.\textsuperscript{171}

Supermarkets and mail-order pharmacies
In the recent years, supermarkets have been gaining prescription market share. From 2012 to 2013, the number of prescriptions dispensed through supermarket pharmacies increased from 522 million to 536 million (2.7 per cent increase) which corresponds to an increase in market share of 0.3 per cent.\textsuperscript{172}

By contrast, mail prescriptions have been declining in absolute size and market share. The number of prescriptions dispensed through mail pharmacies declined by 9.2 per cent from

\textsuperscript{167} OECD 2014b, pp. 3-4.
\textsuperscript{168} SK&A 2015, p.3.
\textsuperscript{169} SK&A 2015, p.2.
\textsuperscript{170} OECD 2014b, p.4.
\textsuperscript{171} Health Strategies Consultancy LLC 2005, p.2.
\textsuperscript{172} Fein 2014a, IMS Institute of Healthcare Informatics 2014, p.49.
717 million prescriptions in 2012 to 651 million in 2013, which corresponds to a loss in market share from 16.7 per cent in 2012 to 15.2 per cent in 2013 of 1.5 per cent.173

State Drug Discount Programmes and Buying Clubs

In the US, a number of states have established State Drug Discount Programmes, sometimes termed ‘Rx Buying Clubs’ or ‘Discount Cards’. Rx Buying Clubs organises their members’ collective buying power, i.e. the large-volume purchasing power of the states, to negotiate discounts on a wide range of prescription drugs and generics and to purchase drugs that are difficult to be obtained independently.

They typically contract with Pharmaceutical Benefit Managers (PBMs), which in term handle the price negotiations with the drug suppliers.174 Up to 2014, 27 states have created or authorised Rx Buying Clubs that offer drug discounts for eligible or enrolled residents, from which 16 are currently in operation.175 Some states charge a small fee to cover pharmacists’ professional services and the administration of the programmes, which ranges from USD $20 to USD $35. Fees may be waived for low-income members.

Pharmaceuticals are distributed through participating pharmacies. Participants typically pay the resulting discounted price at the pharmacy counter.176 In Ohio, for example, instead of paying a participating pharmacy’s usual charge to an individual with no drug insurance coverage, participants pay the so called ‘Best Rx price’. The Best Rx price is ‘the weighted average of what the state employee and state retiree health plans pay for that prescription, minus any rebate offered to the program by the drug’s manufacturer’.177

Most states that have implemented Rx Buying Clubs emphasise on supporting population segments, such as populations over the age 65 or populations with total and permanent disabilities. Eligibility criteria vary between states. All states however require participants to be state residents.178

Pharmacy Benefit Managers

Pharmacy Benefit Managers (PBMs) are third party administrators that manage pharmaceutical costs for health plans sponsors, such as self-insured employers, insurance companies, and health maintenance organisations. Their objective is to provide high-quality

A complete list of Rx Buying Clubs in the United States can be found at http://www.statersplans.us/.
177 Ohio’s Best Rx 2015.
178 StateRxPlans 2015a; 2015b; 2015c; 2015d.
drug care at the lowest possible cost.\textsuperscript{179} Approximately two-thirds of all prescriptions written in the US are processed by a PBM.\textsuperscript{180}

PBMs achieve lower drug prices for plan sponsors by:

- managing formularies;
- negotiating price discounts and rebates from retail pharmacies and pharmaceutical manufacturers; and
- developing and maintaining pharmacy networks, where pharmacies are preferred when they offer discounted prices to plan sponsors.

In addition, most PBMs in the US run their own mail-order pharmacies, which enable them to reduce costs through efficiency gains achieved through using automated dispensing processes and increasing generic or therapeutic substitution. Additional services provided by PBMs include prospective and retrospective drug utilisation reviews (DURs), the promotion of prescription compliance and disease management programmes.\textsuperscript{181}

## Drug pricing

Drug pricing in the US is influenced at different levels of the pharmaceutical supply chain. Pricing is determined at three transaction areas along the supply chain, i.e.:

- at the transaction between manufacturers and wholesalers
- at the transaction between wholesalers and retailers, and
- at the transaction between retailers and patients.\textsuperscript{182}

Pharmaceutical manufacturers have the most influence over drug prices in the US, as they establish the Wholesale Acquisition Cost (WAC), i.e. the price at which wholesalers and self-warehousing chain pharmacies purchase drugs from them. The WAC is a published catalog or list price determined by manufacturers based on forecasted demand, projected marketing costs and competing drugs in the market. Most wholesalers receive discounts and rebates on the WAC by manufacturers based on market share, volume and prompt payment.\textsuperscript{183} The Average Manufacturer Price (AMP), i.e. the average price paid to manufacturers by wholesalers for drugs distributed to retail pharmacies, takes these discounts and rebates into account.\textsuperscript{184}

\textsuperscript{179} FDA 2011; OECD 2014b, pp.3-4.
\textsuperscript{180} Health Strategies Consultancy 2005, p.2.
\textsuperscript{181} Health Strategies Consultancy 2005, p.2.
\textsuperscript{182} Mattingly, J. 2012.
\textsuperscript{183} Source: Berndt & Newhouse 2010, pp. 11-12.
\textsuperscript{184} The Average Manufacturer Price was a benchmark created by Congress in 1990 in calculating Medicaid rebates and is not publicly available.
Source: Health Strategies Consultancy 2005, p.28.
Wholesalers in turn sell drugs to retail and mail order pharmacies, usually at a few per cent above the WAC, and at a 15 to 20 per cent or larger discount off the Average Wholesale Price, the national average of list prices charged by wholesalers to pharmacies.\(^{185}\)

The Average Wholesale Price has two purposes: It serves third-party payers as the basis for reimbursement and as base price for negotiations between manufacturers and purchasers of drugs, such as health plans, PBMs and self-insured employers.\(^{186}\)

The final price at which pharmacies purchase a drug from wholesalers as defined, calculated and reported by the relevant state Medicaid programmes is called the Average Acquisition Cost (AAC). The Average Acquisition Cost includes all deductions from rebates and discounts and is derived from audits of pharmacy invoices.

States are required by law to reimburse prescription drugs based on the Estimated Acquisition Cost (EAC) or the usual or customary charge to the public. Most states use the Average Wholesale Price to calculate the EAC. In addition, the federal government sets a price ceiling for certain drugs, the Federal Upper Limit (FUL). The FUL limits the amount at which multi-source drugs can be reimbursed by state Medicaid programs. It is established for drugs that have three or more versions rated therapeutically equivalent. Pharmaceutical manufacturers that want their drugs covered by Medicaid must provide rebates to Medicaid programmes, which are usually the larger of 15.1 per cent of the Average Manufacturer Price or the difference between the Average Manufacturer Price and the lowest price the manufacturer offers to other purchasers.\(^{187}\)

At the end of the supply chain, patients purchase the drugs from the pharmacies. Patients without insurance cover pay the Usual and customary (U&C) price, or ‘cash price’. Patients that are covered by a health plan do not pay the full U&C price. Instead, they pay their health plan in form of a premium and a small portion of the price when the pick up their prescription drug from the pharmacy. The pharmacy is then reimbursed for the balance by the health plan’s PBM.\(^{188}\)

\(^{185}\) The Average Wholesale Price is sometimes referred to as a ‘sticker price’, as it is not the actual price larger purchaser pay.

\(^{186}\) Health Strategies Consultancy 2005, p.17.

\(^{187}\) Mattingly 2012; and Health Strategies Consultancy 2005, p.25.

\(^{188}\) Mattingly 2012; and Health Strategies Consultancy 2005, p.25.
Appendix 5– Germany

In Germany, over 80 per cent of the population is insured in the Statutory Health Insurance (SHI), which usually covers prescription drugs only.\(^ {189} \) Reimbursement of prescription drugs through the SHI is based on reference prices set by the GKV Spitzenverband (the National Association of Statutory Health Insurance Funds). Any difference between the set reimbursable price and the retail price is paid by the patient, in addition to a general co-payment.\(^ {190} \)

There are approximately 900 companies registered in Germany as being active in the pharmaceutical industry, i.e. producers of licensed pharmaceutical products.\(^ {191} \)

Pharmaceuticals are distributed through different distribution channels, including hospitals, community and mail-order pharmacies. Hospitals dispensing drugs usually purchase the drugs directly from the manufacturer. However, the majority of drugs are distributed through Germany’s 21,000 community pharmacies, from which most are individual, independently-owned pharmacies (16,661).\(^ {192} \)

In Germany, manufacturers of pharmaceutical products are generally free to set their ex-factory prices for generics and prescription drugs. The Arzneimittelpreisverordnung (Ordinance on Drug Prices), however, fixes the margins along the pharmaceutical distribution chain for prescription drugs. Hence, the retail price of a drug is calculated based on the ex-factory price set by the manufacturer and the fixed wholesale and pharmacy surcharges. Due to these fixed margins, the price for a prescription drug is the same in every pharmacy in Germany.\(^ {193} \)

The remuneration of wholesalers varies between human drugs and animal drugs. For drugs approved to be used on humans, the wholesaler margin is set at €0.70 plus 3.15 per cent of the manufacturer price per package, with an upper limit of maximum €37.80 per package.\(^ {194} \)

The remuneration of pharmacies is based on a model combining a fixed fee with a linear mark-up. Pharmacists receive a 3 per cent margin and a fixed pharmacy fee of currently €8.35 plus a lump sum payment of €0.16 per package on pharmaceutical products. However, for pharmaceuticals that are not grouped in reference prices groups, i.e. pharmaceuticals that do not include active ingredients for which reference prices are set,

\(^ {189} \) OECD 2014c, p.2.  
\(^ {190} \) OECD 2014c, pp. 5-6.  
\(^ {191} \) OECD 2014c, pp. 5-6.  
\(^ {192} \) According to the Federal Union of German Associations of Pharmacists (ABDA), there were 20,662 community pharmacies in Germany in 2013, which relates to one pharmacy per 3,846 inhabitants (ABDA 2013, pp. 6-9 & p.12).  
\(^ {193} \) OECD 2014, p.3; Hogan Lovells 2014, pp.15-16.  
\(^ {194} \) vdek(2014, p. 14; Hogan Lovells 2014, p.16.
pharmacists have to grant a range of mandatory discounts that are deducted from their reimbursement claim against public SHI funds. These discounts include:

- a manufacturers discount of 6 to 7 per cent (6 per cent for generic drugs and 7 per cent for prescription drugs) on the ex-factory price for SHI and private health insurance funds;\(^{195}\)
- a generic’s discount of 10 per cent on the ex-factory price for SHI and private health insurance funds; and
- a pharmacist’s discount of currently €1.80, which is granted by pharmacists out of their margin to SHI funds.\(^ {196}\)

Under the German model the remuneration for wholesalers and pharmacists are separate. The margins have a hybrid flat and percentage based structure and the remuneration varies depending on the price of the product.

\(^{195}\) Until 31 December 2013, legislation provided for a mandatory manufacturer's discount at even 16 per cent.

\(^{196}\) Heinsohn & Flessa 2013; Hogan Lovells 2014, p. 16.
Appendix 6– List of interviews

As part of our research to understand emerging trends in logistics and supply chains we talked to several agencies and logistics experts including:

- Australian Government Department of Health
- Australian Government Department of Industry
- Green Cross (New Zealand)
- healthAlliance – New Zealand
- Health Shared Services British Columbia (Canada)
- Onelink (New Zealand)
- Waikato DHB re Pharmacy Margins in Canada, and

- Professor Paul Childerhouse, Professor in Logistics and Supply Chain Management, Massey University.