Submission to

Review of Pharmacy Remuneration and Regulation

30 September 2016

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EXECUTIVE SUMMARY

The Pharmacy Guild of Australia (the Guild) is the peak organisation representing the owners of the community pharmacies that are responsible for dispensing of medicines under the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS) and for the provision of related medicine services, support and advice to the Australian public.

The Guild welcomes the Pharmacy Remuneration and Regulation Review (the Review) which was agreed as part of the negotiation of the Sixth Community Pharmacy Agreement (6CPA).

The Guild agrees with the Panel that the objective of the Review should be to achieve arrangements that are cost-effective, financially sustainable, and effective in delivering quality health outcomes and promoting equitable access and quality use of medicines.

The policy aims articulated for the National Medicines Policy (NMP) are directly relevant to the broader public policy objectives that should guide the Review. The NMP sets out the following four policy objectives for the distribution and supply of medicines to Australian consumers:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

The Review provides a timely opportunity to build on the proven record of the community pharmacy network in ensuring that all Australians have timely and affordable access to the highest standards of pharmaceutical care in accordance with the objectives of the NMP.

The Community Pharmacy Model

The community pharmacy model continues to enjoy very high levels of public trust and support. Qualitative and quantitative research has confirmed that community pharmacies consistently meet the needs and expectations of consumers. Overall, the empirical evidence strongly supports the position that community pharmacy regulation meets the Federal Government’s and the public’s health objectives. While there is always room for improvement, radical changes would invariably create new risks and trade-offs. A high burden of proof should therefore lie on those who advocate change, especially with schemes that are novel and untested.

Medicines are not a normal item of commerce and pharmacies are not like other small businesses in a free market environment. Rather, community pharmacies are explicitly tasked to deliver Quality Use of Medicines (QUM) related health outcomes to patients through the professional dispensing of PBS and RPBS medicines and related services, working effectively as agents of the Federal Government.

The success of the community pharmacy model provides strong support for the Government’s ongoing market stewardship role in the sector. The Government has a legitimate interest in shaping the way in which publicly subsidised medicines and associated services are delivered, particularly as equity of access and patient outcomes are central objectives in public health policies. Given these objectives, it is valid and unsurprising that key features of the community pharmacy model differ from those that would emerge if competition and market forces alone were to determine the location of outlets, or if interdependencies with the broader health system were not important.
The regulation and remuneration of community pharmacy involves a number of strands, including successive Community Pharmacy Agreements (CPAs), as well as rules that govern the location of pharmacies, and their licensing and ownership. Individually and in combination, these provisions have shaped the evolution of community pharmacy to date in a manner that has supported the Federal Government’s broader health objectives.

For over 25 years, this public-private partnership has been successfully underpinned by six successive CPAs, negotiated between the Federal Government representing taxpayers and consumers and the Guild representing the proprietors of the community pharmacies who invest in the privately capitalised infrastructure that enables the delivery of these health outcomes.

These agreements have provided the negotiating parties with the necessary certainty to enable ongoing investment in the community pharmacy network and to ensure that all Australians continue to have timely and affordable access to PBS and RPBS medicines.

The Pharmacy Location Rules (Location Rules) ensure that Australians have a very high level of access to community pharmacies, both in absolute terms and compared to other services. Pharmacy services are readily accessible, not only in well-off urban areas, but also for older and disadvantaged consumers, and for consumers located outside the metropolitan centres. Notably, the Location Rules have not had the effect of unduly restricted competition. The Location Rules have furthermore ensured that high levels of access are achieved with a relatively low number of outlets that are able to secure economies of scale and scope. The effect overall is to support a pharmacy distribution system that is both cost-effective and sustainable, while being equitable and offering choice to consumers.

Pharmacy ownership is not explicitly part of this Review. However, requiring pharmacies to be owned by pharmacists means that health professionals with ‘skin in the game’ focus first and foremost on delivering quality health outcomes to maximise their professional and business goodwill. It also prevents an over concentration in pharmacy ownership and means the Federal Government is not forced to negotiate the CPAs with a small number of entities with substantial market power.

When one recognises the primary purpose of the community pharmacy network and the core responsibility it is tasked with on behalf of the Federal Government, it becomes clear why the regulated community pharmacy model is both effective and superior to any proposed alternative approaches. Indeed, where it has occurred in other countries, the market structure that has emerged following pharmacy deregulation has arguably not served the broader public interest.

**The Future of Community Pharmacy**

The Review rightly asks interested parties to cast their minds forward and envisage the future of community pharmacy. In order to be valid, any future predictions must be informed by an understanding of the major contributing factors to change which include: changing demographics, consumer preferences, medicine trends, government and other funding models, technology, pharmacist practice and international comparisons.

In its submission, the Guild has included a comprehensive piece on the future of community pharmacy along with observations about the integration of pharmacy with the broader health system and the increasing impact of health data on policy-making and service delivery.

While community pharmacy faces a range of challenges, there are significant opportunities for pharmacies that genuinely understand their patients and are able to meet their needs by building on their core medicines expertise and working collaboratively with other health providers in an integrated and technology-enabled, outcomes-focussed approach to health care.
Consumer Expectations and Attitudes

Community pharmacies are the most frequently accessed and most accessible health destination, with over 350 million individual patient visits annually and the vast majority of pharmacies open after-hours, including on weekends.

Community pharmacies regularly achieve consumer satisfaction ratings that are well in excess of 90% with pharmacists consistently recognised as one of the top two or three trusted professions.

However, there is always a need to improve in order to meet consumer expectations and needs.

Consumer surveys consistently report a lack of public awareness and understanding of the patient services available through community pharmacies. They also identify a lack of privacy as an impediment to more consumers using their pharmacies to access a wider array of health services and support.

Australia’s levels of medicine adherence lag world’s best practice and consumers should have ready access to understandable medicines related information and support that is available through a range of channels, including face-to-face with their pharmacist, in the traditional paper form, and online.

It is also important to ensure that consumers have timely access to medicines and other critical community pharmacy products and services after-hours in emergency situations.

The Guild is committed to working with community pharmacies, the government, pharmacists and other health professions, consumers and their representatives in delivering practical enhancements that deliver increased awareness, confidence, accessibility and health outcomes for consumers.

In particular, it is recommended that the Federal Government should fund an ongoing campaign to raise public awareness of the role of community pharmacy as a trusted health destination, and the availability of pharmacy services.

In addition, the Primary Health Networks (PHNs) should provide incentives for local community pharmacies to coordinate emergency after-hours patient access to PBS medicines and other critical community pharmacy services.

Standards, Quality and Compliance

Community pharmacies and pharmacists are among the most highly regulated health providers and health professionals. This is appropriate given their responsibilities and the importance of ensuring the highest standards of safety and quality in pharmaceutical care and pharmacist practice.

The Guild supports the existing multi-tiered approach to regulation, standards, quality and compliance, which includes a requirement that pharmacies are accredited to an Australian quality standard to access a range of government subsidised incentives, as well as a range of professional standards and guidelines, and strict controls in relation to medicines licensing and advertising.

It is important that government and industry regulators consistently apply and enforce all relevant regulatory requirements and professional standards. To that end, it should be ensured that the Pharmacy Board has the necessary authority, funding and support to take a stronger role in regulating professional pharmacist practice across all health settings in the public interest.

Government regulators should ensure that community pharmacies and pharmacists are made fully aware of their regulatory obligations and that there are avenues for redress in the event of breaches.
Complementary Medicines

The Review asks whether it is appropriate for community pharmacies to retail health products such as complementary medicines for which there may not always be the same levels of therapeutic evidence that is expected of PBS listed and other scheduled medicines.

Consumer research clearly shows that consumers want and expect community pharmacies to stock these products in an environment where they are able to seek advice from a trusted health professional.

Community pharmacies should not be precluded from stocking legal health products. However, to provide consumers with the necessary confidence regarding the safety, efficacy and responsible marketing of complementary medicines, it should be ensured that the Therapeutic Goods Administration (TGA) implements strong and transparent licensing and marketing arrangements for these products.

Sustainability of the PBS, viability of community pharmacies and the supply chain

After nearly ten years of reforms, including Price Disclosure, the PBS has become one of the most sustainable parts of the health system, growing more slowly than other major health cost drivers like the MBS and public hospitals. During the 6CPA between 2015 and 2020, it is estimated that PBS reforms will deliver $20 billion in savings to the Federal Government.

While community pharmacy has helped facilitate these important and necessary reforms, it must be recognised that they have a real impact on the ability of pharmacies to remain viable, employ staff and provide patient services, support and advice.

While the 6CPA provides a floor under official dispensing remuneration, the loss of trading terms continues to seriously undermine dispensing margins and put the viability of many community pharmacies at risk. This makes it vitally important that future CPAs reinvest a fair proportion of the savings from PBS reforms into ensuring that the core clinical role of dispensing remains viable and is remunerated at a level that reflects the cost pressures on pharmacies.

It is the interests of both consumers and community pharmacies that the medicines supply chain is sustainable. The 6CPA and future agreements should include a wholesale mark-up floor that takes into account the impact of the PBS reforms as well as maintaining the Community Service Obligation (CSO) so that all Australians have timely access to the full array of PBS medicines, regardless of where they live.

Dispensing and related services

The role of community pharmacists in delivering QUM outcomes is more important than ever, with our ageing population and the growing prevalence of complex, chronic health conditions making it vital that medicine adherence is maximised and adverse medicine events are minimised.

Dispensing is the core clinical service performed by community pharmacists with the same professional obligations for assessment, review and counselling applying equally for all prescriptions. The remuneration for dispensing medicines should not vary based on whether the prescription is an original or a repeat or whether the dispensing is considered to be simple or complex. Time-based systems of remunerating medicine dispensing would be impossible to administer, encourage gaming and undermine genuine patient care and support.

The optional $1 co-payment discount undermines the universality of the PBS and should be abolished. Instead there should be a thorough review of all PBS Patient Co-payments and Safety Net Threshold levels to ensure that PBS medicines are affordable for consumers.
Certain dispensing related services provided by community pharmacists, where there is a strong evidence of positive benefits for patients, should be remunerated on a fee-for-service basis. These include Dose Administration Aids (DAAs), Staged Supply (SS) and enhanced Clinical Interventions (CIs) such as Prescription Adaptation and Non-Dispensing.

The Opiate Dependence Treatment (ODT) program should be funded consistently across Australia both for pharmacies and eligible patients.

The National Diabetes Services Scheme (NDSS) should be funded and administered parallel to the PBS with pharmacies also receiving funding to have an enhanced role in supporting patients with diabetes.

The Federal Government should take responsibility for the national implementation of a real-time recording system for Controlled Drugs. The S2 and S3 medicines schedules should be maintained.

Funding for chemotherapy should reflect the efficient costs of delivery. It should not differentiate between TGA and non-TGA facilities and should be administered through PBS Online.

The Rural Pharmacy Maintenance Allowance (RPMA) should continue with the RPMA matrix reviewed to ensure the allowance continues to be targeted to pharmacies where there is a geographic and community need.

**Medication management services**

The Guild recognises the importance of evidence-based medication management support services in achieving QUM outcomes. All Federally-funded pharmacist professional services should be evaluated for their clinical and cost-effectiveness with established medicines management services such as Home Medicines Reviews (HMRs) targeted at those patients with greatest clinical need and the least capacity to pay.

All pharmacist delivered professional services should be delivered to a recognised quality standard and should be uploaded to an e-health record to ensure coordinated patient care. Medicine related services delivered by pharmacists in health settings outside community pharmacy should be funded separately from the CPAs; should not duplicate community pharmacy medicine related services; and should provide a link back to the patient's usual community pharmacy.

**Community pharmacy and primary health care**

The successful future of community pharmacies and the pharmacist profession are intricately linked to their ability to integrate with the broader primary health care system.

Immediate action can be taken to better utilise community pharmacies to the benefit of patients and the broader health system across a range of areas of health need including: minor ailments, the ordering of pathology tests, vaccinations, continued dispensing and prescription renewal, a new medicines service and the establishment of community pharmacy health hubs in areas of unmet need, which would have a strong focus on health checks, risk assessment, triage and referral.

At the same time, the Federal Government should remove the policy and regulatory barriers that are preventing community pharmacies and pharmacists from being fully recognised as essential participants in an integrated health care system. The role of community pharmacy and pharmacists as medicines experts needs to be explicitly recognised in relation to the Health Care Home, the PHNs, the funding of pharmacy services by Private Health Insurers, the National Immunisation Program (NIP) and the Community Care and Home Support Programs.
E-health, e-prescriptions, and medicines data

As part of the broader integration of community pharmacy into the health system, it is vital that dispensing and medicine-related community pharmacy services are incorporated into the e-health system with community pharmacies receiving financial incentives that reflect the value of their work uploading and maintaining medicine profiles in the MyHealth Record.

Any transition to paper optional prescriptions should be approached with caution, with a need to prohibit the channelling of patients by prescribers and to ensure that patients continue to receive the necessary levels of professional pharmacist counselling required to deliver QUM outcomes.

With future health decisions at all levels increasingly dependent upon the intelligent analysis of rich sources of health data, it will be important that government maintains and provides open and secure access to PBS and related data in order to inform health policy development and population health planning and service delivery.

High cost medicines, Section 100 listed items, and hospital pharmacies

The Federal Government needs to urgently address the issues associated with the supply and dispensing of very high cost medicines, such as the recently listed Hepatitis C drugs, either by creating a high-cost PBS schedule capping the amount paid by wholesalers and pharmacies or through a consignment model.

A number of anomalies between the remuneration for S90 community pharmacies and S94 hospital pharmacies also need to be addressed in ways that enhance patient access to medicines, make greater use of Hospital Medicine Charts and increase the level of transparency in the hospital pharmacy supply chain. Large corporate private hospital providers should not be able to use their hospital pharmacy buying power to supply medicines to associated community pharmacy franchises.

A broad range of issues, anomalies and inconsistencies relating to the supply and dispensing of Section 100 medicines also need to be urgently addressed.

Supply of medicines and pharmacy services for Aboriginal and Torres Strait Islander Peoples

With Aboriginal and Torres Strait Islander Peoples the most disadvantaged of consumers, the supply of medicines and pharmacy services are critical to enhancing their health outcomes and Closing the Gap (CTG).

The existing array of community pharmacy related services for Aboriginal and Torres Strait Islander Peoples have made a real difference in terms of improving availability, access and patient support. The established partnerships between community pharmacies and remote and non-remote Aboriginal Health Services (AHSs) have delivered significant improvements in QUM outcomes.

However these arrangements can be improved in a number of ways. Aboriginal and Torres Strait Islander Peoples need improved access to community pharmacy delivered medication management and education support services, as well as DAAs. Medicines that are individually dispensed to patients in Remote Area Aboriginal Health Service’s (RAAHSs) should be remunerated accordingly.

The Close the Gap PBS Co-Payment program and the S100 RAAHS program need to be better integrated so that patients are not disadvantaged when they travel and are able to maintain consistent access to free and subsidised prescriptions, using their Medicare Card to demonstrate their eligibility.
Pharmacist Workforce

The Review is being conducted at a time when there is significant concern about the future of the pharmacist profession. The Guild shares these concerns as all of our members are registered pharmacists and community pharmacies are by far the largest employer of pharmacists.

Around the world, it is increasingly recognised that pharmacists can play an enhanced role in the health system, working mainly within their current scope of practice, but also through sensible expansion of their scope where there is evidence of unmet health need and it is demonstrated that pharmacists, with the right training and referral pathways, can meet those unmet needs in a safe and cost-effective way.

The answers to the current challenges facing the pharmacist workforce must be evidence-based with a need to resist ad hoc solutions without having a thorough understanding of their flow-on implications.

A comprehensive pharmacist workforce strategy should be developed by the broader pharmacy sector and pharmacist profession working together toward common objectives and fully informed by the best available data and evidence relating to future supply and demand as well as the major national and international health and medicines trends.

The Monash Pharmacy Faculty has provided strong leadership in pharmacist workforce planning in recent years and it would make sense for its work to be built upon with the backing of the broader sector, possibly working under the umbrella of the Australian Pharmacy Leaders Forum (APLF). As the vast majority of pharmacists work either directly for government or deliver clinical services, such as dispensing, that are funded by government, an investment by the Federal Government in the development of a comprehensive 10 to 20 year pharmacist workforce planning project would provide major impetus to this work.
Summary of recommendations

Recommendation Number 1
The Guild recommends that:

- the Pharmacy Guild, as the recognised representative of the majority of community pharmacy owners who fund and manage the infrastructure to deliver the PBS to patients, and who have ultimate responsibility for the professional integrity of that infrastructure, should continue to have responsibility for negotiating future Community Pharmacy Agreements with the Federal Government.
- the Community Pharmacy Agreements should be focused on the remuneration of community pharmacies and wholesalers for the dispensing of PBS and RPBS medicines and related services delivered through community pharmacies.
- future negotiations should be preceded with formalised consultation arrangements to ensure that the views and interests of relevant stakeholders are fully taken into account in the negotiations.

Recommendation Number 2
The Guild recommends that:

- the Location Rules should be retained given the clear evidence of their social benefits as well as meeting the objectives of the National Medicines Policy, particularly in terms of access and efficiency.
- the prohibition within the Location Rules in relation to the co-location of approved pharmacies in supermarkets should be retained.
- the Federal Department of Health and the Guild should establish a joint working group, with the aim of identifying and addressing any anomalies that have arisen over time, to ensure the Location Rules remain responsive to the evolving needs of the community.

Recommendation Number 3
The Guild recommends that:

- the Federal Government funds an ongoing campaign to raise public awareness of the role of community pharmacy as a trusted health destination and the availability of pharmacy services.
- consumers should expect that community pharmacies who are providing professional services are accredited to an Australian Standard including in respect to privacy and confidentiality.
- the Federal Government should use the PHNs to provide incentives for local community pharmacies to coordinate emergency after-hours patient access to PBS medicines and other critical community pharmacy services.

Recommendation Number 4
The Guild recommends that immediately:

- the Pharmacy Board of Australia should be given authority and be appropriately funded and supported to take a stronger role in regulating professional pharmacist practice in all settings in the public interest.
- the TGA should implement transparent and stronger licensing and marketing processes for complementary medicines sold in Australia to provide the community with confidence with regards to safety, efficacy and responsible marketing.
**Recommendation Number 5**
The Guild recommends that:

- consumers should continue to have the benefit of timely access to health and other ancillary products as well as professional pharmacy services from community pharmacies.
- community pharmacy should continue to provide products, service and advice without superficial separation of the two.

**Recommendation number 6**
The Guild recommends that:

- in future Community Pharmacy Agreements a mechanism should be put in place to increase the floor on per prescription dispensing remuneration for community pharmacies to take into account the ongoing loss of trading terms as a result of price disclosure.
- in future Community Pharmacy Agreements appropriate risk sharing arrangements need to be explicitly included to ensure that agreed funding commitments to community pharmacies are delivered in full.

**Recommendation Number 7**
The Guild recommends that:

- community pharmacies should continue to receive the same remuneration for dispensing original and repeat PBS prescriptions for ready-prepared Schedule 4 medicines.
- community pharmacies should continue to receive the same remuneration for dispensing simple and complex PBS prescriptions for ready-prepared Schedule 4 medicines.
- in future Community Pharmacy Agreements dispensing related remuneration, including the Administration, Handling and Infrastructure fee (AHI), dispensing fees (ready-prepared and extemporaneous) and Dangerous Drug fee, should be set to a level that is commensurate with increased overhead costs in community pharmacy businesses.
- additional remuneration be provided for cytotoxics and items requiring refrigeration.
- in future Community Pharmacy Agreements the Premium Free Dispensing Incentive (PFDI) should be maintained to encourage community pharmacies to increase the uptake of generic medicines.
- in the interest of PBS universality, the pharmacy funded optional $1 discount should be immediately abolished.
- there should be a thorough review of all PBS Patient Co-Payments and Safety Net Threshold levels to ensure that PBS medicines are affordable for consumers.

**Recommendation Number 8**
The Guild recommends that:

- the Federal Government should immediately take responsibility for providing opiate-dependent patients with access to high quality standardised care by:
  - funding a fee for service Opiate Dependence Treatment (ODT) program for eligible community based patients that is delivered through community pharmacy.
  - ensuring consistency in terms of patient contributions so as to reduce financial barriers for eligible patients to access the service.
ensuring appropriate remuneration for community pharmacies so as to encourage a greater level of community pharmacy participation.

Recommendation Number 9

The Guild recommends that:

- for greater efficiency and patient care, the National Diabetes Services Scheme supply and remuneration model should run parallel to the PBS:
  - NDSS community pharmacies should be able to purchase NDSS products directly from their CSO wholesalers at the approved Price to Pharmacist, inclusive of appropriate wholesaler mark-up.
  - NDSS pharmacies should be able to use their dispense and point-of-sale systems for recording, claiming and stock management.
  - remuneration for NDSS community pharmacies in the next Agreement should be structured to reflect the PBS, inclusive of a commensurate AHI and recording fee.
- the Federal Government should immediately:
  - fund an Appliance Use Review in NDSS community pharmacies to support people with diabetes in the use of their blood glucose monitors.
  - provide funding incentives to NDSS community pharmacies to undertake Diabetes Educator training.

Recommendation Number 10

The Guild recommends that:

- the Federal Government take immediate responsibility for the national implementation of a real-time recording system for Controlled Drugs (e.g. Electronic Recording and Reporting of Controlled Drugs – ERRCD).
- dispense software vendors are funded to develop an integrated Controlled Drug electronic register.
- the TGA should immediately introduce a recordable schedule in the Poisons Standard for all drugs at risk of abuse or misuse.

Recommendation Number 11

The Guild recommends that:

- in the interests of accessibility and public safety, the Schedule 2 and Schedule 3 medicine schedules must be retained and expanded.

Recommendation Number 12

The Guild recommends that immediately:

- the Department of Veterans’ Affairs (DVA) should review both the administration process and the level of remuneration for the DVA Dose Administration Aid (DAA) service and apply annual indexation.
- the 6CPA should be used to fund a fee for service DAA program for eligible community based patients delivered through community pharmacy.
• the 6CPA should be used to fund a fee for service Staged Supply program for eligible community based patients delivered through community pharmacy.

• the 6CPA should be used to fund a fee for service payment for enhanced clinical interventions for eligible community based patients delivered through community pharmacy.

Recommendation Number 13

The Guild recommends that:

• all Community Pharmacy Agreement professional programs should be delivered and funded through community pharmacy.

• in order to receive Federal Government funding, all pharmacist delivered professional services must be delivered to a quality standard that meets the Australian Standard 85000:2011.

• in order to receive Federal Government funding, all pharmacist delivered professional services must be uploaded to an e-health record to ensure coordinated patient care.

• in order to receive Federal Government funding, all pharmacist delivered professional services should be evaluated for clinical and cost-effectiveness.

• the Home Medicines Review (HMR) program should have well defined eligibility criteria to ensure services are targeted to those with the greatest clinical need and with the least capacity to pay.

• medicine related services delivered by pharmacists in health settings outside the community pharmacy should be funded separately to the Community Pharmacy Agreement and should not duplicate established community pharmacy based medicine related services or fragment patient care by not linking back to the patient’s usual community pharmacy.

Recommendation Number 14

The Guild recommends that:

• the Federal Government should fund a fee for service minor ailments program in community pharmacy that uses a recordable pharmacist-only medicine schedule.

• the Federal Government should allow community pharmacies to order a standard range of pathology tests in line with best practice for patients receiving ongoing stable therapy for chronic conditions.

• to provide equity and enhanced patient access, community pharmacies involved in the National Immunisation Program (NIP) should be eligible for relevant MBS payments.

• all vaccinations undertaken in community pharmacies should be uploaded to the appropriate vaccination register.

• the Continued Dispensing arrangements for urgent PBS medicine supply should be expanded to include other medicines used to treat chronic health conditions, with a requirement to inform the prescriber.

• the Federal Government should fund a fee for service prescription renewal service in community pharmacy to support patients with stable chronic conditions with a requirement to inform the prescriber.

• the Federal Government should immediately trial a New Medicine Service under the Pharmacy Trial Program to help patients with chronic conditions to understand and use newly prescribed PBS medicines.
• the Federal Government should provide incentives for community pharmacies to become local Health Hubs in areas of demonstrated need.
• the Federal Government should fund a fee for service health check, risk assessment and referral program through community pharmacies.
• transitional care to and from hospitals should use digital health systems, including *My Health Records*, to maintain links with the patient’s usual community pharmacy and usual GP.

**Recommendation Number 15**
The Guild recommends that:

• the Federal Government considers the Guild’s proposals for immediately addressing the problems associated with purchasing and dispensing high-cost PBS medicines by:
  o creating a high-cost PBS Schedule with caps on the amount paid by pharmacies and wholesalers with the balance paid directly to the manufacturer OR
  o implementing a consignment model for payment by pharmacies when the PBS medicine is dispensed.
  o addressing the remuneration anomalies between S90 pharmacies and S94 hospitals.

**Recommendation Number 16**
The Guild recommends that immediately:

• community pharmacies should be able to dispense and claim any Section 100 (S100) PBS prescription irrespective of where the medicine is prescribed so that patients can access the medicine from their pharmacy of choice.
• S100 PBS medicines should be included in the Community Service Obligation (CSO).
• the S100 PBS medicines remuneration structure should be commensurate with Section 85 (S85) PBS medicines.
• S100 medicines listed under the Botulinum Toxin, IVF and Growth Hormone programs as well as the S100 Highly Specialised Drugs (HSD) Community Access Category should become S85 medicines.
• the S100 HSD Public and Private categories should be amalgamated into one S100 HSD category.

**Recommendation Number 17**
The Guild recommends that immediately:

• to encourage community patients (i.e. non in-patients) to have maximum access to medicines through the community pharmacy network, any anomalies in remuneration between Section 90 (S90) community pharmacies and Section 94 (S94) hospital pharmacies should be addressed.
• private hospital medicine purchasing and dispensing arrangements should be transparent and equitable, restricting any unfair commercial advantages between S94 private hospitals and S90 pharmacies in which they have an interest.
• the Federal Government should actively encourage and facilitate maximum patient access to all PBS medicines through community pharmacy, including specialised, high-cost and biologic medicines.
• to facilitate continuity of care the Hospital Medication Chart should be able to be used as a PBS prescription in community pharmacies.
• the Safety Net early supply rule should apply to S94 hospital discharge prescriptions.
**Recommendation Number 18**
The Guild recommends that:

- the Federal Government continues to invest in the RPMA, with the RPMA matrix reviewed to ensure the allowance continues to be appropriately targeted to pharmacies where there is greatest geographic and community need.

**Recommendation Number 19**
The Guild recommends that immediately:

- the eligibility for the Closing the Gap (CTG) PBS Co-payment should be verifiable through the patient’s Medicare Card.
- the Listings on the PBS for Aboriginal and Torres Strait Islander Peoples should be expanded to better meet their health needs.
- Remote Area Aboriginal Health Services (RAAHs) and hospitals should be able to write CTG prescriptions.
- the Federal Government should implement an electronic and online registration process for patients accessing the CTG PBS Co-payment measure in order to improve efficiency and access.
- all PBS medicines, including S100 items, should be available under the CTG PBS Co-payment measure.
- the Federal Government should fund actual freight costs related to the provision of medicines under the S100 RAAHS scheme.
- the Federal Government should fund the full dispensing of medicines supplied under the S100 RAAHS program.
- the Department of Human Services (DHS) should implement an electronic claiming and payment system for community pharmacies delivering the S100 RAAHS program with payment timelines consistent with the broader PBS.
- the Federal Government should fund the provision of DAAs for eligible Aboriginal and Torres Strait Islander Peoples under the CTG PBS Co-payment scheme.
- the Federal Government should increase the level of funding for the S100 Pharmacy Support Allowance to enable multiple site visits from the participating community pharmacy each year to increase the quality use of medicines.

**Recommendation Number 20**
The Guild recommends that immediately:

- the Federal Government should manage PBS price disclosure prices reductions, working with community pharmacy, pharmaceutical wholesalers and manufacturers, in a way that maintains continuity of supply while minimising stock value losses, including through consideration of phased implementation of price reductions through the supply chain, as occurs in some comparable international jurisdictions.
- the price disclosure regime should include a mechanism to automatically recognise and adjust ex-manufacturer prices upwards if generic medicines increase in price, as occurs in many comparable international jurisdictions.
• Federal Government budget savings from price disclosure and rebates received from manufacturers as a result of risk sharing arrangements should be transparently identified and re-invested as required to maintain the sustainability of the pharmaceutical supply chain in Australia.

• pharmaceutical wholesalers should have access to any PBS and RPBS listed item in any quantity at no more than the approved ex-manufacturer price.

• the wholesaler remuneration structure should include a floor on wholesaler mark-up and align the level of the payment caps with that of community pharmacies and be implemented in a way that ensures that the wholesaler funding committed to in the 6CPA is fully expended at the estimated volume levels.

• pharmaceutical wholesalers should be remunerated by the Federal Government, with appropriate fees that reflect actual service costs for distribution of all items listed on the PBS, RPBS and NDSS (including S100 medicines), recognising additional costs for Controlled Drugs, fridge lines, cytotoxics and high-cost items.

**Recommendation Number 21**

The Guild recommends that immediately:

• the CSO should be retained and strengthened to guarantee prompt and efficient supply of all PBS, RPBS and NDSS items (including S100 medicines) to any approved pharmacy in Australia in order to meet the needs of the Australian public.

• whilst supporting improved efficiencies, pharmacies should have access to deliveries within 24 hours with no minimum order requirements in order to meet urgent patient needs.

• pharmacies should have access to any PBS and RPBS listed item in any quantity at no more than the approved Price to Pharmacist (PTP) and without any administrative surcharges.

• with the addressing of wholesaler remuneration, the Top 1,000 list and associated lower service provisions should be discontinued as they undermine the CSO and put at risk patient access to PBS medicines.

**Recommendation Number 22**

The Guild recommends that immediately:

• as a condition of listing, all PBS medicines should be available for supply from one or more CSO wholesalers, with the obligation on any CSO distributor that enters into an exclusive supply arrangement with a manufacturer to ensure that all pharmacies have equitable access to the medicine in line with the CSO requirements.

**Recommendation Number 23**

The Guild recommends that:

• the Federal Government should immediately work with relevant stakeholders developing and implementing a strategy to proactively prevent and manage supply shortages for the PBS, NDSS and National Immunisation Program (NIP), which would include:
  
  o more rigorous and ongoing assessment of supply capabilities for newly listed products or brands.
  
  o a risk assessment of currently listed products to identify potential situations of greatest patient risk should a shortage occur.
  
  o a management strategy for PBS listed products to guarantee supply including flexibility in pricing to enable price increases if needed.
o a more stringent approach with manufacturers repeatedly having long-term shortages
o removal of the Brand Price Premium if base-priced generic alternatives are out of stock or unable to meet demand for extended periods.
o provision of more complete and timely communication about shortages to health care professionals to enable more effective patient support.

**Recommendation Number 24**
The Guild recommends that:

- the Australian Digital Health Agency should immediately ensure that community pharmacy dispensing and medicine related services are fully integrated into the *My Health Record* by incentivising community pharmacies to:
  - integrate the *My Health Record* into their systems, practices and workflows.
  - upload and maintain DAA medicine profiles to the *My Health Record* for all community-based and residential DAA patients.
- any possible transition to a paper-optional script environment should expressly prohibit channeling from prescribers; ensure that patients continue to receive the level of pharmacist professional counselling required to deliver QUM outcomes; and should only be progressed following a thorough investigation into the risks and benefits and international precedents.

**Recommendation Number 25**
The Guild recommends that immediately:

- irrespective of TGA licensing arrangements, a flat compounding fee should apply for PBS chemotherapy prescriptions that reflects the service costs.
- the full compounding fee for PBS chemotherapy prescriptions should be paid to the pharmacy as part of the routine PBS claim.
- to manage community-based chemotherapy ordering, supply and PBS claiming, the Hospital Medication Chart should be able to be used as a PBS prescription in community pharmacies.

**Recommendation Number 26**
The Guild recommends that in order to keep older Australians living in their homes for as long as possible the Federal Government should immediately:

- fund community pharmacists to upload and maintain medicine profiles for community-based and residential patients to the *My Health Record*.
- fund pharmacy home delivery services to older Australians.
- fund the role of community pharmacy in the Health Care Home for older Australians.
- actively encourage Aged Care Assessment Teams and Community Care Providers to include medication management support in consumer-directed home care packages.

**Recommendation Number 27**
The Guild recommends that immediately:

- DHS should amend the real-time feedback with PBS Online for S100 HSD prescriptions so that a Rejection rather than a Warning is provided.
• the Federal Government should take full responsibility and honour the payment of all PBS prescriptions dispensed during PBS Online outages when pharmacists do not receive real-time PBS claims feedback.

• DHS should monitor and manage the PBS Safety Net records for automatic issue of a Safety Net entitlement when the threshold is reached.

• the Federal Government should fund community pharmacies for linking and confirming the status of family members as part of the PBS Safety Net process.

• the Federal Government amends the legislation to address the anomaly whereby pharmacies are unable to claim for PBS scripts dispensed at the concessional rate on the day a patient dies.

• the Federal Government should undertake a cost-benefit analysis of moving to a system of reimbursing community pharmacies monthly in-advance on the basis of predicted prescription volume (with subsequent reconciliation) as occurs in international jurisdictions.

**Recommendation Number 28**

The Guild recommends that immediately:

• privacy laws should allow pharmacy regulators to share information to more efficiently and effectively manage matters of pharmacy practice non-compliance.

• all pharmacy regulators should review their policies and procedures with a view to greater sharing of information and referral of complaints, thus enabling one simplified pathway for lodging complaints about pharmacy practice.

• all Commonwealth pharmacy regulators should review their policies and procedures with a view to improving communications about compliance activities and outcomes for greater transparency.

**Recommendation Number 29**

The Guild recommends that immediately:

• the Federal Government should formally recognise in all relevant policies, legislation and regulation, and decision making processes that community pharmacies and pharmacists are primary health care providers.

• the Federal Government should identify and remove any policy, regulatory and funding eligibility barriers that prevent community pharmacies and pharmacists from delivering medicine and related care and support to patients as part of a coordinated and integrated approach to primary health care.

**Recommendation Number 30**

The Guild recommends that:

• the Federal Government should provide access to its PBS and related health data, with appropriate safeguards to protect patients' personal health information, to enable enhanced analysis of population health needs and health outcomes.

**Recommendation Number 31**

The Guild recommends that:

• a comprehensive, evidence-based, industry-led 10 to 20 year pharmacist workforce plan be developed with appropriate investment from the Federal Government.
INTRODUCTION

The Guild welcomes this Review and the opportunity to respond to the many complex issues raised in the Discussion Paper released by the Review Panel.

This submission addresses key areas of concern for the community and in particular issues around equity of access to pharmaceutical services, QUM, the costs and benefits of the regulatory framework, transparency and the need to maintain a viable network of community pharmacies. In so doing, it approaches these complex questions in the spirit intended by the Terms of Reference namely, that there is always scope for improvement within an already efficient and responsive network of community pharmacies.

While this submission makes a number of positive recommendations to improve consumer outcomes, it demonstrates with great clarity that the current model of pharmacy care is an exemplar of public-private partnership, it continues to meet the health needs of the Australian public and it is well positioned to respond to the challenges of decades to come. The challenge facing the Review is how we can build on the existing strong foundations to empower consumers and community pharmacists to collaboratively work towards better health and social outcomes.

The Pharmacy Guild of Australia

The Guild is the national peak organisation representing proprietors of independent community pharmacies. Its mission is to serve the needs and interests of its members, and through them the needs of the communities they serve. The Guild’s aim is to promote and maintain community pharmacies as the most accessible primary providers of health care through optimum therapeutic use of medicines, medicine management and related professional services.

The Guild is a national employers’ organisation, registered under the Fair Work (Registered Organisations) Act 2009, and functions as a single legal entity rather than a federation. It represents owners of community pharmacies who benefit from a range of services including industrial relations, training for non-pharmacist staff, quality assurance programs, specialist training and accreditation, management training, to name a few.

More specifically, the Guild’s activities include:

- Negotiations with the Commonwealth with respect to Community Pharmacy Agreements, including fair remuneration for dispensing and other professional services.
- Representing members in matters of industrial relations including negotiating award variations.
- Maintaining close liaison and negotiation with governments, manufacturers, wholesalers and other organisations involved in the health care delivery system.
- Implementation of programs to assist regulatory authorities aimed at harm reduction – for example, Project STOP and MedsASSIST.
- Implementation of programs aimed at raising and maintaining the standards of care to the community – including the Quality Care Pharmacy Program (QCPP) which has been continuously improved and in operation for nearly two decades.
- Provision of training to support the learning and development of community pharmacists and pharmacy assistants.
- Developing strategies to assist community pharmacists practising in rural and regional areas to ensure that access to medicines is maintained and enhanced irrespective of where patients live.
• Providing economic and management support to community pharmacists to strive for greater efficiencies in the operation of their pharmacies.

PART ONE - COMMUNITY PHARMACY IN AUSTRALIA

The Role of Community Pharmacy

Community pharmacies occupy a unique position in the health care delivery system. They combine their health care delivery functions with retail services. Pharmacies are multi-product, multi-service organisations that are integral to the Australian health care system and are key participants in the Federal Government’s National Medicines Policy (NMP). However, at the same time they also offer products and services that are available from general retailers. As the Discussion Paper notes, these include non-pharmacy complementary products, infant formula, wound care products, cosmetics and skin care products.

Importantly, community pharmacy do not sell products such as tobacco and alcohol that are widely acknowledged as harmful to health which are available from other retailers.

While seemingly ‘odd’, this duality of character is what distinguishes community pharmacy from other health care providers. This model has evolved over many decades out of a necessity to provide as complete a suite of products and services as possible to meet the health needs of local communities. This is the intrinsic nature of community pharmacy: health care products, services and trusted health advice, with a diverse mix of products that may not be exclusively in the purview of health care.

As custodians of controlled substances, the primary role of community pharmacies is to dispense medicines, as requested/directed by prescribers, and to provide relevant counselling to patients. However, there is much more to pharmacy than dispensing. The extensive range of services provided both before and after dispensing includes, among other things:

• Prescription medicines: that is, items listed on the PBS/RPBS whose profit margin is regulated
• Prescription medicines that are not listed on the PBS/RPBS (Private prescriptions)
• Distribution outlet for Government subsidised schemes e.g. NDSS
• Checking whether clients are over-using or misusing prescribed medicines
• Over-the-Counter (OTC) medicines available only from pharmacies without prescription (S2 and S3 medicines)
• Providing advice across a range of health services, including services that enhance the quality use of medicines and reduce costs in other areas of the health system, such as medication management services, dose administration aids, harm reduction services, and many more
• Other products also available from general stores (e.g. non-scheduled OTC medicines, infant formula, skin and hair care, cosmetics)

For a comprehensive list of services see Appendix 5.

Community pharmacy therefore is as much about health care and advice as it is about the distribution of prescription pharmaceuticals. These services are an integral part of the NMP framework in ensuring that medicines are accessible, appropriate for the indicated medical condition, as well as safe to use.

Moreover, the community pharmacy network provides an indispensable platform for public health campaigns, immunisation, healthy living campaigns, baby and maternal health services, screening and care-
management programs as well as harm minimisation programs. While these services are often provided at no direct cost to consumers\(^1\), their contribution to public health should not be underestimated.

**Regulation of Pharmacy**

Community pharmacy practice operates within a complex regulatory framework. In the Foreword to *Australian Pharmacy Law and Practice*\(^2\), Dean Schultz (National Chairman, Pharmaceutical Defence Ltd) states:

> **“Having a clear understanding of the laws and standards that govern the practice of pharmacy in Australia is an essential prerequisite to ensuring the profession is practised in a competent and safe manner.”**

These laws and policy objectives range from the storage, handling and supply of medicines and poisons through to who can own and operate pharmacies, and to rules that govern the circumstances under which PBS prescriptions may be dispensed. They reflect the fundamental need to protect the health and safety of the community by ensuring that appropriate professional standards are maintained.

One of those overarching policies is the Federal Government’s NMP. Community pharmacies are key partners in delivering the objectives of the NMP. The NMP is a co-operative endeavour aimed at delivering better health outcomes for all Australians\(^3\). The overall aim of the NMP is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved, and has as its central objectives:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford
- medicines meeting appropriate standards of quality, safety and efficacy
- quality use of medicines
- maintaining a responsible and viable medicines industry

Important elements of this framework are the PBS, and the complementary RPBS. The PBS is a Federal Government scheme managed by the Department of Health (DoH) that subsidises the cost to consumers of a wide range of medicines, in order to provide timely, reliable and affordable access to necessary medicines for Australians. The RPBS is managed by the Department of Veterans’ Affairs (DVA) and subsidises a range of additional medicines and therapeutic products specifically for eligible veterans and their dependants. The PBS and RPBS are part of the NMP.

The existing regulatory framework for community pharmacies aims to support the achievement of these broad national health policy objectives. Many regulations therefore affect the setting up and operation of community pharmacies. Key regulations are set out in the following sections.

**Poisons Standard**

The *Therapeutic Goods Act 1989* provides a framework for the States and Territories to adopt a uniform scheduling approach to control the availability and safe handling of medicines in Australia. This framework is set out in the current version of the *Poisons Standard*\(^4\), pursuant to the *Therapeutic Goods Act*.

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\(^1\) CRA paper – 38.3% of Australian community pharmacies do not charge the provision of asthma services.

\(^2\) L. Hattingh, JS Low and Kim Forrester; *Australian Pharmacy Law and Practice*; 2\(^\text{nd}\) Edn; 2013

\(^3\) Department of Health 2014

The *Poisons Standard* is the legal title of the *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)* and, along with scheduling of therapeutic substances, it provides guidelines for uniform labelling and packaging requirements throughout Australia. It classifies medicines for human use into four schedules:

- Schedule 2 – Pharmacy Medicine
- Schedule 3 – Pharmacist Only Medicine
- Schedule 4 – Prescription Only Medicine
- Schedule 8 – Controlled Drug

Medicines that are included within any of the above schedules are referred to as ‘scheduled’ medicines, and the advertising, storage, sale and dispensing of those medicines are subject to varying degrees of restriction by State and Territory Acts and Regulations.

Other medicines are referred to as 'non-scheduled' medicines, and are also available for sale through non-pharmacy outlets (e.g. supermarkets).

**Advertising of Therapeutic Goods (medicines and devices)**

Advertising of therapeutic goods, including promotional material inside a pharmacy, must comply with all relevant legislation.

- Advertising to consumers is permitted for many therapeutic products that are available from community pharmacies. However, advertising *Prescription Only Medicines*, *Controlled Drugs* and *Pharmacist Only Medicines* not listed in Appendix H of the *Poisons Standard* to the general public is prohibited.
- Advertisements for therapeutic goods in Australia are subject to the requirements of the:
  - *Therapeutic Goods Act 1989*
  - *Therapeutic Goods Regulations 1990*
  - *Therapeutic Goods Advertising Code 2007*
  - and other relevant laws including the *Competition and Consumer Act 2010*

**Requirements of the Therapeutic Goods Advertising Code**

- The Advertising Code includes a number of sections with which pharmacists who advertise therapeutic goods must be familiar, including (but not limited to):
  - General principles, such as claims being balanced, accurate, not misleading and supported by evidence. This also includes restrictions on testimonials and advertising free samples
  - Restrictions on health retailers and health professional endorsement of therapeutic goods
  - Restrictions and prohibitions on mentioning serious health conditions in advertising
  - Requirements for mandatory statements to be included in advertising
- The TGA has oversight of Australia’s co-regulatory system of advertising for therapeutic goods. Details of the Therapeutic Goods Advertising Code Council (TGACC), pre-approval process, the Complaints Resolution Panel, and the Complaints Register, are described on the Complaints Resolution Panel website.

**Registration of pharmacists**

The Pharmacy Board of Australia (Pharmacy Board) is responsible for the registration of pharmacists in Australia, supported by the Australian Health Practitioner Regulation Agency (AHPRA). The operations of
AHPRA and the Pharmacy Board are governed by the *Health Practitioner Regulation National Law* as in force in each State and Territory.

The Pharmacy Board limits registration to individual persons who have met minimum entry requirements, and reserves the use of the title ‘Pharmacist’ to those registered persons. Qualification for pharmacy registration generally involves meeting a specified educational and practical experience requirement with demonstrated competence in accordance with competency standards expected of entry level pharmacists in Australia.

Registration is required and only those who are registered can practise pharmacy in all States and Territories. A pharmacy must be under the personal control or supervision of a pharmacist while it is conducting pharmacy business.

**Registration of Pharmacies**

With few exceptions, the business of a pharmacy can only be owned and conducted by registered pharmacists to ensure that pharmacists have effective and undisputed control of the decision-making of a pharmacy business. The legislation also prohibits a person from having a pecuniary or proprietary interest in a pharmacy business unless the person is:

- a registered pharmacist
- a company whose directors and shareholders are registered pharmacists (or in some cases close relatives of those pharmacists)
- a friendly society
- a person otherwise approved by the relevant regulatory authority

These legislative requirements are administered by the State and Territory pharmacy premises registering authorities, whose mandate is to protect the public.

**The Pharmaceutical Benefits Scheme (PBS)**

The PBS is established by Part VII of the *National Health Act 1953*. The stated objectives of the PBS are to provide “reliable, timely and affordable access to cost-effective, high quality medicines and sustainable pharmaceutical services”. It provides a universal pharmaceutical subsidy for medicines listed on the scheme, and extra assistance to those most in need, through differential concessional co-payments and safety net arrangements. The RPBS is established under section 91 of the *Veterans’ Entitlements Act 1986*.

Until January 2016, pharmacists were prohibited by law from altering the level of patient co-payment of any PBS or RPBS items which attracted a Federal Government subsidy.

Remuneration to pharmacists for dispensing PBS and RPBS medicines is negotiated through an agreement between the Federal Government and the Guild, referred to as the Community Pharmacy Agreement (CPA), now in its sixth iteration. The determination of fees is given effect by the Pharmaceutical Benefits Remuneration Tribunal (PBRT).

**Pharmacy Location Rules under the PBS**

Under the *National Health Act 1953*, the Commonwealth imposes strict controls on approving a new pharmacy, and on relocating existing pharmacies, for PBS purposes. The current Pharmacy Location Rules

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5 Federal Government, 2015-16 Health Portfolio Budget Statements (Section 2 – Department Outcomes – 2 Access to Pharmaceutical Services, p53).
(Location Rules) are a fundamental component of the 6CPA, and reflect the overall objective of the NMP to improve the health outcomes of all Australians through access to, and quality use of, medicines. This Agreement commenced on 1 July 2015 and terminates on 30 June 2020.6

The Location Rules are divided into two general types: those that apply to the relocation of an existing pharmacy; and those for the establishment of a new pharmacy. The rules set out location-based criteria which must be met in order for the Australian Community Pharmacy Authority (ACPA) to recommend approval of a pharmacist.

The Location Rules relate to the establishment of a new pharmacy or the relocation of an existing pharmacy which has approval to provide PBS medicines under section 90 of the National Health Act 1953 (the Act).

The general objectives of the Location Rules were first articulated in the Second Community Pharmacy Agreement (2CPA):

3.1 The Parties record that it is their intention that the terms of this Agreement will maintain the benefits of restructuring and continue to enhance the development of an effective, efficient and well distributed community pharmacy service in Australia. The Parties undertake to maintain pharmaceutical services in remote and isolated areas of Australia.

3.2 The Parties to this Agreement make it clear that the intention of the provisions of this Agreement relating to the approval of pharmacists is not to provide for an increase in the number of approved pharmacies but rather to encourage the relocation of existing pharmacies. The Parties note, however, that in some few circumstances new approvals might be warranted.

Designed with the aim of ensuring the optimal distribution of pharmacies, the emphasis of the objectives was essentially to discourage clustering in urban areas while encouraging relocations to rural areas, with minimal increase in the overall number of approved pharmacies.

These key objectives have been further refined and amplified over the course of successive agreements. As noted in the Fourth Community Pharmacy Agreement (4CPA) and Fifth Community Pharmacy Agreements (5CPA), they aim to ensure:

- all Australians have access to PBS medicines
- a commercially viable and sustainable network of community pharmacies dispensing PBS medicines
- improved efficiency through increased competition between pharmacies
- improved flexibility to respond to the community need for pharmacy services
- increased local access to community pharmacies for persons in rural and remote regions of Australia
- continued development of an effective, efficient and well-distributed community pharmacy network in Australia

Importantly, the Rules also remain an integral part of the overall objective of the NMP to improve the health outcomes of all Australians through access to and quality use of medicines.

The public interest and economic rationale for the Location Rules is explored fully in Part 2.

**Pharmacy Ownership Rules**

While State and Territory laws, in particular those in respect of pharmacy ownership, are beyond the scope of this Review, the Panel has taken the view that these issues “form the context of pharmacy in Australia and

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cannot be ignored by this Review”. It may therefore be instructive to reiterate the social welfare rationale for those laws in the context of this Review.

There are a number of important public interest reasons for maintaining ownership and control of pharmacies in the hands of licensed pharmacists.

Ensuring that a pharmacist owns and controls a pharmacy practice is a social objective underpinned by pharmacy legislation. It reflects the community expectations and desire to maintain the integrity of the professional relationship between pharmacist and patient. That relationship hinges on trust and personal service, with pharmacists being directly accountable and liable for the services they provide. Needless to say, a level of accountability is also expected of employee pharmacists. However, the clear intent of the ownership legislation is to ensure that professional standards and principles are not subordinated to commercial objectives and pressures in the practice of pharmacy.

The notion of pecuniary or proprietary interest plays a crucial part in State and Territory pharmacy legislation and is designed with a single aim in mind: public safety.

The fundamental public interest rationale of the ownership laws is perhaps best summarised by the European Court of Justice which found that:

“It is undeniable that an operator having the status of pharmacist pursues, like other persons, the objective of making a profit. However, as a pharmacist by profession, he is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint. His private interest connected with the making of a profit is thus tempered by his training, by his professional experience and by the responsibility which he owes, given that any breach of the rules of law or professional conduct undermines not only the value of his investment but also his own professional existence.

Unlike pharmacists, non-pharmacists by definition lack training, experience and responsibility equivalent to those of pharmacists. Accordingly, they do not provide the same safeguards as pharmacists.”

The economic impact of relaxing the current ownership laws are significant. While acknowledging that ownership is beyond the remit of this Review, the public interest and economic argument are fully explored in Part 2.

The Role of the Community Pharmacy Agreements

CPAs play a critical role in giving effect to the NMP in a way that delivers maximum benefit for patients. Each of the four central objectives of the NMP (access; quality, safety and efficacy; QUM, a responsible and viable medicines industry) are enabled by the CPAs. In particular, the CPAs and associated regulation ensure that Australians have timely access to the full array of PBS medicines, delivered through a well-distributed and highly accessible community pharmacy network, with professional pharmacists ensuring consistently high standards of dispensing with associated quality use of medicines support both at the point of dispense and through a range of related medication management programs.

Through the CPAs, the community pharmacy network has a long term partnership with the Federal Government that helps ensure the ongoing fiscal sustainability of the PBS whilst maintaining high standards of medicine dispensing and support for patients. Successive CPAs have established a straightforward compensation structure that is linked to a limited set of defined services, while the Location Rules establish a set of clearly defined criteria that minimise the scope for different interpretations. Notwithstanding high physical accessibility, the distribution supply chain has evolved in a way that there is limited duplication of

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7 Commission of the European Communities v Italian Republic (19 May 2009) at [61]-[62]. This case considered whether European Community law precluded provisions contained in Italian and German legislation which limited pharmacy ownership to qualified pharmacists.
physical outlets, and community pharmacies have been able to secure economies of scale and scope. This has, in turn, reduced the longer-term costs of maintaining the community pharmacy distribution network. These accessibility and cost-effectiveness outcomes have in turn been achieved via a set of instruments and regulations that, although inevitably complex, are relatively tractable and transparent, involve a minimal degree of discretion, and therefore limit transactions costs to government and to the industry.

During the 6CPA, it is anticipated that the Federal Government will extract some $20 billion in budgetary savings from PBS reforms\(^8\). Although the impact of these reforms has flowed through to pharmacies in reduced official remuneration and lost trading terms, the Guild has responsibly agreed to them on the basis that they will help ensure the longer term sustainability of the PBS.

The CPAs provide financial certainty for the Government and the community pharmacy network, enabling both parties to plan ahead with confidence. The Guild has publicly supported enhancements to the agreement negotiation and implementation processes to ensure high levels of accountability and transparency. While the 2015 report of the Australian National Audit Office (ANAO) made no adverse findings in relation to the Guild or community pharmacies, the Guild publicly supported its recommendations as they will help provide a high level of confidence in future CPAs processes. These enhancements have been incorporated into the 6CPA with an increased emphasis on stakeholder consultation, Key Performance Indicators (KPIs), annual reporting, cost-effectiveness and evidence-based professional programs.

The Guild strongly supports continuation of CPAs. They are a true public-private partnership between the Federal Government and Australia’s 5,500 community pharmacies which are tasked with ensuring the safe, timely and efficient delivery of the PBS to the Australian public on the Federal Government’s behalf. In order to undertake this role on behalf of taxpayers, community pharmacy owners risk their own capital and therefore require a level of certainty in terms of their future earnings from dispensing medicines, which is core to their ongoing viability. In turn, the Federal Government has the certainty that its NMP objectives will be delivered efficiently through the community pharmacy network. Over 25 years, the CPAs have consistently delivered on their core objective of dispensing PBS medicines to the Australian community. The fact the CPAs are a partnership rather than a straight supply arrangement has enabled the parties to work together to drive innovation, introduce new technologies and place an enhanced focus on patient care.

It needs to be remembered that the CPAs are not meant to be a ‘cure all’ for all matters relating to pharmacy or pharmacists. Their purpose is to ensure that PBS medicines are dispensed in the community setting in a way that is efficient, safe and timely with a strong focus on QUM outcomes. This work is undertaken by the community pharmacy network on behalf of the Federal Government. Over time, the CPAs have had an increased focus on medicine related patient support, utilising the community pharmacy network. This is sensible given the strong link between pharmacist advice, support, counselling and review and QUM outcomes. However the core objective of the CPAs is the dispensing of PBS medicines in the community setting, so medication management programs funded through the CPAs should maintain a strong link with the dispensing of the medicines through the community pharmacy network.

Each of the six CPAs has been negotiated between the Federal Government and the Pharmacy Guild as the designated representative of the majority of the owners of the community pharmacies that make the capital investment in the infrastructure that delivers the PBS to the Australian public on behalf of the Federal Government. This ensures that the negotiation occurs between the appropriate representatives of the two parties that together have financial and practical responsibility for delivering the CPAs’ core objective of dispensing PBS medicines and related medication management. The Guild contends this approach has worked well and should continue, recognising that the Federal Government effectively represents the interests of consumers in the negotiation.

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\(^8\) Pharmacy Guild estimate from Federal Budget forecasts and extrapolations
The Guild believes that the CPA negotiation should be fully informed by consultations with relevant stakeholders as occurred in the 6CPA. These consultations should occur in a way and at a time that ensures the input, ideas and views of stakeholders are able to be fully taken into account during the negotiation. It also needs to be recognised that concurrent negotiations, including with the pharmaceutical sector in relation to medicines pricing, can directly impact the ability of community pharmacies to deliver the PBS to the Australian public. Similarly, if it is decided in future CPA negotiations that wholesaler remuneration and CSO standards should be negotiated directly with wholesalers, it needs to be recognised that there is a direct flow-on to pharmacy remuneration.

**Recommendation Number 1**

The Guild recommends that:

- the Pharmacy Guild, as the recognised representative of the majority of community pharmacy owners who fund and manage the infrastructure to deliver the PBS to patients, and who have ultimate responsibility for the professional integrity of that infrastructure, should continue to have responsibility for negotiating future Community Pharmacy Agreements with the Federal Government.

- the Community Pharmacy Agreements should be focused on the remuneration of community pharmacies and wholesalers for the dispensing of PBS and RPBS medicines and related services delivered through community pharmacies.

- future Community Pharmacy Agreement negotiations should be preceded with formalised consultation arrangements to ensure that the views and interests of relevant stakeholders are fully taken into account in the negotiations.

**Financial sustainability of pharmacy and the PBS**

The financial sustainability of the community pharmacy network and the PBS are intertwined. A financially sustainable community pharmacy network is essential to the ability of the PBS to deliver on the NMP objectives of timely access to the medicines that Australians need, at a cost individuals and the community can afford. Similarly, a fiscally unsustainable PBS undermines the viability of access to medicines through the pharmacy network at affordable costs, but also potentially undermines the sustainability of the whole pharmaceutical supply chain.

Much attention is given to the NMP objective of timely and affordable access to medicines for patients, yet another objective of the Policy is the maintenance of a responsible and viable medicines industry. It is incumbent on the Federal Government to promote a viable pharmaceutical industry by ensuring a stable and conducive business environment for the industry, including community pharmacy.

Community pharmacy has significantly contributed to the fiscal sustainability of the PBS while at the same time, the Federal Government continues to make budgetary savings from the PBS that put pressure on the viability of the community pharmacy network. In some quarters, the myth continues to be perpetuated that the PBS is not fiscally sustainable and more budgetary savings can be extracted from community pharmacies without jeopardising the sustainability of the network to dispense medicines to patients.

**Financial sustainability of community pharmacy**

The community pharmacy network has undertaken many improvements to business practices, including investment in new technology and in the qualifications and skills sets of staff required to become more efficient and in turn improve the quality of medicines dispensing and health related services to Australian patients. The community pharmacy network has not only done this in order to, first and foremost, enhance

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health outcomes for patients, but also to ensure its own financial sustainability and in turn contribute to the fiscal sustainability of the PBS.

Despite the efforts of the community pharmacy network to invest and improve business and work practices to become more efficient, it faces a series of ‘headwinds’ both in Australia and internationally that are putting pressure on financial sustainability. These include:

- Constraints on health care budgets: despite the PBS being one of the most sustainable areas of Government spending (see below), budgets continue to be squeezed.

- Intensifying competition: discount pharmacy chains that focus on retail offerings and use dispensing as a ‘loss leader’ are putting pressure on the community pharmacy model to race to the bottom in pricing and, evidenced by consumer surveys of their experiences with some discounters, quality of services.

- Transformation of the supply chain, including new channels: dispensing is increasingly a low margin activity as generics and the pricing policies of the Federal Government have resulted in lower prices for high volume medicines, but at the same time the community pharmacy network has to manage the dispensing of high-cost drugs with relatively little volume while taking the financial risks of the very low margins on these high priced drugs.

- Wholesalers are increasingly involved in the community pharmacy network: through their ownership of banner groups and franchising as well as their traditional wholesaling activities. Independent community pharmacies are increasingly unable to secure equal or consistent trading terms as a result of transformation of the supply chain. Some manufacturers also have invested in direct channels of distribution rather than using traditional wholesalers.

- Demand for convenience and expertise: health consumers are increasingly sophisticated and have higher expectations for prescription services, associated advice and clinical services as well as personal care items to be delivered with expertise, convenience and accessibility.\(^\text{10}\)

As a result of these and other factors, community pharmacy sales have declined by an average 1.26% annually from 2010 to 2014. The pressure on the financial viability of the community pharmacy network in recent years is evident by Chart 1 which provides a comparison of performance for pharmacies in key financial indicators from one year to the next.

\[\text{Chart 1: Key financial performance of community pharmacies}\)

\[\text{Source: Pharmacy Guild of Australia, Guild Digest 2016.}\]


Fiscal sustainability of the PBS

A common myth is that the PBS is fiscally unsustainable and a significant drag on the overall Federal Government budget. The reality is that the PBS is fiscally sustainable, albeit there are challenges associated with high-cost drugs, and the Federal Government continues to reap significant savings from the scheme through mandatory price decreases for items listed on the PBS and price reductions associated with price disclosure that flow through the pharmaceutical supply chain.

Federal Government expenses on ‘pharmaceutical benefits and services’ in 2014-15 amounted to $10.3 billion, representing around 2.5% of total Federal Government expenses. Overall pharmaceutical benefits and services expenses in turn constituted only 15.7% of total health expenses of the Federal Government. Moreover, even with the recent spike in 2015/16 related to higher than expected payments under the PBS, primarily as a result of greater than forecast demand for the newly listed Hepatitis C drugs, PBS expenses in 2015/16 were only 2.8% of total Federal Government expenses.

Moreover, PBS spending related to only Section 85 (S85) items in 2014-15 was only $7.1 billion, down 3.1% on 2013-14, pointing to the fact that the magnitude of government spending on PBS items that flows through community pharmacies is even less.

Hence a critically important public policy area – the timely access to the medicines that Australians need at a cost that individuals and the community can afford – comes at a cost to the Federal Government of less than 3% of its total expenses (Chart 2). While this snapshot of 2014-15 puts into perspective the magnitude of the Federal Government’s PBS expenditure and does not in itself demonstrate the fiscal sustainability of the PBS, an examination of the historical and expected trends in PBS expenditure certainly point to its fiscal sustainability.

Importantly the bulk of the growth in PBS expenses over the next decade is likely to continue to be in Section 100 medicines, two-thirds of which are dispensed through hospitals.

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12 Pharmaceutical benefits and services expenses includes veterans’ pharmaceutical benefits, section 100 and other programs, such as highly specialised drugs and chemotherapy drugs and other programs.

Chart 3 demonstrates that the PBS is fiscally sustainable. It shows Federal Government expenses where expenses are given as total spending on pharmaceutical benefits and services (i.e. includes Section 100 and other programs) and Federal Government spending on S85 PBS medicines only, respectively.

From the period 1999-2000 to the projection period 2019-20, the number of Section 85 PBS subsidised scripts (including doctor’s bag) is forecast to grow by 80% (or on average 3% a year) yet the cost of pharmaceutical benefits and services in real terms (2015-16 dollars) is forecast to increase by 53% (or on average 2.1% a year).

Clearly, more PBS scripts are being administered at a lower per script cost to the Federal Government. In real terms, in 1999-2000 the cost of pharmaceutical benefits and services per S85 PBS subsidised script to the Federal Government was $53.40 whereas by 2019-20 the cost per script is expected to be $45.20. Moreover, historically, if we consider only Federal Government spending on S85 PBS medicines, the cost to the Government has fallen in real terms from $36.01 in 1999-2000 to $33.96 in 2014-15.
The sustainability of the PBS and Federal Government health expenditure in the medium term has been investigated by the Parliamentary Budget Office (PBO). The PBO projects that in the next decade, PBS expenditure growth will be far outweighed by expenditure related to Medicare and the Private Health Insurance Rebate (Chart 4).

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14 For PBS S85 medicines, historical PBS cost and script volume data sourced from various PBS Expenditure and Prescriptions reports (various years, including doctor’s bag) available at: https://www.pbs.gov.au/info/browse/statistics.
PART TWO - THE ECONOMIC RATIONALE FOR THE COMMUNITY PHARMACY MODEL

Previous Reviews

As noted in the Discussion Paper, in the two decades between the Hilmer and Harper competition reviews, pharmacy regulation has been reviewed a number of times. The broad-based competition policy reviews have recommended that pharmacy be deregulated, while the more focussed reviews have recommendations that are more circumspect. Importantly, none of the focussed reviews have recommended the removal of ownership and Location Rules.

National Competition Policy (Hilmer) Review (1993)

The landmark Hilmer Review did not specifically consider the pharmacy industry and, indeed, the words ‘pharmacy’ or ‘pharmacist’ are mentioned only once in the main body of the National Competition Policy Final Report. Instead, Hilmer largely focussed on restrictions on competition imposed through government ownership such as “legislated monopolies for public utilities, statutory marketing arrangements for many agricultural products and licensing arrangements for various occupations and professions.”\(^{15}\)


The Wilkinson Review of Pharmacy, which was required under the post-Hilmer Legislation Review Program, assessed State and Territory pharmacy licensing and ownership regulations, and the location restrictions embodied in the Australian Community Pharmacy Authority (ACPA).

The Review recommended removing the restrictions on how many pharmacies a pharmacist can own, but supported the retention of the regulations prohibiting non-pharmacist ownership or control. In addition, the Review concluded that the location rules:

- operated to keep pressures on growth in government expenditure on the PBS to a minimum;
- helped to maintain a stable and sustainable local pharmacy market and minimum market saturation;
- supported a stable distribution network for the PBS; and
- facilitated the placement of new and relocated pharmacies in localities where there is genuine need for pharmacy services, particularly regional, rural and remote areas, and for areas of new population growth in metropolitan areas.


The Productivity Commission’s Review of National Competition Policy Reforms (2005) was another broad-based review of the status of microeconomic reform. The Commission was non-committal in relation to ownership and Location Rules though it recommended the introduction of CPI-X type price controls of PBS dispensing fees.

In addition, the Commission recommended a focussed review of pharmacy before the commencement of the 5CPA (2010-2015).

Urbis Review (2010)

In 2010, Urbis was engaged by DoH to undertake an independent review of the pharmacy Location Rules, which was a requirement of the 4CPA (2005-2010). The objectives of the Review were to consider:

\(^{15}\) Hilmer Report, p.184
the effectiveness and efficiency of the Rules in meeting the objectives outlined in 4CPA, including the impact of the Rules in different geographic locations, such as rural Australia (Clause 28, 4CPA).

The Urbis Review largely focussed on process issues, notably whether the application process (for new pharmacies) was effective and efficient. The Final Report did not make an assessment of whether the Location Rules should be retained or removed.

Post-implementation Review (PIR) of Pharmacy Location Rules (2014)
Three years into the 5CPA, the PIR was conducted by, or on behalf of, the Department of Health to evaluate the ongoing effects of the Location Rules. It concluded that the costs:

were outweighed by the benefits of the Rules, which maintain a reasonably well-distributed geographical spread of pharmacies in Australia, including (and especially) in rural and remote areas.

Importantly, the targeted modification of the Rules were considered and adopted in the context of the 5CPA.

National Commission of Audit (NCOA) (2014)
In October 2013, the Abbott Government appointed a National Commission of Audit (NCOA) immediately after winning government in September 2013. Tony Shepherd chaired the NCOA and was given three months to provide an initial ‘Phase One’ report.

Despite the condensed reporting timeframe, the NCOA's terms of reference were perhaps the broadest conceivable, covering:

• the roles and responsibilities of the Federal Government
• the efficiency and effectiveness of Federal Government expenditure
• medium-term risks to the integrity of the federal budget position (NCOA, ToR, Phase One)

The NCOA considered pharmacy in the context of medium-term risks to the budget and, therefore, focussed its analysis and recommendations of the costs of providing the PBS.

Nonetheless, the NCOA recommended ‘opening up the pharmacy sector to competition, including through the deregulation of ownership and Location Rules’ (Recommendation 19, part e).

“Encouraging greater competition within the sector could be undertaken by moving to deregulate pharmacy ownership and Location Rules. Such reform would be expected to lead to more efficient delivery and the development of alternative retail models - such as pharmacists available to dispense medicines at supermarkets.” (NCOA, Phase One Report, p.112).

No supporting evidence was provided in the NCOA report.

In December 2013, the Abbott Government announced an independent 'root and branch' review of Australia's competition laws and policy.

A key area of focus for the Harper Review was to:

“identify regulations and other impediments across the economy that restrict competition and reduce productivity, which are not in the broader public interest” (Harper, ToR Overview).
In its work, the Panel was to have regard to the following principle:

“no participant in the market should be able to engage in anti-competitive conduct against the public interest within that market and its broader value chain” (Harper, ToR 1.1).

The Harper Panel found:

“The Panel considers that current restrictions on ownership and location of pharmacies are not needed to ensure the quality of advice and care provided to patients. Such restrictions limit the ability of consumers to choose where to obtain pharmacy products and services, and the ability of providers to meet consumers’ preferences.” (Harper, Recommendation 14, p.190).

Harper recommended:

“The Panel considers that the pharmacy ownership and Location Rules should be removed in the long-term interests of consumers. They should be replaced with regulations to ensure access to medicines and quality of advice regarding their use that do not unduly restrict competition.

Negotiations on the next Community Pharmacy Agreement offer an opportunity for the Federal Government to implement a further targeted relaxation of the Location Rules, as part of a transition towards their eventual removal. If changes during the initial years of the new agreement prove too precipitate, there should be provision for a mid-term review to incorporate easing of the Location Rules later in the life of the next Community Pharmacy Agreement.

A range of alternative mechanisms exist to secure access to medicines for all Australians that are less restrictive of competition among pharmacy services providers. In particular, tendering for the provision of pharmacy services in underserved locations and/or funding through a community service obligation should be considered. The rules targeted at pharmacies in urban areas should continue to be eased at the same time that alternative mechanisms are established to address specific issues concerning access to pharmacies in rural locations.” (Harper 2015, Recommendation 14, p.190).

Very little if any public evidence was provided in support of these recommendations. The unsatisfactory experiences of deregulation in other countries, cited in the Guild submissions, were not commented upon.

The Federal Government, in its response to Harper, noted but did not support the recommendations in the final report in relation to pharmacy.

**Public interest and economic rationale for pharmacy regulation**

The Guild agrees with the Panel that the objective of the Review should be to achieve arrangements that are cost-effective, financially sustainable, and effective in delivering quality health outcomes and promoting equitable access and quality use of medicines. These goals reflect the broader public policy objectives that underpin the framework of community pharmacy regulation and remuneration as it has evolved to date.
Pharmacy and its regulation are complex and interactive; the sector and its regulation and remuneration have co-evolved as community preferences have shifted, the broader health industry has changed, and the Federal Government has sought to modify successive CPAs to reflect public policy priorities.

The Discussion Paper released by the Panel canvasses a broad range of suggestions that would, if implemented, affect how community pharmacies are regulated and remunerated and, therefore, how well they contribute toward the achievement of public health policy objectives. Many of these initiatives have far-reaching implications that extend beyond the specific issues being raised, and imply important costs and trade-offs that are not immediately apparent.

The following parts of this submission accordingly seek to address key questions put by the Panel within the broader economic policy framework that reflects the objectives of community pharmacy regulation. To that end, Part Two describes the framework that describes the public policy objectives for the community pharmacy sector, and how the current system of community pharmacy regulations and remuneration support these objectives.

As discussed in Part 1 - Introduction, community pharmacies are instrumental in ensuring that the medicines that consumers purchase are accessible, appropriate for their medical condition and safe for them to use. Community pharmacies dispense medicines and provide relevant counselling to accompany the sale of medicines, and assist members of the public who may seek pharmaceutical advice.

Although these services are supplied through retail outlets, community pharmacy is not merely another retail service. In ordinary retail, consumers pay the full commercial price of their purchases, which covers their cost. In contrast, consumers of PBS medicines mostly pay a price that is less than cost, and maybe substantially less.

Rather, community pharmacy is a crucial part of the health system, providing services to consumers on behalf of the Federal Government. Services, such as dispensing and the range of quality control, advisory and ancillary services, have a major impact on health outcomes — if they are not readily available to those who need them, or are not provided correctly, they can seriously damage the health and quality of life of consumers.

The Federal Government, and the community more broadly, therefore have a vital interest in the provision of these services. That interest is made all the greater by the fact that community pharmacy, if it performs well, reduces the costs of achieving the overall objectives of the health system, while poor performance in community pharmacy increases the health system’s costs, including in terms of the burden that then falls on other parts of the system, such as medical practices and hospitals.

If the Federal Government is to achieve value for money in the health system, and deliver the health outcomes Australians expect, and in an equitable fashion, it therefore needs an efficient and effective community pharmacy sector. Part Two: The Economic Rationale for the community Pharmacy Model describes the following:

- the public policy framework for community pharmacies as it is currently applied by the Federal Government; and
- the regulation and remuneration arrangements that have been put in place to achieve these public policy objectives.

**Public policy framework for community pharmacies**

The Federal Government uses taxpayer dollars to procure from the community pharmacy sector the service of providing medicines, advisory and ancillary services to consumers, in a manner that serves the needs of the community.
As outlined in Part One – Introduction, the policy objectives for the distribution and supply of medicines to Australian consumers are articulated in the Federal Government’s NMP. The NMP’s overall aim is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved.16

Furthermore, the policy aims articulated for the NMP are directly relevant to the broader public policy objectives that should guide the regulation and remuneration of community pharmacy. Given the flow of PBS and other prescriptions, and considering the non-dispensary services that community pharmacies do or could supply, the objective of policy should be the high quality, cost-effective, timely and accessible supply of medicines and of related services, where:

- effectiveness means providing the greatest net benefit to consumers, with additional weight being placed on the outcomes for those most in need of health interventions and those least able to pay for them
- cost is comprehensively defined to include not only taxpayer funds, but also the necessary burdens placed on the consumers and others in the community, as well as the broader health system

To achieve that overall policy objective, a system would need to satisfy the following major criteria, reflecting the public health objectives of the Federal Government and the community:

- to provide a high level of consumer access, including for older or disadvantaged consumers and consumers with special needs
- to minimise costs by avoiding unnecessary duplication and securing economies of scale and scope where they arise, noting that a poorly performing community pharmacy sector may impose costs elsewhere in the health system
- given the broader policy aim of ensuring that consumers are provided with effective and safe medicines, to align incentives in the distribution chain and manage agency problems, thus ensuring effective quality control and encouraging pharmacies to undertake their functions cost-effectively
- to avoid unnecessary transactions costs, both because such costs directly increase the costs of supplying medicines, and because unduly complex structures are likely to create unintended consequences, which in turn may require further costly government interventions

This submission demonstrates that the existing regulatory framework for community pharmacies supports the achievement of these broad public policy objectives, including by meeting each of these criteria. The main community pharmacy regulations and their outcomes are set out in the following sections.

**Regulation and remuneration of community pharmacy and its outcomes**

As discussed earlier in Part One, the regulation of community pharmacy involves a number of strands, including rules that govern the location of pharmacies, and their licensing and ownership. The remuneration of community pharmacy has in turn been determined through successive CPAs, with the 6CPA taking effect from 1 July 2015. Individually and in combination, these provisions have shaped the evolution of community pharmacy to date.

**Government as market steward in community pharmacy**

The regulation of community pharmacy is an exemplary case of what the Harper Review called ‘market stewardship’ by government in the human services area. As noted by the Harper Panel (Federal Government 2015, p.225):

> Stewardship relates not just to governments’ direct role in human services but also to policies and regulations that bear indirectly on human services sectors.

The Harper Panel recognised that the public interest is sometimes not best served by the removal of all restrictions on competition. This is more likely to apply in the area of human health services than elsewhere, because the information that consumers need to make a well-formed decision is both uncertain and asymmetrically shared, and because of the important and possibly irreversible results that can ensue from bad advice or decisions. The Harper Panel then suggested roles for government as market steward in a world in which human services are more responsive to consumer choice (p.229):

> High-quality human services can significantly improve peoples’ standard of living and quality of life. Particularly with Australia’s ageing population, the size and importance of the human services sector will increase into the future.

> Governments cannot distance themselves from the quality of human services delivered to Australians — they will continue to have an important role as market stewards in human services sectors, including through policy and funding decisions.

The concept of market stewardship is central to how the regulation and remuneration of community pharmacy should be assessed. The organisation of the community pharmacy sector does not reflect outcomes in an unfettered market in which multiple independent agents compete and the Federal Government is a dispassionate onlooker, and community pharmacy should not be assessed against such an ideal. Rather, the regulatory framework applied to community pharmacy and how it has shaped the sector has enabled the Federal Government to exercise control over the costs of the distribution and supply of medicines and advisory services, while ensuring that access and quality objectives are met at the required standard.

At a high level, and setting aside the arrangements that have been put in place to provide specialised services (such as chemotherapy) or to service particular populations (such as remote Australians and the Aboriginal community), the Federal Government’s role as a market steward is reflected in three key instruments that it has applied over the years:

- the community pharmacy remuneration arrangements, as reflected in consecutive CPAs;
- the Location Rules; and
- the community pharmacy licensing and ownership rules.

As is set out in the following sections, individually and in combination, these instruments have played (and continue to play) a key role in enabling the Federal Government to achieve its health policy objectives, including by shaping the organisation of the community pharmacy sector.

**Community Pharmacy Agreements**

The five-year 6CPA is the most recent of a series of five-year agreements that the Federal Government has entered into with the community pharmacy sector since 1990. The objectives of the CPAs have evolved...
over time. The 6CPA explicitly recognises the integral role of community pharmacies within the infrastructure of the health care system, and articulates three key objectives:

- promoting the sustainability, efficiency and cost-effectiveness of the PBS within the broader context of health reform
- ensuring that community resources are appropriately directed across the health system
- supporting the sustainability and viability of an effective community pharmacy sector

Furthermore, 6CPA clarifies that the pharmacy remuneration and medicines pricing arrangements are intended to support the objectives of the NMP by balancing the need to:

- ensure consumers can continue to have access to new and innovative PBS subsidised medicines at an affordable price that are necessary to maintain the health of the community
- promote and improve the quality use of medicine
- ensure a cost-effective and sustainable PBS

In the context of the 6CPA, the Federal Government’s objectives, in terms of equitable access to high quality medicines are given effect through the community pharmacy remuneration arrangements. Key components of these include a tiered Administration, Handling and Infrastructure (AHI) fee, general dispensing fees, as well as dispensing fees for dangerous drugs. In particular, consumers’ contribution to the price of medicines is limited to the cost of the co-payment, which, in the case of concession card holders or consumers falling under the concessional safety net, is set at $6.20 or zero. Charges, such as the AHI fee and dispensing fees, are either subsumed in the general co-payment, where applicable, or paid by the Federal Government.

In effect, therefore, the community pharmacy remuneration regime supports the goal of ensuring equitable access by separating consumers’ willingness to pay from pharmacists’ income. The 6CPA furthermore explicitly references the community pharmacy Location Rules, the purpose of which is explicitly linked to the achievement of equitable health outcomes (DoH 2015):

_The Pharmacy Location Rules (the Rules) are a fundamental component of the Sixth Community Pharmacy Agreement. The Rules contribute to the overall objective of the National Medicines Policy to improve the health outcomes of all Australians through access to, and quality use of, medicines._

The Federal Government’s objective, in terms of the cost-effectiveness and sustainability of PBS arrangements are also reflected in the revised remuneration arrangements. More broadly, the key characteristics of the fee structure, as described in Section 4.2 of 6CPA is that it is both transparent and administratively tractable, given that it is linked to specific (community pharmacy) ‘outputs’.

**Location Rules**

The Location Rules that apply to community pharmacies set out location-based criteria which must be met in order for the ACPA to recommend the approval of a pharmacist. These rules apply both to the establishment of a new pharmacy and the relocation of an existing pharmacy. In particular, minimum distance requirements apply for new or additional pharmacies wishing to locate in the vicinity of an existing community pharmacy, and community pharmacies must not be accessible from within a supermarket. In practice, the Federal Government has relied primarily on Location Rules as the instrument it uses to shape the geographical structure of community pharmacy.

Following a review, these rules were amended in 2011 to simplify the application process and to encourage pharmacies to be established in areas of community need. An existing pharmacy PBS approval is now no longer required before a new pharmacy can be established in facilities such as shopping centres, large medical centres and private hospitals, or in towns where there is only one pharmacy. Certain rules relating
to pharmacy relocations were removed, and a new catchment test was introduced for new pharmacies and new additional pharmacies.

The DoH’s Post-Implementation Review- Amendments to the National Health Act 1953 to extend the Pharmacy Location Rules to 30 June 2015 that was conducted in 2011, provides an outline explaining the need for the Location Rules.

*The community pharmacy network is the distribution system for the PBS. If the pharmacy network, left unaided, cannot deliver reasonable access for all Australians, as was the case immediately prior to the commencement of the First Agreement, then some regulatory intervention in the market is needed to ensure that medicines are available (to all Australians) efficiently and equitably through the PBS.*

Without a well distributed network of pharmacies, consumers in rural and remote areas would experience distance barriers to access to pharmacies. As was the case before the First Agreement, it can then be difficult or expensive for consumers to access needed prescription medicines, which is counter to the key pillars of the NMP. This also results in poorer health outcomes for rural and remote Australians than for those in urban or near-urban areas.

*The Government is interested in a well distributed network of approved community pharmacies that closely matches the demographic distribution of the Australian community which, in addition to the supply of medicines subsidised under the PBS, can deliver a range of pharmacy services that form part of the Fifth Agreement.*

The review also stated:

*The Government is seeking to ensure that any regulatory intervention in the community pharmacy network is consistent with the goals of reasonable access; efficient and equitable delivery of medicines; and ensuring competition between pharmacies is only restricted to the extent justified by this need.*

Prior to the Location Rules being created under the First Community Pharmacy Agreement (1CPA), many pharmacies were clustered in few, and mostly urban areas. Conversely, there were some areas with few or no pharmacies. In addition, there were a number of relatively inefficient pharmacies which were primarily in commercially attractive urban areas. There was also a concern that the pharmacy to population ratio, at that time, was too high compared to other developed nations.

In conclusion, the pharmacy network, left to market forces alone up to 1990, did not deliver reasonable access to PBS medicines for all Australians.

**Rationale**

The Federal Government has two basic objectives with respect to the location of community pharmacies:

- to ensure equitable access, which requires that pharmacies are reasonably accessible to all consumers, regardless of where they live, their income or age
- to secure cost-effectiveness in the distribution structure, achieving economies of scale and scope in distribution and avoiding unnecessary duplication

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18 Post-Implementation Review (Amendments to the National Health Act 1953 to extend the Pharmacy Location Rules to 30 June 2015) 2011, 11
19 IBID, 12
20 IBID, 13
21 IBID, 30
The goal of achieving equitable access is pursued partly through the remuneration arrangements, including those established under the 6CPA, as these weaken the link between the income pharmacists receive for dispensing and related services and consumer ability and willingness to pay. As a result of those arrangements, pharmacists face stronger incentives than they otherwise would to locate in areas where consumers’ ability and willingness to pay would be low relative to the costs of community pharmacy. The Location Rules then complement and reinforce that effect by providing pharmacists with a limited assurance of securing revenues in respect of a geographical catchment area.

At the same time, as the Federal Government, through the PBS, bears the bulk of the costs of dispensing, it has a legitimate interest in avoiding unnecessary distribution costs. The Location Rules advance this objective by avoiding both the excess entry that the economics of retail location suggest might occur when prices are largely fixed to cover average total costs and entry is unrestricted, as well as the associated clustering of retail outlets in central business areas and major shopping centres.

Finally, the Location Rules interact with the ownership rules, which are discussed in greater detail below. In particular, by defining (albeit limited) ‘catchment areas’, the rules incentivise pharmacists to invest in pharmacy facilities and to build goodwill in their pharmacy, all the more as that goodwill is at least partially saleable on exit.

Achieving the twin goals of providing for pharmacies to be located where they are needed, and yet avoiding duplication, requires a geographical pattern of pharmacy location that has some degree of dispersion to it, with less clustering of outlets – and so less close duplication – than usually characterises retail markets. In other words, to meet the Federal Government’s aims, pharmacies should be located in places that differ from those that would likely be chosen simply from the perspective of maximising profits, and in a manner that limits purely overlapping outlets.

Outcomes

The natural starting point for any examination of the Location Rules for community pharmacy should be how well outcomes under the rules conform to the Federal Government’s locational objectives. So as to secure a reliable evidence base in this respect, in 2014 and 2016, the Guild commissioned a detailed mapping of the geographical distribution of community pharmacy from MacroPlan Dimasi, a highly respected firm that specialises in analysing retail location. MacroPlan Dimasi assessed:

- the level of access consumers enjoyed to community pharmacy
- the degree to which non-metropolitan areas, socially disadvantaged areas and areas with above average numbers of older Australians secured equity of access
- compared locational outcomes in community pharmacy with those for banks, supermarkets and medical practices

The 2016 findings, tabulated in Appendix 2, reinforce the evidence from the 2014 geospatial analysis. These findings provide clear evidence of the high level of consumer access, including for older or disadvantaged consumers and for consumers with special needs, that has emerged under the Location Rules:

- Australians—including especially older and disadvantaged consumers—have a very high level of access to community pharmacy. In the capital cities, the average resident is located less than one kilometre from the nearest pharmacy, while 97% of consumers are no further than two and a half kilometres from a pharmacy. Outside of capital cities, country residents are just 6.4 kilometres on average from the nearest pharmacy, with 65% having a pharmacy within two and a half kilometres. As a result, travel times to pharmacies are also very low. Some 50% of Australians enjoy a travel

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22 Banks were included in 2014 analysis only.
time of less than five minutes to their preferred pharmacy, with a further 30% having a trip time of between five and ten minutes. In total then, 80% of consumers take ten minutes or less to get to the pharmacy of their choice.

- Community pharmacies are also highly accessible in terms of their opening hours. Thus, 55% of consumers shop at a pharmacy that is open seven days, with a further 32% shopping at a pharmacy that is open on Monday to Saturday but is closed on Sunday. These are remarkable levels of access to a complex, professional service. And that service is speedy as well: 40% of consumers estimate it generally takes five minutes or less for their prescription to be filled, with an additional 40% waiting no more than ten minutes. 23

- Moreover, Australians typically have a choice of local pharmacies; that is, the Location Rules do not materially detract from effective competition. Most Australians are in reasonably close proximity to competing pharmacies, with MacroPlan Dimasi finding that 94% of metropolitan consumers are within two and a half kilometres of at least two pharmacies and 76% of non-metropolitan consumers are within no more than five kilometres of at least two pharmacies.

The findings of MacroPlan Dimasi’s comparison of the location of community pharmacy to that of other services are also informative. While there are inevitably some localised variations, it is clear that on balance, consumers are more likely to be close to a community pharmacy than to a supermarket, bank or medical centre. Moreover, the proportion of consumers who are reasonably close to two or more pharmacies is as high, if not higher, for community pharmacy than it is for the other services that were analysed by MacroPlan Dimasi.

There are, no doubt, some difficulties in undertaking comparisons between the accessibility of different services. Perhaps the most significant is that medical centres, particularly in non-metropolitan areas, are often part-time, only opening on a few days of the week. In contrast, pharmacies, as noted above, typically have long opening hours. Nonetheless, even treating each medical centre as if it were a full-time operation, access to medical centres is, on average, lower than that to community pharmacy.

It is important to stress that community pharmacy achieves these high levels of access with relatively low numbers of outlets. For example, community pharmacy provides no lower a level of access than medical practice (broadly defined) but does so with 16% fewer outlets. That means there is less duplication of fixed costs and a greater ability to achieve economies of scale, thus saving resources and ensuring that the network of community pharmacies is sustainable over the longer term. The supporting savings are substantial: were the density of pharmacy equal to that of medical practice, access would scarcely rise but costs to consumers and taxpayers would be higher, in present value terms, by $1 billion.

**Meeting the Accessibility Target set by the Government in 2015-16**

While the MacroPlan Dimasi geospatial analysis amply demonstrates the success of the Location Rules, it is also important to view the distribution of pharmacies in the context of current Federal Government criteria.

The Federal DoH has a specified target24 that more than 90% of urban centres/localities (UCL) in Australia with a population in excess of 1,000 people should have a resident community pharmacy or approved supplier of PBS medicines.

We note that the findings from MacroPlan Dimasi’s analysis are consistent with independent research conducted by the University of Adelaide on behalf of the DoH (DoH, Lange and Franzon 2016)25. The

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23 Institute for Choice Consumer survey 2014


authors assessed DoH data on the location of community pharmacies for the years 1990, 2007 and 2014. Their research indicates that:

- The total number of pharmacies in 2014 was lower than in 1990, despite Australia’s increasing population over that timeframe. At the same time, and while population to pharmacy ratios increased overall, these ratios decreased in rural locations.

- At least on the basis of the available data, there appeared to be no relationship between pharmacy locations and socio-economic status.

The report also showed that in 2014 there were 926 non-urban UCLs without a local pharmacy. However, the bulk of these locations had populations of less than 1,000 persons, and around 96 non-urban UCLs with a population of over 1,000 did not have a pharmacy within the UCL boundaries. The report identified a further ten UCLs where their population have access to a pharmacy within 150 metres outside of the UCL boundaries. In addition, there are 11 UCLs that have a pharmacy between 150 metres and 2 km outside of their boundaries.

While the DoH’s minimum target criteria may be useful, it needs to be pointed out that these boundaries are arbitrary. Firstly, the report showed that within 150 metres of the UCL boundaries, there are ten pharmacies that do not strictly belong to a UCL. Secondly and more importantly, the report also shows that many UCLs (244) with populations less than 1,000 have access to a pharmacy within them.

These findings thus suggest that lower socio-economic ‘catchments’ are as well served by community pharmacy as is the case for higher socio-economic areas. Furthermore, high accessibility has been achieved at a less than proportionate expansion of the number of community pharmacies than the Australian population, as well as broadly meeting the Federal Government’s quantitative performance criteria in relation to consumers’ access to community pharmacy or approved supplier of PBS medicines.

**Overseas experience**

As noted in the Discussion Paper, regulations relating to the location of pharmacies is not unique to Australia.

Most European countries apply statutory provisions to regulate the establishment of new pharmacies. Typically, demographic criteria (e.g. minimum number of persons that will be supplied by the pharmacy) and geographic criteria (e.g. minimum distance to existing pharmacies) are taken into consideration. Usually, these regulations relate to the whole country but specifications at regional levels are possible.

The outcomes as regards the location of community pharmacies in Australia can be contrasted with those that have occurred when location restrictions on community pharmacies were lifted in some European countries. Location Rules were removed in England (although some were reintroduced in 2012), Ireland, the Netherlands, Norway and Sweden (Vogler et al. 2012). Based on a comparison of these countries, Vogler et al. (2012) concluded that, while more new pharmacies opened after the liberalisation of establishment rules, they tended to be established at attractive locations (urban clustering) and not in places where no pharmacy had existed before, such as in rural, sparsely populated areas. Vogler (2014) finds that:

- In Sweden, 67% of new pharmacies are located in areas of very high accessibility (urban areas of at least 60,000 inhabitants), 28% in areas of high accessibility (at least 30,000 inhabitants), 6% in

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26 Ibid
27 Ibid Appendix 5.
https://www.adelaide.edu.au/apmrc/research/completed/APMRC_Report_Pharmacy_AccessClustering_2016_Appendix_5.xlsx
28 Vogler – Competition issues in the distribution of pharmaceuticals – March 2014, 3
areas of medium accessibility (at least 3,000 inhabitants) and no pharmacies in areas of low and very low accessibility (at least 1,000 (200) inhabitants)

- In England, new pharmacies have tended to cluster around existing pharmacies. Before the 2005 reforms, 54% of the openings occurred at a distance of more than one kilometre to the nearest pharmacy; in 2012, the corresponding share was 14%. These developments might have led to a change in regulations in September 2012 with the removal of some of the exemptions for the ‘control of entry’ test.

Of particular relevance are recent proposals by the National Health Service (NHS) in England aimed at reducing the number of pharmacies precisely because of excessive clustering in urban areas. In the absence of location rules, the number of pharmacies has increased by 20%, from 9,748 in 2003 to 11,674 in 2015. More importantly, and as a direct consequence of deregulation in 2005, 40% of pharmacies are in clusters of 3 or more and within 10 minutes walking distance of at least two other pharmacies. The intent of the 2015 NHS proposals is to encourage the closure of between 1,500 and 2,000 pharmacies in England. This bears a direct analogy to the situation that existed in Australia prior to the introduction of locational rules in 1990, when approximately 50% of pharmacies were located within 200 meters of each other.

Anell (2005) notes that in Iceland, pharmacy numbers have increased by 40% since deregulation, mainly in the main urban centre of Reykjavik, and that there has been a pattern of parallel closures of rural pharmacies. These changes follow general population trends, but were perceived as a problem by the Department of Health. In Norway, new pharmacies also opened in urban areas but deregulation did little to improve the availability of pharmacies in rural areas. While more than 130 new pharmacies have been established in Norway since the liberalisation act of March 2001, only nine of them were opened in municipalities without a pharmacy or a branch pharmacy. In the summer of 2005, pharmacy services were still not available in 199 out of 434 municipalities (46%).

Moreover, with respect to potential benefits of competition, the overseas evidence shows that:

- deregulation of the pharmacy sector does not necessarily lead to more competition. In practice, competition has been compromised by the emergence of dominant new actors. In some cases, this has required new regulatory intervention to address competition concerns. (Vogler et al. 2012)
- there was no evidence from the studied countries about price competition in non-regulated OTC medicines, and consistent decreases in the prices of OTC medicines was not confirmed. A reduction in overall pharmaceutical expenditure in these countries was therefore found to be unlikely. (Vogler et al. (2014)
- vertical integration distorted competition and impacted the accessibility of medicines

In summary, the empirical evidence of pharmacy deregulation highlights the complexity of reforms. Unconstrained competition has not delivered cost savings and interventions required to address these concerns have themselves been costly.

More recently, the Organisation for Economic Cooperation and Development (OECD) Review concluded that:

- Denmark also reported prices of non-pharmacy OTC medicines increased by 23%. Overall the report concluded that a decrease in the prices of OTC medicines was not confirmed across the European countries studied.

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the report points to no clear benefit to deregulation and highlighted significant risks (i.e. increased market concentration).

Policy alternatives

The question has been raised of whether a similarly desirable locational spread of community pharmacies could not be obtained using other policy instruments, such as direct subsidies. As a purely theoretical proposition, that may be possible, but the experience in other parts of the health system is not at all encouraging.

For example, data compiled by the Australian Institute of Health and Welfare shows that the supply of medical practitioners remains significantly lower in regional and remote areas of Australia than in major cities. While major cities have 426 full-time equivalent (FTE) medical practitioners per 100,000 people, the corresponding number of FTEs is only 257 in remote/very remote areas, and well below 300 FTEs in regional areas. At the same time, and while perhaps not exactly comparable, the Macro Dimasi analysis suggests that pharmacy is more accessible than medical centres in regional areas (as well as in capital cities). In Australia’s regions, access to a pharmacy within a two and half km radius is 72% compared to 58% for medical centres.

These outcomes have arisen despite significant and rising subsidies provided by successive governments, including the General Practice Rural Incentives Program (GPRIP), which offers (significant) financial incentives to medical practitioners to relocate and practice in rural and remote communities; the HECS Reimbursement Scheme, which reimburses HECS fees for medical students and graduates working in rural and remote areas; as well as the National Rural Locum Program, the Rural Locum Education Assistance Program (Rural LEAP), the Bonded Medical Places (BMP) scheme and Medical Rural Bonded Scholarships (MRBS). Indeed, given the persistence of the disparities, even in outer metropolitan areas, the previous Labor Government intended to directly fund medical centres in those places in which access was judged to be inadequate.

Nor are the difficulties that have been encountered in respect of medical practice unusual. On the contrary, experience in other industries, such as telecommunications, highlights the many problems that can arise when direct subsidies are used in an effort to ensure equity of access to geographically dispersed facilities. No doubt, those problems need to be assessed in the light of the cost and demand characteristics of each sector; but the broad message—that achieving the desired geographical pattern of activity is not easy or straightforward – underscores the risks involved in moving from a system that works in practice to alternatives that, at best, work in theory. A high burden of proof should therefore lie on those who advocate change, especially with schemes that are novel and untested.

Adjustments to the Location Rules

Throughout the six CPAs the Location Rules have evolved to meet the objectives of the Federal Government and to address any unintended consequences. Of necessity, the Location Rules require adjustment from time to time to render them responsive to the evolving needs of the community.

The Guild acknowledges there are currently some anomalies in the Location Rules that warrant further investigation and possible amendments, particularly in the areas of:

- Relocating existing pharmacies/ short distance relocation
- Pharmacy in a facility (shopping centre and medical centre)
- Various procedural issues, including Ministerial Discretion arrangements

As such the Guild would welcome an opportunity to discuss these anomalies further with the Federal Government with the aim of addressing them early in the 6CPA.
Licensing and ownership rules

While the Federal Government sets the Location Rules, the ownership rules are a matter for State and Territory Governments. The effect of these rules is that, by and large, pharmacies can only be owned and operated by registered pharmacists, where the owner-pharmacy must have effective and undisputed control of decision-making. The ownership rules do not, however, prevent pharmacies owned by different pharmacists from operating under a common name or brand.

As described in the following, the rules regarding pharmacy ownership play an important part in achieving national health policy goals, in terms of:

- preventing horizontal and vertical integration and therefore concentration of the pharmacy sector, thus minimising costs and financial risks to the Federal Government and to taxpayers; and
- ensuring that quality of service standards are adhered to, since pharmacists who breach the standards risk losing the considerable human and physical capital invested in their pharmacy.

Rationale and outcomes

A key feature of the existing pharmacy ownership rules is that they have preserved a dispersed ownership structure, with very low levels of ownership concentration. Such a structure provides crucial benefits to the Federal Government, as it prevents a situation from emerging where the Federal Government, to meet its objectives, would have to purchase dispensing services from suppliers with substantial market power.

For example, the geo-spatial data compiled by MacroPlan Dimasi shows that to obtain the same level of access community pharmacy provides through supermarkets, the Federal Government would need agreements with both Coles and Woolworths, as well as with independents. It is inevitable – and consistent with any economic theory of bargaining – that Coles and Woolworths would have a high degree of bargaining power in this situation. Simply put, they could threaten to pull out of providing dispensing services, making it difficult for the government to achieve its access objectives; as pharmacy would be a minute part of their revenues and net earnings, the loss associated with making good on that threat would be much lower to them than to the Federal Government. As a result, if they acquired a predominant position in dispensing services, it is likely that they would secure monopoly rents at taxpayers’ expense. Obviously, that risk would not only arise if retail supermarket chains controlled a high share of the sector; rather, it would also occur under other concentrated ownership scenarios. By avoiding those high levels of concentration from arising, the ownership rules can secure a substantial public benefit.

The second benefit of the ownership laws is that they ensure owner-pharmacists have significant ‘skin in the game’. Pharmacists invest considerably in human and physical capital to operate their businesses, which is usually their principal asset. Because the rules limit dilution of equity, pharmacists cannot spread the risk associated with that asset to other investors in the way a listed entity would. By placing the pharmacist and his or her professional reputation at the centre of the distribution relationship, a position that the pharmacist stands to lose if quality standards are not met, the Federal Government effectively ‘raises the stakes’ for non-performance.

Owner-pharmacists therefore have an enhanced incentive to conduct themselves and their pharmacies ethically and professionally, so as to not risk loss of registration and, therefore, loss of value in the pharmacy. In addition, owner-pharmacists are accountable to the public through the regulation of their registration. A non-pharmacist owner would be accountable to their shareholders first and foremost.

The ownership rules therefore contribute to the trust consumers have in community pharmacy, which in turn helps achieve the Federal Government’s public health objectives of ensuring access to safe and effective medicines. Here too the empirical evidence supports this claim. An important component of that evidence is a survey commissioned by the Guild from the Institute for Choice, an international leader in the conduct of
rigorous consumer surveys. Using a large and representative sample of Australian consumers, the survey found that on a scale from one to five, over 50% of consumers gave their pharmacy a trust score of five, which corresponds to trusting it ‘completely’, with an additional 37% giving it a trust score of four. Very few consumers expressed a low level of trust in community pharmacy. Those differences in trust are not unrelated to the ownership rules, with some 90% of consumers believing pharmacies should be owned by pharmacists.

There is, furthermore, an important interaction between the public benefits that arise from the pharmacy ownership rules, and those from the Location Rules. As noted above, the ownership rules necessarily impose risk on owner-pharmacists who (with some historical exceptions) cannot diversify the investment risk they incur across pharmacies or by selling significant equity to non-pharmacists. Australia’s health policy relies on pharmacists to fund the sunk investments that providing widespread access to dispensing services requires. The effect of free market entry for competing pharmacies would be to increase the risk on pharmacists, and to potentially increase the cost of capital to pharmacy, ultimately raising the costs consumers and taxpayers need to bear. The Location Rules help mitigate that risk, as they give pharmacists some (limited) assurance that, having incurred those sunk costs and built local custom, they will not be exposed to completely unrestricted entry. As such, the location and ownership rules are complementary and self-reinforcing.

Overseas experience

The outcomes as regards the industry structure in Australia can be contrasted with those that have occurred when ownership restrictions on community pharmacies were lifted. In countries where the ownership of pharmacies has been deregulated, this process has set in motion horizontal and vertical consolidation and, in the case of Norway, has required new regulatory intervention by antitrust authorities.

Anell and Hjelmzgren (2001) and Anell (2005) compared the effects of pharmacy deregulation in Iceland (1996) and in Norway (2001). They found that oligopolies formed, which led to new policy interventions:

- In Iceland, the number of independent pharmacies fell dramatically post deregulation. The number of pharmacies increased, the average number of customers per pharmacy decreased, as did the prices of medicines as a result of aggressive discounting on consumers’ co-contributions (in urban, but not rural areas). This resulted in decreased pharmacy revenues, which in turn led pharmacies to add non-pharmaceutical products to their range, moving to smaller premises and reducing personnel. Horizontal mergers gave pharmacies power to negotiate discounts from wholesalers, which in turn encouraged wholesalers to merge in order to increase their negotiating power. Intervention by the Icelandic competition authority was required to force one group to sell off specific pharmacies in order to prevent the formation of local private monopolies. In 2001, the three dominant chains (including individually owned pharmacies collaborating in purchasing from wholesalers) controlled about 85% of the market; by 2004 concentration had increased further, and two pharmacy groups controlled 85% of the market.

- In Norway, deregulation of the pharmacy sector resulted in significant merger activity with the result that the competition authority was forced to intervene to prevent any one pharmacy group from controlling more than 40% of the market. Individually owned pharmacies began forming purchasing chains in anticipation of deregulation, and subsequently began merging with wholesalers. In 2002, one year after the reforms, three main pharmacy groups controlled more than 55% of the market; by March 2004, 97% of all community pharmacies had entered into alliances with the three main pharmacy groups, 77% through full ownership. In contrast to the experience in Iceland, however, Norwegian pharmacies did not compete with one another on the basis of discounts or lower prices.

32 It seems unlikely, given the current debate, that similar levels of trust would, fairly or unfairly, be expressed in respect of banks, which were not covered by the survey. What one can say, however, is that there is a stark contrast between consumer perceptions of community pharmacy and supermarkets, which the survey did cover. Thus, while around 90 percent of consumers trust their community pharmacy completely or nearly so, over 50 percent of consumers do not trust supermarket chains at all or barely trust them.
According to an evaluation by the Norwegian Department of Health, the integrated groups did negotiate discounts from pharmaceutical companies, in particular for generic drugs, but these discounts were not passed on to consumers or to the national Government in the form of reduced subsidies.

Overall, Anell and Hjelmgren (2002) and Anell (2005) conclude that:

- Rather than leading to more competition, deregulation of community pharmacies in both Iceland and Norway resulted in horizontal mergers and coalitions between pharmacies and, in Norway, vertical integration between pharmacies and wholesalers. The distribution of pharmaceuticals was rapidly transformed into an oligopoly.

- The extent of vertical integration in Norway created new entry barriers, given that independent pharmacies do not enjoy the same discounts as pharmacists linked to wholesalers.

- In neither country, was a key reform objective – the control of public expenditures for subsidised medicines - achieved. In both countries, the respective Governments were surprised and frustrated by the rapid changes in competitive behaviour and market structure. Ad hoc interventions were necessary to prevent developments in the market that were not in line with Government expectations.

Similar trends towards vertical integration and industry consolidation were also observed in the United Kingdom (UK) (Lluch and Kanavos 2010). In 2002, 40% of pharmacy outlets belonged to big chains and supermarkets; by 2003 the percentage of pharmacy chains had increased to 53%.

In a general survey of the effects of the deregulation of community pharmacies, Vogler et al. (2012) found that, in practice, competition has been compromised by the emergence of dominant new actors, in particular wholesalers establishing large pharmacy chains. In all five deregulated countries, the removal of ownership rules led to the establishment of pharmacy chains and vertical integration with large international wholesalers.

Overall, and while comparisons of pharmaceutical sectors between countries can be problematic, a clear trend of industry consolidation has been observed in countries that have relaxed their pharmacy ownership rules. In some countries, this has been a gradual and ongoing process; in others (such as Norway and Iceland) the industry landscape changed very rapidly. The empirical evidence suggests that deregulation has not delivered the expected results, nor has it produced the competitive market environment that may be said to be in the long-term interests of consumers. These are trends that are difficult or impossible to reverse once they have been set in motion. Given the relatively small size of the market and existing concerns about market power in retailing, the consequences of ownership deregulation in Australia would therefore need to be carefully assessed.

There do not appear to be comparative studies of the ‘quality’ of advice or similar measures provided by pharmacists pre- and post-deregulation. However, Vogler (2014) provides some indication that in the absence of ownership restrictions other aspects of quality may have suffered:

- In Norway, where the industry consolidated rapidly, vertically integrated pharmacies were observed to align their product range to the supply of their owners, and less frequently requested medicines became less available in pharmacies.

- In Denmark, a focus on the wholesaler’s product range and limited availability of less frequently requested medicines was also reported. Despite a growth in OTC medicines sales of 54% from 2001 to 2011, the availability of OTC medicines only increased for a few top-selling medicines.

- In Sweden, pharmacies tended to focus more on body and beauty products; fewer prescription-only medicines were held in stock, and there are indications that such medicines take longer to supply.
Policy alternatives

While the ownership rules have engendered high levels of trust and ethical behaviour in community pharmacy, the experience in Australia with other industries where ownership rules were lifted or government-subsidised services were opened to competition also points to potential risks in that regard. While there are invariably industry-specific factors at play, there are a number of examples were reforms of this type have resulted in unintended consequences, including with:

- ABC Learning, a childcare centre operator that was able to apply for government-subsidised child care places, expanded rapidly and was subsequently liquidated in 2008; and
- the expansion of vocational education and training (VET) colleges to access government-subsidised (VET-FEE-HELP) training places, and which resulted in a rapid expansion of the sector, fraud, students being enrolled in courses they could not complete and collapses of some training colleges.

The common theme is that, in both cases, liberalisation led to outcomes that were distorted by the interaction between other policy instruments (such as childcare subsidies and student loans) and commercial entry incentives. In other words, the complex nature of the relevant policy regime caused significant unintended consequences, which continue to play themselves out. Arguably, the resulting disruption caused significant harm to the (for-profit) childcare and education sector and, at least in education, have prompted a significant rethink on the part of government.

Whether similar outcomes would arise in community pharmacy is inherently difficult to predict. On the one hand, as noted above, the PBS pricing and remuneration arrangements drive a wedge between prices as paid by consumers, and the payments accruing to pharmacists, respectively, potentially creating incentives for the type of rent-dissipating entry observed in child care and in VET. On the other hand, the total subsidy payment, rather than being as open-ended as it has been in the other sectors, is effectively capped by the number of medicines prescribed, and which entry is unlikely to affect. Nonetheless, the experience of these other sectors highlights the possibility of unintended consequences, underlining the importance of careful and cautious market design.

The concept of government as a ‘market steward’ is therefore central to how the regulation and remuneration of community pharmacy should be assessed.

In examining how governments have implemented their market stewardship role in the sector, there are useful parallels to the relationship between community pharmacy and the Government, on the one hand, and a franchise relationship, on the other hand that serve to clarify the role of community pharmacy regulations. Franchise agreements are generally made between an upstream franchisor (such as a manufacturer) and a number of downstream franchisees (such as retail outlets or ‘dealers’) to arrange for the supply of goods or services. In that context, the franchisor aims to encourage franchisees to boost their sales or output, but not in an unrestricted manner. Instead, franchise agreements are generally characterised by a range of provisions, imposed by the franchisor, that require franchisees to adhere to certain quality standards, locational rules and other provisions.

The rules or ‘restraints’ that apply in a franchise relationship have been extensively studied in the literature and have clear efficiency rationales. In the context of the Government – community pharmacy relationship, the Government (as the franchisor) has similarly applied a system of rules and regulations to incentivise community pharmacies (the franchisees) to provide a range of services to the community in a manner that achieves the Government’s public policy objectives.

The parallels with franchise agreements are immediately apparent in the past six CPAs entered into by successive governments spanning more than 25 years. These agreements are, in effect, contracts with pharmacy for the delivery of essential dispensing and associated professional services to quality standards that are in accordance with the Federal Government’s health and social policy aims, and on pricing terms that support equity of access for all Australians. The CPAs articulate the Federal Government’s intentions to
deliver equity of (physical) access to pharmacy services through Location Rules, and enshrine the notion of maintaining a viable pharmacy network, upon which the success of the NMP relies.

The Location Rules have demonstrably given rise to a geographical spread of pharmacies that provides a very high level of access and choice without unnecessary duplication of fixed costs. These rules have thereby reduced the costs incurred by Federal Government. At the same time, the ownership rules encourage efficiency in the provision of pharmacy services while ensuring that these services are provided to an appropriate quality standard. By contracting with independent owner-pharmacists, the Federal Government preserves the strong efficiency incentives that exist in franchise relationships. Furthermore, by placing the pharmacist and his or her professional reputation at the centre of the distribution relationship, a position that the pharmacist stands to lose if quality standards are not met, the Federal Government effectively ‘raises the stakes’ for poor quality performance. Owner-pharmacists therefore have an enhanced incentive to conduct themselves and their pharmacies ethically and professionally, and not risk loss of registration and, therefore, loss of value in the pharmacy.

Additionally and importantly, the ownership rules limit concentration in the supply of dispensing services. This provides crucial benefits to Federal Government, as it both facilitates benchmarking and prevents a situation emerging where the Government, to meet its objectives, would have to purchase distribution services from suppliers with substantial market power.

The experience in those countries in Europe where rules such as these have been removed highlight the complexity of reforms that fundamentally influence competitive behaviour. Contrary to what is claimed by the proponents of deregulation of the pharmacy sector, unconstrained competition has not delivered cost savings, has raised concerns about access to medicines, and has consistently resulted in horizontal and vertical industry consolidation into pharmacy chains, and pharmacy chains owned by wholesalers. Deregulation has not improved access to pharmacies outside urban areas, and there is some indication that accessibility of medicines has been affected because pharmacies owned by wholesalers tend to emphasise their own product range.

Specific issues - Location and Ownership Rules

Removal of the Location Rules

The Location Rules have given rise to a physical distribution of pharmacies that provides a very high level of access and choice for the overwhelming number of Australians without unnecessarily duplicating fixed costs. Comparable private sector services that are provided without locational restrictions are characterised by a lower level of access.

Access outcomes similar to those achieved by community pharmacy only seem to be achieved where the public sector directly determines location – as it does for post office, police and emergency services. But while those cases combine public regulation with public service provision, pharmacy meets the equitable access goals in a system that retains the benefits of private ownership, financing and operation.

Although it is difficult to model and predict location decisions in retail markets, it is likely, for reasons canvassed previously, that removing the Location Rules, resulting in free entry combined with partially regulated prices, would result in urban ‘clustering’ of pharmacies. To that extent, it would decrease access to medicines, in the sense that existing and newly established pharmacies could be expected to move to more ‘desirable’ locations, for instance, locations with more foot-traffic, or locations with a more advantageous socio-economic status.

The expectation that a removal of the Location Rules would lead to urban clustering and negatively affect access is borne out by the experience in Europe following the removal of pharmacy Location Rules where more new pharmacies opened after liberalisation. However, these pharmacies tended to be established in
attractive locations (urban clustering) and not in places where no pharmacy had existed before, such as in rural, sparsely populated areas.

From a public policy perspective, therefore, a concern is that clustering will impose opportunity costs on consumers, in terms of increased travel costs, time spent and inconvenience to access medicines. Given that older and sicker people are likely to be less mobile, accessibility for these groups is likely to be particularly affected, contrary to the objective of improving the health outcomes of all Australians through access to and quality use of medicines.

A second important concern is that the (rapid) new entry of pharmacies in locations that are already well served by community pharmacy services implies that, over time, the community pharmacy network would expand more than is either necessary from an accessibility perspective or efficient from a cost perspective.

The implications over the longer term are difficult to foresee. In the event that the Federal Government elects to increase dispensing and other fees, so as to ensure the viability of most, if not all existing community pharmacies, the costs of maintaining the community pharmacy network to the Federal Government and to taxpayers would clearly rise. In a scenario where the fees paid to the sector do not increase commensurately, returns to community pharmacy would decrease with attendant negative implications for investment and quality of service. Moreover, from an economy-wide perspective, the reduced cost-effectiveness of the network, which is unlikely to be associated with improvements in service provision, would merely reduce the social gain from community pharmacy.

**Removal of the location rules in urban areas**

It is important to note that the Location Rules are likely to predominantly be relevant (or ‘bind’) in urban areas. This is because, as is the case for any other retail outlet seeking to maximise profits, community pharmacies will tend to prefer to locate in populated areas where there is a sufficient catchment of potential customers. Given the (significantly) higher population densities in urban areas relative to regional and remote parts of Australia, the commercial forces driving pharmacies to cluster in similar locations are therefore likely to be stronger.

The removal of location rules in urban areas would then not affect access for regional and remote consumers. Rather, as discussed above, the removal of the location rules in urban areas is expected to set in motion a process of clustering whereby pharmacies would (re-) locate to Central Business Districts (CBDs), larger shopping centres, or higher-income locations. As these areas are adjacent to areas of lower retail concentration, geographical ‘ripple effects’ – whereby each area in a series of concentric rings of areas draws custom away from outlets located slightly further out – would ensure that the increased clustering in the inner areas thinned the retail network in outer-lying areas with lower population density and lower incomes, thus undermining the Federal Government’s equity objectives. Furthermore, and to the extent that the removal of location rules would result in significant new entry in urban areas, the overall costs to the Federal Government of maintaining a larger distribution network would also be expected to increase with attendant impacts on costs, investment and quality of service.

**Partial or full removal of location rules and removal of ownership rules**

The location rules have been instrumental in terms of generating a distribution of community pharmacy outlets that meets the Federal Government’s objectives for a distribution system that is both accessible and cost-effective. Removing these rules would lead to poorer accessibility, with related consequences for community health outcomes, and likely higher costs to the Federal Government over the longer term. This fundamental conclusion does not depend on whether or not the ownership rules are modified.

As discussed above, the ownership rules incentivise pharmacists to offer services of a high quality and in an ethical manner, and to invest in the human and physical capital required to carry out their functions to such a standard. The removal of the ownership rules, combined with the partial or full removal of the Location Rules
would therefore compound the negative impacts that can be expected from changing either of these rules in isolation. This is particularly the case given that the Location Rules support and reinforce quality performance incentives that arise from the ownership rules. Thus, well-defined ‘catchment’ areas:

- Assure pharmacists that competitors will not ‘free-ride’ on costly advisory and other services they provide, incentivising pharmacists to provide quality health services without being undercut on price by competitors who do not provide similar services; and
- Encourage pharmacists to invest in the human and physical capital required to carry out their functions to a high standard (for example, in ongoing professional training and in the quality of their facilities) because they have some assurance that they will earn a return on that investment.

The removal of the ownership rules is also relevant to an issue raised in the Discussion paper with regards to the possible co-location of pharmacies and supermarkets. As set out in the Guild’s response, such an outcome would be highly problematic from two perspectives:

- Consumers place a high degree of trust in their local pharmacy, as well as valuing travel distance, trust, and access to health advice and other services. This trust does not, however, extend to supermarkets. The analysis of these findings in a consumer valuation framework then suggests that consumers would, in aggregate, be materially worse off if supermarkets became the predominant owners of pharmacies, and that this loss in welfare is likely to be particularly pronounced for older and disadvantaged consumers.
- Large-scale entry of supermarkets into community pharmacy would represent a significant shift in the bargaining power relative to the pharmacy sector, with attendant costs and risks for taxpayers.

Approval fees and compensation for surrender

The Discussion Paper poses whether it would be desirable for pharmacies to be allowed to enter new locations on payment to the Federal Government of an ‘appropriate approval fee’, set so as to ‘prevent excessive entry into the pharmacy market’. At the same time, any pharmacy ‘competitively impacted’ by such a new entrant should receive compensation for surrendering its own approval number.

The scheme referred to in the Discussion Paper raises a number of broader concerns that go to its objectives, its potential costs and complexity, as well as the unintended consequences that such an approach may bring.

The scheme to introduce approval fees such that ‘excessive’ entry would be prevented may be aimed at achieving the same objectives as the Location Rules, in the sense that, on the basis of the available evidence, the Location Rules can be shown to have encouraged an industry structure that simultaneously offers equity of access while limiting distribution costs. Whether that is indeed the objective of this proposal, however, is unclear. The concept of ‘excessive’ entry as it is referred to in the Review Discussion Paper presupposes an understanding of what constitutes ‘optimal’ entry, yet the Review Discussion Paper does not indicate which of the Federal Government’s multiple policy objectives (such as equity of access, or cost sustainability) would be considered to constitute ‘optimal’ entry. If the object of the scheme were solely equitable accessibility of medicines, for instance, uniform approval fees would presumably discourage entry in low socio-economic areas, in which case the Government would need to determine a tiered set of location-specific fees (or subsidies), with all the attendant complexities.

The Discussion Paper appears to suggest that facilitating entry is an objective of the scheme; in and of itself, the replacement of some or all Location Rules with an entry fee arrangement would tend to depress the market value of existing pharmacies. However, depending on how it is designed (the Review Discussion Paper offers no guidance on this issue), the compensation scheme may partly or completely offset that effect in the market for pharmacies generally. If the purpose of the compensation arrangement is solely to recompense pharmacies that have been directly affected by competing entry, crucial questions then relate to
the quantum of compensation and who funds it. Furthermore, if the aim is for the incumbent to be ‘kept whole’ (that is, indifferent as to whether entry has occurred or not) the quantum of compensation would need to vary pharmacy by pharmacy.

In the absence of a clear statement of purpose and an approximate indication of its workings, very little can then be said about the merits of the scheme itself. The key point is instead that a scheme whereby the location of pharmacies would be determined on the basis of approval fees and compensation payments raised a host of questions that highlight concerns about potential complexity, administrative costs, and likely arbitrariness of such a scheme, for instance:

- how and on the basis of what information the Federal Government would decide that entry would be ‘excessive’;
- how the Federal Government would go about determining the level of the fee such that entry would not be ‘excessive’;
- whether the Federal Government would determine uniform or location-specific approval fees, and on what basis these fees would be determined;
- how the Federal Government would determine whether an existing pharmacy had been ‘competitively impacted’, and would thereby be eligible for compensation;
- whether the ‘compensation for surrender’ would be set equal to the approval fee, so that, in effect, the new entrant would compensate the existing pharmacy (though to an extent that might be materially lower than the harm the incumbent had suffered); or alternatively, whether the compensation would be funded through revenues generally, imposing a fiscal burden on taxpayers;
- whether there would be a moratorium on new entries subsequent to the payment of an approval fee, such that the scheme would effectively create a new localised monopoly.

Overall, therefore, and while a scheme of price incentives may be thought to be theoretically superior to a set of locational rules that largely rely on a limited number of distance-related rules, its implementation in practice is likely to be formidable. In particular:

- The Location Rules are perhaps imperfect, but they are also simple to interpret and apply, and entirely predictable. Most important, these rules have demonstrably achieved an outcome – in terms of the distribution and numbers of community pharmacies – that has supported equitable access for the community and is relatively efficient.
- In contrast, the alternative – designing a pricing structure to shape both the entry and exits of pharmacy outlets – is likely to be complex, requiring the Government to assemble a large amount of information, unpredictable in terms of the outcomes that it would achieve, and, relatedly, contentious. In particular, depending on how such a scheme is implemented, it is possible that it would lead to a general reduction in the market value or goodwill of existing pharmacies, while at the same time causing an increase in the number of pharmacies with local market power.

**Location rules and profitability**

The Discussion Paper suggests that, by limiting competition for existing pharmacies, the location rules may raise the profitability of some or all community pharmacies.

As described above, the franchising literature suggests the location and ownership rules can interact in ways that create net gains to the community. Thus, the location rules can support and reinforce quality performance incentives that arise from the ownership rules. These effects arise because well-defined ‘catchment’ areas for pharmacies can assure pharmacists that competitors will not ‘free-ride’ on the advisory and other services they provide. Pharmacists are therefore encouraged to invest in human and physical capital required to carry out their functions to a high standard, since they have some assurance that they will earn a return on that investment.
Notwithstanding this efficiency rationale for location and ownership rules, the discussion paper offers no evidence of 'excess' profits earned by community pharmacies, and the empirical evidence suggests that any such profits are unlikely to be the norm. The geospatial analysis undertaken by MacroPlan Dimasi negates the claim that locational rules lead to local monopolies:

- Across Australia’s capital cities, accessibility to at least two pharmacies within two and half kilometres is 94%, and marginally better than for supermarkets (90%) and two percentage points lower than for medical centres (96%)
- Outside the capital cities, accessibility to at least two pharmacies within five kilometres is 76%, higher than for supermarkets (68%) and medical centres (74%)

Ownership of multiple pharmacies
While ownership concentration is sometimes a concern in an unregulated market environment, in the case of community pharmacy, the effects of a single owner-pharmacist owning multiple community pharmacies in a particular area are likely to be limited to non-PBS medicines. The pharmacy remuneration arrangements, as defined in 6CPA, regulate the maximum retail price that may be charged for PBS medicines.

More generally, the discussion paper offers no evidence that (material) restrictions on competition as a result of the concentrated ownership of community pharmacies is currently a concern. As set out in Part Two, the current ownership rules have inherently served to preserve the current diffuse ownership structure of the community pharmacy sector. This outcome can be contrasted with substantial horizontal and vertical industry consolidation in the pharmaceutical industry in European countries where community pharmacy has been deregulated, and where competition concerns have, in fact, emerged.

In practice, ownership of multiple pharmacies may simply reflect an underlying efficiency rationale, particularly in smaller regional centres. In those centres, the owner of an established pharmacy may be the only potential investor in a second or third pharmacy, as that owner can spread the risk over his or her network of pharmacies and more generally, can achieve economies of scale and scope in purchasing, logistics and administration. As a result, when other owners are exiting the market, that owner’s multiple ownership may allow more pharmacies to operate than would otherwise be the case.

Those forces, which can operate with particular force in outer-lying and regional areas, make it dangerous to assume competition would be greater without some degree of multiple ownership, than with it. To that extent, restrictions on multiple ownership risk harming the very consumers they were intended to protect.

Furthermore, to put the issue in perspective, the Guild has analysed the 423 towns in the Pharmacy Access/Remoteness Index of Australian (PhARIA) 4–6 category with a pharmacy, of which 196 towns have more than one pharmacy. There are 32 towns in rural and remote Australia that have common pharmacy ownership in a single town. Of these, there are 16 with multiple of the same owners with no variation in partnerships and only eight towns with a single ownership. By any objective assessment, this makes up a very small proportion of the total community pharmacy network.

Restrictions on pharmacy and supermarket co-location
As the discussion paper notes, the Location Rules have a general requirement that all premises approved to provide pharmaceutical benefits must not be accessible from a supermarket. Similar restrictions regarding the co-location of pharmacies and supermarkets are also contained in most of the States and Territory legislation.

Proposals to permit the co-location of pharmacies and supermarkets risk undermining consumer confidence in the provision of PBS medicines, corresponding to a significant loss in consumer welfare, particularly on
the part of concession card holders. Every bit as important, the entry of supermarkets into the pharmacy space raises longer-term concerns about market concentration and market power.

The Institute for Choice survey commissioned by the Guild showed that consumers overwhelmingly held community pharmacies in high regard:

- 89% of consumers trust their local pharmacist either very highly or completely
- community pharmacies have a clear advantage over supermarkets in terms of trust and quality of service
- in absolute terms, the overwhelming majority of survey respondents place a high degree of trust in the ability of their local pharmacy to provide the best service and advice

A corresponding willingness-to-pay analysis indicated that consumers place a relatively high marginal value on pharmacy ownership, travel distance, trust, and access to health advice and other services. One of the most important results is that there are significant differences in the marginal valuations placed on various attributes for general patients and concession cardholders. Since a large share of annual prescription volumes is driven by the medical needs of concession card holders as well as policies that are specifically targeted at this group, this finding has important implications for the efficiency and equity evaluation of policy changes to ownership and Location Rules.

Using these findings, the outcomes of a modelled scenario whereby supermarket chains could become the predominant owners of pharmacies indicate that even hypothesised cost or price reductions (to the extent that these are feasible under the PBS pricing arrangements) could not offset consumer welfare losses. Consumers would, in aggregate, be materially worse off. For example, the data from the Institute for Choice implies an annual loss in consumer welfare equivalent to nearly a quarter of the pharmacy sectors value added. The predicted welfare costs from the co-location of pharmacies and supermarkets are furthermore expected to be an underestimate, for three reasons:

- First, the modelling takes no account of the likely costs to taxpayers and consumers from the bargaining power the supermarket chains would have relative to the Federal Government. Once dispensing was dependent on those chains, the Federal Government could find itself ‘over the barrel’, paying more for pharmacy services than it does today.
- Second, a decline in trust in pharmacy would not only affect consumers’ perceptions of the service they receive; it could also affect their compliance to prescribed treatments, with any reduction in the quality of pharmacy service aggravating those effects. The result would be a deterioration in health outcomes whose overall consequences and costs are not captured in the modelling.
- The third and final reason for believing the results are underestimates of the likely costs is technical but important. The valuations used in the modelling are determined in terms of consumers’ willingness to pay: for instance, how much the average consumer would be willing to pay in dollar terms to reduce travel time to pharmacy by 10%. However, older and disadvantaged consumers have lower incomes; it is therefore highly likely that they would be willing to pay less for a reduction in travel time than would a wealthier consumer, even if it improved their quality of life every bit as much. As a result, the losses from the change in policy put relatively little weight on older and disadvantaged consumers, who are the major recipients of dispensing services and whose welfare figures prominently in the Federal Government’s health care objectives.

From a broader policy perspective, the Guild considers that it is not in the interest of the community that a pharmacy be located in a premise inappropriate for the dispensing of medicines. Having a pharmacy co-located in a supermarket risks diluting the delineation between scheduled medicines (which can cause harm if used inappropriately) and ordinary items of commerce. In addition, there are some critical services currently available through community pharmacies (such as opioid dependency treatment and needle syringe programs) that a supermarket pharmacy would be unlikely to provide.
The Guild also believes that it is incompatible from a health perspective for a business to sell medicines as well as alcohol and cigarettes, two products which have been shown to be major causes of disease and death in the community.

This is a view shared by the Pharmacy Board of Australia which stipulates in its guidelines that:

“The sale or supply of tobacco products, alcoholic beverages, home brewing or alcohol distilling kits by a pharmacist is inconsistent with the practice of pharmacy and is considered as unprofessional conduct within the meaning of the National Law.”

Therefore, the Guild strongly believes that the prohibition within the Location Rules in relation to the co-location of approved pharmacies in supermarkets should be retained.

Pharmacy regulations and public policy objectives

The Discussion Paper poses a broader question about the extent to which the location and ownership rules in some sense ‘protect’ community pharmacies from normal market forces.

As the Harper Panel recognised, the public interest is sometimes not best served by the removal of all restrictions on competition. In particular in the area of health services, Government has a central and essential role in shaping the quality of services and the manner in which they are delivered to the community. The concept of Government as a ‘market steward’ is therefore central to how the regulation and remuneration of community pharmacy should be assessed.

Part Two sets out that the organisation of community pharmacy does not reflect outcomes in an unconstrained market in which Government is a dispassionate onlooker. Rather, the Government has adopted a ‘market stewardship’ role, whereby it applies a series of instruments to exercise control over the costs of the distribution of medicines and advisory services, while ensuring that public policy objectives in relation to access and quality are met. Individually and in combination, successive CPAs and the location and ownership rules applicable to community pharmacies support the public interest in providing strong incentives to owner-pharmacists to ensure that medicines are dispensed in a safe and effective manner, with due regard to questions of equity of access.

In examining how governments have implemented their market stewardship role in the sector, there are useful parallels to the relationship between community pharmacy and the Government, on the one hand, and a franchise relationship, on the other that serve to clarify the role of community pharmacy regulations. Franchise agreements are generally made between an upstream franchisor (such as a manufacturer) and a number of downstream franchisees (such as retail outlets or ‘dealers’) to arrange for the supply of goods or services. In that context, the franchisor aims to encourage franchisees to boost their sales or output, but not in an unrestricted manner. Instead, franchise agreements are generally characterised by a range of provisions, imposed by the franchisor, that require franchisees to adhere to certain quality standards, locational rules and other provisions.

The rules or ‘restraints’ ‘that apply in a franchise relationship have been extensively studied in the literature and have clear efficiency rationales. In the context of the Government-community pharmacy relationship, the Government (as the franchisor) has similarly applied a system of rules and regulations to incentivise community pharmacies (the franchisees) to provide a range of services to the community in a manner that achieves the Government’s public policy objectives.

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The rules or ‘restraints’ that apply in a franchise relationship have been extensively studied in the literature and have clear efficiency rationales. In the context of the Government – community pharmacy relationship, the Government (as the franchisor) has similarly applied a system of rules and regulations to incentivise community pharmacies (the franchisees) to provide a range of services to the community in a manner that achieves the Government’s public policy objectives.

The parallels with franchise agreements are immediately apparent in the past six CPAs entered into by successive governments spanning more than twenty-five years. These agreements are, in effect, contracts with pharmacy for the delivery of essential dispensing and associated professional services to quality standards that are in accordance with the Federal Government’s health and social policy aims, and on pricing terms that support equity of access for all Australians. The CPAs articulate the Federal Government’s intentions to deliver equity of (physical) access to pharmacy services through location rules, and enshrine the notion of maintaining a viable pharmacy network, upon which the success of the NMP relies.

The Location Rules have demonstrably given rise to a geographical spread of pharmacies that provides a very high level of access and choice without unnecessary duplication of fixed costs. These Location Rules have thereby reduced the costs incurred by Federal Government. At the same time, the ownership rules encourage efficiency in the provision of pharmacy services while ensuring that these services are provided to an appropriate quality standard. By contacting with independent owner-pharmacists, the Federal Government preserves the strong efficiency incentives that exist in franchise relationships. Furthermore, by placing the pharmacist and his or her professional reputation at the centre of the distribution relationship, a position that the pharmacist stands to lose if quality standards are not met, the Federal Government effectively ‘raises the stakes’ for poor quality performance. Owner-pharmacists therefore have an enhanced incentive to conduct themselves and their pharmacies ethically and professionally, and not risk loss of registration and, therefore, loss of value in the pharmacy.

Additionally and importantly, the ownership rules limit concentration in the supply of dispensing services. This provides crucial benefits to Federal Government, as it both facilitates benchmarking and prevents a situation emerging where the Federal Government, to meet its objectives, would have to purchase distribution services from suppliers with substantial market power.

The experience in those countries in Europe where rules such as these have been removed highlight the complexity of reforms that fundamentally influence competitive behaviour. Contrary to what is claimed by the proponents of deregulation of the pharmacy sector, unconstrained competition has not delivered cost savings, has raised concerns about access to medicines, and has consistently resulted in horizontal and vertical industry consolidation into pharmacy chains, and pharmacy chains owned by wholesalers. Deregulation has not improved access to pharmacies outside urban areas, and there is some indication that accessibility of medicines has been affected because pharmacies owned by wholesalers tend to emphasise their own product range.
**Recommendation Number 2**

The Guild recommends that:

- the Location Rules should be retained given the clear evidence of their social benefits as well as meeting the objectives of the National Medicines Policy, particularly in terms of access and efficiency.

- the prohibition within the Location Rules in relation to the co-location of approved pharmacies in supermarkets should be retained.

- the Federal Department of Health and the Guild should establish a joint working group, with the aim of identifying and addressing any anomalies that have arisen over time, to ensure the Location Rules remain responsive to the evolving needs of the community.
PART THREE - CONSUMER EXPECTATIONS AND ATTITUDES

Overall consumer experiences

Australia’s network of over 5,500 community pharmacies is a stand-out success in our health system, ensuring that Australians have equitable and affordable access to subsidised medicines through the PBS. Every year, Australians make around 350 million visits to their local community pharmacies.

Community pharmacists have consistently rated among the most trusted health professionals in Australia, and have ranked 2nd for the past three consecutive years of the Roy Morgan’s Annual Image of Professions Survey. In addition, pharmacy continues to score highly as an ethical profession, and is ranked 2nd when compared to all other health destinations in Australia.

A number of surveys have also shown that consumers have a high level of satisfaction with community pharmacy as a health care destination. A 2012 survey by the Menzies Centre for Health Policy where participants were asked about their level of satisfaction with their most recent visit to a range of health care services found that Australians expressed the highest level of satisfaction with pharmacists.

The CFEP Patient Experience Survey also demonstrated similar results with community pharmacy scoring an average satisfaction rating of 4.62 (higher than GPs at 4.37 and physiotherapists at 4.56). Additionally, a recent report by customer satisfaction and ratings agency Canstar Blue, found that 94% of consumers trusted the advice of their pharmacists and 83% preferred to buy their medicines from a pharmacy rather than a supermarket.

Whilst there is overwhelming evidence to show that community pharmacy is trusted and valued by consumers in Australia, there are some community pharmacy models throughout Australia that have shown varying levels of consumer experience and satisfaction. Consumer reviews undertaken with

34 http://www.roymorgan.com/findings/6797-image-of-professions-2016-201605110031
35 Governance Institute Ethic Index, 2016.
37 CFEP Patient Experience Survey (2011 to 2016)
respect to some “discount” pharmacy models have indicated a lower level of consumer satisfaction. At the time of writing, one product review survey that contained over 550 individual reviews showed that seven out of ten consumers rated Chemist Warehouse as terrible.\(^{38}\)

**Customer Review Rating | Chemist Warehouse**

While it may be argued that larger businesses are, as a matter of course, more likely to bear the brunt of negative consumer feedback, the evidence suggests that the level of complaints has more to do with the approach to the practice of pharmacy than the size of the pharmacy business. In particular, the bulk of the complaints appears to be directed against aspects of the ‘discount’ pharmacy model.

Chart 5, shows an analysis of the complaints against the four major banner groups posted over the past three years, using the same source. Relative to their pharmacy numbers, Chemist Warehouse pharmacies recorded the worst results at ten times the number of complaints registered against Amcal, Priceline and Terry White Chemists combined. There is little doubt that aggressive discounting comes at a significant cost to service quality and standards, and consumers react. The problem for community pharmacy, however, is that those negative sentiments filter through to consumers’ general satisfaction rates and attitudes towards the broader pharmacy network.

**Chart 5: number of pharmacies and complaints by pharmacy group**

Consumers have generally been in consensus around the importance of pharmacy offering a private area within community pharmacy,\(^{39}\) and the Guild believes that consumers should expect that pharmacies are delivering professional services in a community pharmacy setting that meets expectations with respect to privacy and confidentiality.

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There is some evidence to suggest that the perceived privacy available in community pharmacy creates a barrier to the uptake of health services. Guild data shows that currently 91% of pharmacies have an appropriate place for confidential conversations, and that there is evidence to suggest that approximately 49% of pharmacies have a defined consulting room in order to deliver professional services such as flu vaccinations.

The Community Pharmacy Service Charter

Australian pharmacies are committed to providing quality services to the community as part of a patient’s health care team. As part of this commitment, a pharmacy patient charter was developed through consultation with key external stakeholders in 2011.

The Pharmacy Charter covers a number of key areas including access, safety, respect, communication, participation and privacy. The Charter is displayed by over 94% of community pharmacies that meet Australian Standard 85000:2011.

The Pharmacy Charter which is based on the principles of the Australian Charter of Healthcare Rights provides information on the rights of consumers and the responsibilities of pharmacists.

The Charter outlines the level of service consumers can expect to receive when visiting a community pharmacy, and allows for a shared understanding of the rights of people receiving health care. It also explains how consumers can give positive or negative comments on the care they receive in pharmacy.

**Consumer Medicines Information**

Pharmacists have a professional responsibility to counsel patients about the use of their medicines and this is reflected in the PSA's Professional Practice Standards and the Pharmacy Board's guidelines for pharmacists which recognises that counselling is mostly verbal and may make use of other resources such as CMIs. Pharmacists are not required by law to provide a CMI but use their professional judgement on the need for and provision of the counselling.

While it is not obligatory for a pharmacy to provide a CMI, pharmacists are encouraged to consider providing them in the following circumstances:

- At the request of the patient
• When the medicine is provided for the first time
• When the dosage form changes (e.g. from tablet to injection)
• If there is a significant change in the CMI by the manufacturer
• At the professional judgement of the pharmacist

Some have argued that pharmaceutical companies should include CMIs as package inserts; however in the past companies have had to recall medicines if there were any significant changes to the information leaflet and this was a very costly exercise.

Given the advances in technology CMI’s are now available free from www.medicines.org.au and this ensures that the consumer receives the most up to date version. The CMI on this site are now displayed in user friendly html format for easier reading online. For printing, there are both standard three column formats and large print formats available.

The Guild believes that consumers should have access to accurate information about their medicines and discretion as to the type of advice they receive (oral and/or written), and when and from where they would like to receive it. The Guild believes community pharmacy is an appropriate and reliable location for CMI to be provided to improve a person’s understanding of a medicine and enhance the quality use of medicines, improve adherence and reduce medicine misadventure.

**Demand for pharmacy programs and services**

High-quality dispensing is more critical than ever with a greater concentration of patients needing more intensive counselling, monitoring and support as a higher prevalence of chronic conditions and multiple morbidities increases the likelihood of adverse medicine events. Australia’s community pharmacy network offers consumers and patients a wide range of professional programs and services that go beyond the traditional dispensing role.

The provision of programs under successive CPAs have aimed to improve the quality use of and individual management of medicines and reduce adverse drug events experienced by consumers taking multiple medicines. Research commissioned by the Federal DoH found that consumers indicated a high level of satisfaction with programs and services delivered by their pharmacists, regardless of age, general health status and number of medicines. ⁴⁰

In addition to providing services and programs funded under CPAs, pharmacists offer a wide range of health services, support and advice to consumers. A recent survey by the Consumers Health Forum (CHF) found that 79.5% of consumers indicated that their local community pharmacy offered one of several primary health care services including blood pressure checks, weight management, diabetes management, vaccinations, and mental health support. ⁴¹

The demand for community pharmacy services becomes even more critical in rural and remote Australia as consumers are more likely to rely on their community pharmacy for health care advice and information in the absence of easy and/or affordable access to a GP or other health care provider.

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Currently, one in five Australians wait for a GP appointment longer than they feel is acceptable. Australians living outside of capital cities are particularly affected, being less able to secure a GP appointment the same day (46% versus 64% for those living in a capital city) and having to wait more than five days for an appointment (24% versus 8%). Evidence shows that consumers in rural areas seek health advice from their community pharmacy at a much higher rate than those in metro areas of Australia (74% vs 35%).

Consumers have shown overwhelming support for pharmacies providing a wider range of health services. A recent survey found that seven in ten consumers not only want pharmacies to do more, but would personally support their local pharmacies providing more services. This is also consistent with findings by PricewaterhouseCoopers, and the Griffith University which found that 51% of consumers would choose pharmacy in the first instance for advice on minor ailments or chronic conditions. In addition, consumers strongly believed in the value of the community pharmacy becoming a health hub; a health care destination that involved more than just the provision of medication advice.

Research has found that although community pharmacists had an important role to play in the management of chronic health conditions, consumers may not be aware of pharmacists’ breadth of expertise and skills. It is this lack of awareness that is a notable barrier to service utilisation.

There is a need to increase consumer awareness around the types of health services that are offered by community pharmacies. This is particularly important in terms of increasing consumer awareness around the extended role that pharmacists can play in the primary health care team.

**Accessibility**

Community pharmacies are often the first port of call for consumers in Australia looking for health care advice. Numerous surveys and research have found that community pharmacies are both easily accessible and convenient as a health care destination. Research undertaken by PricewaterhouseCoopers showed that 98% of consumers surveyed reported that they did not have any issues with accessibility under the current model of community pharmacy. Additionally, 94% of consumers have reported that the opening hours of community pharmacy suit their needs.

Further, analysis undertaken by MacroPlan Dimasi, found that consumers have a very high level of access to community pharmacy. In the capital cities, the average resident is located one kilometre from the nearest pharmacy, while 95% of consumers are no further than two and a half kilometres from a pharmacy. In regional areas, on average consumers are six and a half kilometres from the nearest pharmacy, with 72% being able to access a pharmacy within two and a half kilometres.

The net result is that travel times to pharmacies for Australian consumers are very low. Approximately 50% percent of consumers have a travel time of less than five minutes to their preferred pharmacy, with a further 30% having a trip time of between five and 10 minutes. This means that 80% of consumers take 10 minutes or less to get to the pharmacy of their choice.

Under the 6CPA, the Guild and the DoH agreed to work together on strategies and activities in relation to improving patient access to community pharmacies including through increased opening hours. The

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44 Consumers Health Forum, Survey: Should Pharmacists play a bigger role in Primary Care, May 2015.
47 Ibid.
49 Consumer Experience Index, Pharmacy Guild of Australia, 2015-16
50 MacroPlan Dimasi Analysis, 2016.
issue of access by patients to PBS medicines and pharmacy services is not only limited to opening hours but also covers such things as the location of pharmacies, number of pharmacists and the breadth and reach of pharmacy services.

In a recent survey of Guild members to gain a better understanding of patient access to community pharmacy, it was found that on average, community pharmacies in Australia are open 61.7 hours per week, and the average pharmacy is open for 10 hours a day during the week. In addition, 73% of pharmacies are open at 6pm on a weeknight and 92% are open at 10am on a Saturday. Further to this, MacroPlan Dimasi found that 55% of consumers visit a pharmacy that is open seven days, with a further 32% visiting a pharmacy that is open from Monday to Saturday. These are remarkable levels of access to a complex, professional service.\(^{51}\)

One of the primary objectives of the CPAs is to ensure there is network of viable and accessible community pharmacies throughout Australia – including in rural and remote locations. Currently the mechanism to ensure this takes place is the Location Rules which ensure that pharmacies are in areas of need.

The number of community pharmacies continued to grow over the life of the 5CPA (from 5,088 in 2010 to 5,457 in 2014) and into the 6CPA (5,587 at 30 June 2016). The growth in the number of community pharmacies over the last six years (9.8%) has mirrored the growth in the Australian population over the same period (9.5%).\(^{52}\) Importantly, there has also been a steady increase in the number of community pharmacies located in rural areas of Australia, climbing from 876 in 2010 to 908 in 2016.

A Federal Government commissioned report has found that the increasing numbers of community pharmacies in both urban and rural Australia broadly seems to be in line with the population growth. This combined with the fact that ratio of people to pharmacy remains relatively even across areas of Australia suggests that the current assessment and approval of new pharmacies under the Location Rules are enabling patient access to community pharmacy services based on need.\(^{53}\)

**After-hours access to a pharmacy**

Community pharmacy also compares extremely well in terms of after-hours accessibility compared to other vital services. Analysis by MacroPlan Dimasi\(^{54}\) shows that after-hours pharmacy access on both weekdays and weekends is significantly better than medical centres in both capital cities and the rest of Australia. Pharmacy also compares well to supermarkets, both large and small. For example, in capital cities on weekdays a consumer is about as likely to find a pharmacy within 2.5 km as a supermarket.

On average across Australia, close to three quarters (72%) of pharmacies are still open on weekdays after the nearest Medical Centre (within 200 metres) has closed. On weekends, 41% of pharmacies are still open after hours after the nearest medical centre has closed. Conversely, just 9% of medical centres are open after the nearest pharmacy has closed. Outside of capital cities, 31% of pharmacies are still open on weekends after the nearest Medical Centre has closed.

Media report September 30, 2016

Outside of capital cities, 88% of pharmacies are still open on weekdays after the nearest Medical Centres (defined as 5km in regional cities) has closed. On weekends, 85% of pharmacies are still open after hours after the nearest medical centre has closed.\(^{55}\) In contrast, just 22% of medical centres are open.

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\(^{51}\) Ibid


\(^{53}\) Australian Department of Health, Combined Thematic Review of Access, Consumer Experience and Quality Use of Medicines, PricewaterhouseCoopers, 2015.

\(^{54}\) MacroPlan Dimasi, Guild submission to the Review of Pharmacy Remuneration and Regulation, Table 6 – Appendix 2

\(^{55}\) MacroPlan Dimasi, Guild submission to the Review of Pharmacy Remuneration and Regulation, Table 6 – Appendix 2
after the nearest pharmacy has closed on weekdays. On weekends 25% of medical centres are open after the nearest pharmacy has closed.

**24 hour access to pharmacy**

The Discussion Paper questions whether hospitals could improve consumer access by allowing hospitals to provide PBS medicines to community patients 24 hours per day.

Some State Governments, including Victoria have recently implemented trials that involve the State government co-funding the extension of trading hours of particular pharmacies via a tender process based on areas of defined need. These trials which only commenced in mid-2016, require rigorous evaluation prior to the Federal Government giving consideration to broadening or extending such initiatives.

In 2014, the Commonwealth funded a Review of After-hours Primary Health Care Services (Jackson Review). The Jackson Review proposed a number of recommendations, including that after hours service planning should be integrated as part of the PHN local service delivery mapping, with their focus being to identify gaps and to plan, coordinate and support population-based after-hours health services. In addition, a recent geo-spatial analysis found that 88% of consumers have access to a community pharmacy within a two and a half km radius of where they live. The same analysis found that although 32% of consumers have access to a hospital within a two and a half km radius, this did not equate to a greater number of consumers having access to either a pharmacy or hospital – the results maintained that 88% of consumers had access to a community pharmacy and a hospital, concluding that allowing hospitals to provide medicines and services to the community did not improve access.

As identified in the Jackson Review, PHNs are ideally placed to identify areas of need and provide incentives to enable local community pharmacies to deliver tailored after-hour solutions to meet local community need, including coordinating emergency after-hours access to PBS medicines.

**Affordability**

The PBS, part of the NMP, provides timely, reliable and affordable access to necessary medicines for Australians. Under the PBS, the Government subsidises the cost of medicines for most medical conditions.

Research has found that for those consumers who are aware that community pharmacists are able to provide additional health services, the pharmacy is welcomed as a source of affordable health care advice and other health services. However, the cost of medicines is often cited by consumers as a barrier to filling prescriptions.

The NMP states that ‘cost should not constitute a substantial barrier to people’s access to medicines they need’, however, cost appears to remain a barrier for a cohort of consumers. Survey results from the Australian Bureau of Statistics (ABS) show that one in thirteen persons aged 15 years and over (7.6%) delayed getting or did not get prescribed medicines due to cost. The survey also provides a statistic on delaying getting a prescribed medicine by remoteness, socio-economic index for areas (SEIFA) and long term health condition status. The ABS reports that while the figure was generally consistent amongst areas of remoteness, it was higher in the most disadvantaged areas (10.5%) and also higher in patients with long term health conditions (9.2%).

Community pharmacy has actively supported the Government’s policies to make medicines more affordable for consumers. Pharmacies have been an active participant in the promotion of generic

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medicines and have also participated in PBS reform measures including price disclosure which is anticipated to save the Government $20 billion over the life of the 6CPA.

Trading terms on generic medicines have, until now, been able to cross-subsidise the costs associated with a range of core services that pharmacies have been providing to patients either free or below cost – which has contributed to the perception of affordable health care services by consumers.

One example of these services are DAAs. Community pharmacies pack about 11 million DAAs a year. While the volume of services being delivered is indicative of there being limited barriers to access for consumers, the cost of DAAs has been reported as being a barrier by consumers despite their perceived high value. While incentive payments under the CPA have gone some way to help offset the cost of providing this service, pharmacies are not paid a fee for service by the Federal Government and the incentive payment does not fully cover the cost.

People living in rural and remote areas and Aboriginal and Torres Strait Islander Peoples are more likely to rely on their community pharmacy for health care advice and information in the absence of affordable access to a GP or other health care providers. A Federal Government DoH Review reported that:

This underscores the importance of the Rural Pharmacy Workforce Program and the Rural Pharmacy Maintenance Allowance working together to ensure that there are future cohorts of pharmacists interested in working in rural pharmacy, that those pharmacists currently working in rural pharmacies are able to access professional education and that rural pharmacies remain open. Combined, these programmes enable access to consumers living in rural and remote areas.

Recommendation Number 3

The Guild recommends that:

- the Federal Government funds an ongoing campaign to raise public awareness of the role of community pharmacy as a trusted health destination and the availability of pharmacy services.

- consumers should expect that community pharmacies who are providing professional services are accredited to an Australian Standard including in respect to privacy and confidentiality.

- the Federal Government should use the PHNs to provide incentives for local community pharmacies to coordinate emergency after-hours patient access to PBS medicines and other critical community pharmacy services.

Standards and Quality

Quality Assurance

The Guild believes it is important for community pharmacies participating in Federal Government funded programs to be able to demonstrate their ability and commitment in providing the relevant services.

Australian Standard 85000:2011 Quality Care Pharmacy Standard: quality management system for pharmacies in Australia (Australian Standard) was drafted by an external stakeholder Standards

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58 Pharmacies receive a quarterly incentive payment under the 6CPA to ensure that patients receive the highest quality of care, information and service through a quality framework.


60 Australian Department of Health, Combined Thematic Review of Access, Consumer Experience and Quality Use of Medicines, PricewaterhouseCoopers, 2015.
Committee in accordance with requirements of the Australian Board for Standards Development Organisations. The draft Australian Standard was then approved by Standards Australia for publication through SAI Global in 2011. As is required by all Australian Standards, the standard undergoes a major review every 5 years that is coordinated by the Standards Committee again in accordance with requirements of the Australian Board for Standards Development Organisations to ensure it remains relevant to contemporary pharmacy practice. As an accredited standards development organisation the Pharmacy Guild is coordinating the review process in direct consultation with the Standards Committee, in which the draft standard is expected to be available for public consultation in late September 2016 for a period of 60 days.

**Pharmacy Accreditation**

QCPP is accredited by the Joint Accreditation Scheme for Australia and New Zealand (JASANZ), and as such has demonstrated and is required to continue to demonstrate compliance with International Standard 17065 Conformity assessment – requirements for bodies certifying products, processes and services. As such QCPP accreditation provides the platform through which a community pharmacy demonstrates it has a Quality Management System in place supporting the work practices and business functions of the pharmacy. This ensures the pharmacy provides quality services that promote high levels of consumer services, community safety, health outcomes and sound business practices.

To maintain QCPP accreditation, community pharmacies are required to undergo an onsite assessment by an independent endorsed QCPP Assessor (noting assessment services are coordinated and conducted by Ernst and Young EY). The assessment process requires the pharmacy to demonstrate compliance with all requirements of the Australian Standard, including but not limited to business functions, and ensure that the delivery of pharmacy and professional services is in accordance with the industry guidelines as outlined below.

**Professional Conduct**

In the interests of public safety and wellness, the professional practice of pharmacy in Australia is regulated by the Pharmacy Board under the auspices of the AHPRA and its governing legislation. As part of the Pharmacy Board’s functions it develops standards, codes and guidelines for the pharmacist profession and handles notifications, complaints, investigations and disciplinary hearings related to professional practice. Australian pharmacists must comply with the Code of Conduct for registered health practitioners and be guided by the code of ethics for pharmacists of relevance to their practice.

**Professional Standards and Guidelines**

Under the National Law, the Pharmacy Board develops professional guidelines for pharmacists in relation to matters of professional practice not set down in legislation or a registration standard. Evidence of practice contrary to the Pharmacy Board’s guidelines can be used in proceedings under the National Law as evidence of unprofessional practice or conduct. In its guidelines, the Pharmacy Board states that when considering notifications, it will have regard to relevant professional practice and quality-assurance standards depending on the nature of the matter under consideration.

The Pharmacy Board has published guidelines of relevance to a number of professional practice matters of interest to the Review Panel, including:

- Dispensing of medicines, covering multiple supply, distance supply, labelling, counselling, confidentiality, dispensing errors, returned medicines, pharmacist workloads and use of dispensary technicians

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63 The National Law is contained in the schedule to the Health Practitioner Regulation National Law Act 2009 (Qld).
• Practice specific issues covering supply of drugs of abuse, pseudoephedrine, Schedule 2 and Schedule 3 medicines, screening and risk assessment, supply of tobacco and alcohol, complementary medicines and allied health and alternative therapies from a pharmacy premises

• Compounding of medicines complemented by background on relevant regulations and professional practice profiling for pharmacists undertaking complex compounding such as chemotherapy

• DAAs and SS covering both services with particular reference to packing and labelling of DAAs and use of automated packing systems or third-party packing

• Advertising of health services and products

• Continuing professional development, covering the ongoing learning and development throughout a pharmacist’s career to maintain competence to practice

Regulating professional practice
The benefits of managing these professional practice matters through a regulator for which the primary role is protecting the public is that it provides the flexibility for a professional to practice in situations which are variable and for which setting strict regulations could be problematic. As an example, the Pharmacy Board recommends the dispensing threshold at which dispensary technicians, interns or another pharmacist may be required. The Pharmacy Board’s recommendations recognises unpredictable practice issues that would be difficult to regulate – spikes in activity during specific times, days or months, types of prescriptions and associated services (harm-minimisation services, compounding), the use of advanced dispensing technologies and accommodating other non-dispensing responsibilities and new professional initiatives.

If pharmacy workload was regulated through legislation e.g. one pharmacist per X prescriptions dispensed, what happens when prescription number X+1 is reached? What happens if one of the rostered pharmacists calls in sick and no replacement is available? Regulating this practice via the Pharmacy Board’s guidelines provides the flexibility for the pharmacy to operate in exceptional circumstances, with an expectation to make the necessary changes if the situation becomes prolonged or routine.

In addition to complying with all legislation relevant to the practice of pharmacy, the Pharmacy Board expects pharmacists to be aware of and comply with the profession’s standards and guidelines from the Pharmaceutical Society of Australia (PSA) and the Society of Hospital Pharmacists of Australia (SHPA). The Pharmacy Board actively participates in the review of the Australian Standard to ensure the pharmacy business also supports high quality consistent practice.

In the interests of the public, the Guild would support the Pharmacy Board being given the authority through regulation with appropriate funding and resourcing to take a stronger more proactive role in regulating professional pharmacist practice in all settings.

Complementary medicines
The Review’s Discussion Paper raises a number of questions regarding the sale of complementary medicines from community pharmacies. The Guild acknowledges the widespread use of complementary medicines by Australians and that most, if not all community pharmacies carry some complementary medicines, including products such as iron, calcium, vitamin D supplements, fish oil and other dietary supplements. Many pharmacies also stock one or more product ranges of complementary medicines.

Guidelines for dispensing of medicines #11, Pharmacy Board of Australia
The TGA is the regulatory body responsible for scheduling a complementary medicine under the Australian Register of Therapeutic Goods (ARTG) to ensure safety, quality and efficacy. With TGA Listed Medicines (Aust L), including the majority of complementary medicines, the TGA does not assess or evaluate the evidence for efficacy, but rather requires the manufacturer to have such evidence available on request. Scheduled medicines (Aust R) must provide demonstrate safety, quality and efficacy to the TGA for evaluation prior to entry on the ARTG. All complementary medicines on the ARTG can only use TGA permitted indications and claims. In addition, safety warnings and contra-indications must be displayed on the labels in compliance with TGA legislation.

Part of the mandatory reference texts required by the Pharmacy Board is ready access to an evidence-based work on complementary and alternative medicines. This allows a pharmacist to advise if there is evidence for an active ingredient for a particular indication (e.g. Echinacea for upper respiratory tract infections), appropriate dosage, potential interactions or side-effects and if there are any contraindications or cautions. However, community pharmacists have neither the information nor the capacity to evaluate the evidence of individual complementary medicine products. Commercial-in-confidence arrangements typically mean that only the TGA has access on demand to the evidence base for which the licensing approval has been based.

As is the case for all medicines supplied from community pharmacy, pharmacists are reliant on the TGA to ensure that all complementary medicines comply with the mandatory quality, safety and efficacy standards. It is the TGA’s role to ensure that all medicines are safe for public consumption and pharmacists and the public should have confidence that the regulator is ensuring that all medicines comply with the Therapeutic Goods Act and Regulations.

There has been criticism that the availability of complementary medicines from a pharmacy provides pseudo-credibility to particular therapies. An example of this is the availability of homeopathic medicines from community pharmacies despite the 2015 review by the National Health and Medical Research Council (NHMRC) which concluded ‘that there are no health conditions for which there is reliable evidence that homeopathy is effective’. Questioning why pharmacies sell homeopathic products deflects from the real issue which is why there is no evidence base given the extensive use of these therapies internationally. Current arrangements mean there is little incentive for manufacturers of complementary medicines to conduct and publish expensive research.

The national census of medicines use conducted by the National Prescribing Service (NPS) showed that almost 50% of Australians used complementary medicines with evidence showing that Australians want to use, think differently and appear satisfied with their use of complementary medicines. It also shows the care needed with using them. NPS has reported that over 50% of all calls to its Medicines Line about complementary medicines are about drug interactions.

Australians have demonstrated that they want the choice of using complementary medicines, therefore it is incumbent on the Federal Government to ensure that this use is consistent with the NMP. Community pharmacies are the only supply outlet that provides Australians with access to a medicines expert who can advise on both orthodox and complementary medicines to ensure they are using all medicines correctly, safely and appropriately. It is however important that the TGA continues to monitor the marketing and promotion of complementary medicines so as not to create unwarranted consumer expectations with appropriate controls in place to manage irresponsible, unethical or unlawful practices.

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66 Guidelines on practice-specific issues – Guideline 1 (List of reference texts for pharmacists); Pharmacy Board of Australia


69 NPS; Information Use and Needs of Complementary Medicines Users; Dec 2008

70 Take complementary medicines with care: NPS MedicineWise; 17 May 2016
The Guild’s firm position is that the sale of complementary medicines from community pharmacies is not only appropriate, but essential to ensure the use of these medicines is consistent with the NMP. It makes little sense to consider prohibiting a pharmacy from selling a complementary medicine with a registered pharmacist always on duty, but allow other outlets without a trained health professional present to sell such products.

The Guild believes the majority of complementary medicines are responsibly marketed in Australia and supported by evidence. While the Guild would support the TGA revising the licensing and marketing arrangements for complementary medicines, the complementary medicines industry must be supported to research and publish the necessary evidence so that only credible products are marketed in Australia and consumers and all Australian supply outlets have confidence in the Australian complementary medicines market.

As the professional regulator, the Guild believes the Pharmacy Board is the appropriate regulator to work with the profession in the interests of the public to ensure the professional and responsible supply of all medicines, including complementary medicines, from community pharmacies.

**Recommendation Number 4**

The Guild recommends that immediately:

- the Pharmacy Board of Australia should be given authority and be appropriately funded and supported to take a stronger role in regulating professional pharmacist practice in all settings in the public interest.

- the TGA should implement transparent and stronger licensing and marketing processes for complementary medicines sold in Australia to provide the community with confidence with regards to safety, efficacy and responsible marketing.
PART FOUR - COMMUNITY PHARMACY PRACTICE

Pharmacy business models

Pharmacies are health providers operating in the retail environment. Their role is to deliver health solutions for patients which in the majority of cases entail a combination of the provision of evidence-based health products and associated advice and support, as well as increasingly the provision of related patient services.

While the 6CPA does not reference a particular aggregate formula or target to determine either revenues or some measure of profit, it explicitly references the objective of “supporting the sustainability and viability of an effective community pharmacy sector”. As such, it is understood that the remuneration arrangements in the 6CPA are intended to help pay for and maintain an effective distribution channel by which PBS medicines are supplied to the public.

Broadly speaking, the community pharmacy model that emphasises health support and services along with dispensing in a retail environment is well established and enjoys the overwhelming support of the Australian population, which finds it convenient, accessible and consistently meeting their needs.

However there is no single model of pharmacy business operating in Australia. Rather, the retail pharmacy market has undergone disruptive change over the past decade, as ‘big box’ pharmacy chains have built up their market share using a business model of prescription based dispensary transactions bringing in foot traffic for OTC medicines and other retail offerings (cosmetics, complementary medicines, etc.).

At the same time, consolidation has not only occurred towards the high transaction/strong retailing focus model of pharmacy, but also towards strong patient-focused service models. For example, the recent merger of Terry White Group and Chemmart will see the rise of a new, large pharmacy network of around 500 pharmacies that aims to deliver front-line health services.

There are many successful smaller pharmacies that have a balanced service model offering strong patient support through services and also competing with larger discount pharmacy chains on price and convenience. Hence, pharmacies have and can continue to be both retailers and health service providers – the remuneration structure under consecutive CPAs and regulations have enabled various business models of pharmacy to evolve and meet the varying priorities and needs of their communities. Some consumers seek a retail experience while others look for primary health care and advice, and both have been accommodated successfully in Australia, providing genuine choice.

Table 1 underscores the wide spectrum of pharmacy business profiles typically described as the archetypal community pharmacy model: from the smaller business model that predominantly focusses on medicines (dispensary) and related health services relative to ‘front of shop’ retailing, through to the much larger mixed dispensary-retail business model with a greater proportion of sales of non-prescription goods.
There is no one-size-fits-all in terms of the operational mix of health services and retail offerings. From a NMP perspective, the diversity of models ensures that prescription services are highly accessible to Australians, through a range of community pharmacies with varying levels of health services and retail offerings, consistent with the needs of their communities. Together, these suggest that the current mixed model of community pharmacy, one where dispensing and health services are core but where also complementary products and services are provided to meet consumers' broader health needs, is the optimal model in Australia.

**Restrictions on retail products**

Given the operational profile of different community pharmacy business models in Australia, separating the sale of health products from the provision of services, support and advice (including around those products) may produce inferior health outcomes (especially if a two tier community pharmacy system results where consumers may choose to “trade off” the advice component if they perceive a lower out of pocket price to be paid), prevent pharmacists from practising their profession, and make it harder for patients to access the care they need in their local community setting.

Concerns about the broader cost implications of proposals to restrict retail sales in one form or another arise because the margins earned by pharmacies on such sales currently contribute to meeting overhead costs (such as rent, which tends to be higher for community pharmacies that choose to locate in shopping strips and shopping centres so that they are accessible, and business taxes).

Restricting or eliminating retail sales would deprive community pharmacies of a revenue stream that currently contributes to meeting these costs, and hence the fixed costs of the distribution network. If such restrictions were put in place, fixed overheads would need to be either defrayed from medicines dispensing fees, or the contribution towards these costs from dispensing fees would need to rise. In either case, a greater share of community pharmacy costs would need to be recovered through dispensing services, subsidised by the Federal Government.

The implication is that:

- the prescribed fees paid by the Federal Government – the purpose of which is to support a sustainable distribution network – may need to increase to compensate for lost revenues, with corresponding cost implications for government.
- if the prescribed fees do not increase commensurately with cost shares, community pharmacies would experience a loss of value in their assets. In the context of the ownership rules, the value

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71 Unlike what is suggested in the Review Discussion Paper, varying contributions by different product groups to defray joint costs such as overheads do not constitute a ‘cross-subsidy’ in an economic sense, and should not therefore be considered inefficient.
embodied in community pharmacies represents a considerable incentive on pharmacists to offer a service that is both ethical and of a high quality.

- if the prescribed fees do not increase sufficiently, community pharmacies would experience a loss of value in their assets, and some, maybe many, would go out of business, with a consequent reduction in physical accessibility for consumers.

Apart from the fundamental concern about the impact of such a restraint of trade on meeting overhead costs, there are concerns about the transactions costs of any schemes that seek to limit the range of products sold by community pharmacies because of the likely difficulties of defining, implementing, and monitoring and enforcing such arrangements. Newly introduced restrictions on retail space or the types of products that may be sold would, at a stroke, mean that a significant aspect of most established pharmacy businesses would be made redundant. This would require established pharmacies to bear the cost of making significant changes to their lay-out, for instance to substantially increase dispensing areas relative to the remaining floor space, or to remove entire ranges of products. These restrictions would also have significant employment implications, including for pharmacist support staff (i.e. pharmacy assistants) as well as pharmacists.

Perhaps the more important concern goes to the potential administrative and compliance costs of such retailing restrictions. Such provisions would introduce an additional layer of regulations and associated monitoring requirements, especially if certain products could no longer be sold by pharmacies. In particular, restrictions in relation to permissible retail products would likely need to be both detailed and intrusive, and would presumably require ongoing updates.

There would be also ongoing questions as to where the line should be drawn and on what basis it is drawn. A recent practical example is when the Review Panel visited the Charnwood Capital Chemist in Canberra and asked about their stocking of cosmetic products. The proprietor responded by informing the Panel that the pharmacy provides a beauty and make-up support service for its cancer patients, which is a recognised way of building their personal self-confidence and their overall sense of health and self-esteem, while undergoing treatment.

There are finally questions about whether restrictions on retail sales by community pharmacies may lead to wider health effect if products that may not have an obvious health connection are no longer permitted to be sold. Products, such as skincare or shampoo, for instance, are clearly in a different category than medicines, but it is not unreasonable to expect pharmacists to be able to answer consumers’ questions about them (and certainly more reasonable than to expect a supermarket employee to do so). In this sense, retail restrictions that would diminish the role of pharmacists and other trained pharmacy staff, as a general ‘port of call’ for health-related questions in the broadest sense do not seem appropriate.

The market (consumer preferences) within the existing remuneration structure will continue to dictate which of the business models will thrive and which may not. The notion that pharmacies that are currently in the middle of the spectrum of pharmacy models, and which consistently meet the health needs of patients, should be forced to choose one end of the spectrum or the other is misplaced and would restrict choice and innovation. There is no need for a revolution in pharmacy business models when evolution has and continues to be the optimal path.

**Remuneration and pharmacy business models**

The Discussion Paper appears to contemplate a situation where the nature or quantum of Federal Government funding for dispensing services would be modified to reflect different ‘business models’.

There is no doubt that many community pharmacies both in Australia and internationally are increasingly focused on providing a broader range of health services to their patients, in ways that ensure there are
the right linkages with other health care providers. This transition is enabling pharmacies to play an enhanced role, delivering an array of services that meet patient needs and add value to the broader health system.

These services should build on pharmacists’ core medicines related expertise and create opportunities and incentives for accelerating the transformation of pharmacies into health and wellness hubs, focussed on preventative health, screening, and supporting patients with chronic diseases. This work needs to be integrated into the broader health system with the right referral pathways.

This is part of the evolution of pharmacy and should be actively encouraged through appropriate additional remuneration for community pharmacies. This has been rightly recognised in the 6CPA with a near doubling in the funding for evidence-based, community pharmacy professional programs and this funding needs to be expanded in future CPAs.

However a remuneration system that is somehow linked to a particular pharmacy business model potentially raises concerns about unintended consequences (and competitive neutrality), as well as the transactions costs of such a scheme. Remuneration arrangements that differentiate payments according to the ‘type’ of pharmacy would likely influence how pharmacies arrange their business, including the balance of activities dedicated to dispensing medicines, providing advice, and selling retail products, respectively.

Implementing a scheme linking remuneration to a particular business model would require the Federal Government to develop a detailed view about the overall levels of patient service and support under different business models; for instance, whether a discount pharmacy should be paid more or less per script than a community pharmacy. In practice, determining such fee arrangements is likely to be both complex and contentious, and potentially add considerably to the cost of developing and administering the scheme.

**Separating remuneration from advice**

With some exceptions, the provision of advice to consumers without charge is the norm in the broader retail environment. One rationale for introducing separate compensation arrangements for advice relates to ‘free-rider’ problems, which occur when one party takes actions that benefit another without being able to charge for such benefits. Free-rider problems may occur when consumers seek advice in a service-focused outlet, but then purchase a product online or at a discount store. However, within the current regulatory framework for pharmacies, free-rider issues are, at least to an extent, addressed both by the ownership and Location Rules and by professional standards, assuming that the latter are properly enforced.

It is also critically important to recognise that medicines are not normal items of commerce but vital health products, with a need to ensure that every patient receives the required level of professional advice and support at the point of purchase, regardless of the model of pharmacy that supplies the medicine. This necessitates a standards-based approach, rather than a two-tiered system whereby patients may receive higher or lower levels of advice or support depending upon the pharmacy they frequent and the levels of remuneration that pharmacy is receiving for dispensing medicine. Overall, therefore, and noting the potential complexities and transactions costs associated with implementing and monitoring separate charging arrangements for professional advice, it is difficult to conclude that such schemes would be beneficial to consumers or able to be practically implemented.
Recommendation Number 5
The Guild recommends that:

- consumers should continue to have the benefit of timely access to health and other ancillary products as well as professional pharmacy services from community pharmacies.

- community pharmacy should continue to provide products, service and advice without superficial separation of the two.

Dispensing Remuneration
The viability of community pharmacy as the delivery mechanism for the PBS and RPBS depends critically on an appropriate level of remuneration for the dispensing of medicines. Without this, this critical part of the medicine supply chain is jeopardised and the objectives of NMP related to ensuring Australians have timely access to medicines at an affordable cost are undermined.

Community pharmacy operates as a business and must survive in a commercial environment. Profitability is an essential part of that landscape and, as with any business, sales generated by pharmacies must outweigh expenses incurred. Unlike other businesses however, community pharmacy is also required to respond to and manage government reforms relating to the sale of PBS medicines, and the impact those reforms have on the profit margins of business.72

The importance of dispensing remuneration to the viability of community pharmacy is evident by considering the contribution of dispensing remuneration to pharmacy operations. The average community pharmacy in Australia dispenses around 58,000 prescriptions a year, with these prescriptions accounting for approximately 66% of total sales revenue. The gross margin (sales less cost of goods sold) is just over $1 million for the average pharmacy and, after overheads, average annual net profit equates to around $110,000.73

Official remuneration for dispensing by community pharmacies has for the past 20 years been set through CPAs between the Federal Government and the Pharmacy Guild of Australia. Through each CPA, various dispensing and other fees have been negotiated and agreed to remunerate community pharmacies. Under the 6CPA, when a community pharmacy dispenses a Government subsidised PBS medicine, the pharmacist is paid the PBS-dispensed price of the medicine, less any patient contribution, which includes:

- The cost of the medicine to the pharmacist - known as the approved Price to Pharmacist (PTP)
- An AHI fee ranging from $3.54 (PTP < $180) to $70.92 (PTP > $2,089.71) per maximum quantity supplied
- Dispensing fees, for example, the ready prepared fee is $7.02 and extemporaneously prepared fee is $9.06
- Other fees the pharmacist is entitled to, such as, for example, the Dangerous Drug fee of $2.95.

Dispensing is a core pharmacist clinical service providing patients with a safety mechanism that ensures the independent review of a prescription by a health professional prior to commencement of therapy. In addition to the labelling and supply of a medicine in accordance with legal requirements, dispensing

involves the clinical interpretation and evaluation of the prescription along with a professional and clinical review by a pharmacist.

While automation may increase efficiency in some of the routine processing activities undertaken when dispensing a prescription, there is a standard level of clinical involvement required of the pharmacist for dispensing any prescription which should be fully remunerated. Appendix 4 is a Dispensing Fact Sheet prepared and published by the Guild summarising the dispensing process, breaking it into ten steps from accepting and checking the prescription details to counselling on safe and appropriate use. The Fact Sheet reflects the Pharmacy Board’s *Guidelines for dispensing of medicines* developed to provide guidance to registered pharmacists in the interests of public safety, and the *Guide to good dispensing* published by Pharmaceutical Defence Limited (PDL), Australia’s largest pharmacist indemnity insurance provider.

The Discussion Paper notes that a total of $18.9 billion has been allocated in the 6CPA. Importantly, this funding covers not only pharmacists’ remuneration with respect to dispensing functions, but also the wholesalers’ remuneration (of $2.8 billion) as well as professional programmes (of $1.26 billion). (The total funding also includes a quantum of approximately $580 million for unidentified new listings for which no definitive explanation has been provided by the Federal DoH). The total funding allocated for pharmacists’ remuneration for core dispensing functions is approximately $14.3 billion over the course of the 6CPA. For 2015-16, the allocated funding is approximately $466,000 per pharmacy. This is, in effect, the cost of maintaining the Australian community pharmacy network, based on a public-private partnership.

It is instructive to put this funding level in perspective by comparing with similar overseas models. While comparisons of dispensing costs across countries are clearly complicated by differences in prescribing habits and the broader health care system in which pharmacies operate, as well as differences in the geographical scope of pharmacy networks, they do nevertheless provide a high level metric to measure the relative cost-effectiveness of the pharmacy networks. Notwithstanding the limitations of the analysis, on a number of high-level indicators, community pharmacy has performed well in terms of the cost-effectiveness with which scripts are filled.

There is little doubt that dispensing costs (remuneration) in the US and Canada are generally higher than those in Australia (ranging from US$7.50 to US$13.00 per prescription compared with US$7.78 in Australia).

The UK and New Zealand, on the other hand, are often held up as comparative models at the lower end of the remuneration spectrum. However, the evidence may not be as conclusive as one might expect in terms of cost to the community.

Table 2 shows that cost of the network as percentage of the GDP is in fact lower in Australia than that of the UK or New Zealand. While their costs per prescription may be lower, the cost per capita is not. At 0.15% of GDP (in US$), the Australian pharmacy network is more cost-effective than that in the New Zealand (at 0.16%) and the UK (at 0.18%). Moreover, if cost-effectiveness is instead measured on a per capita basis as a percentage of average weekly earnings, the Australian pharmacy network remains more cost-effective than that in England and only marginally more costly than New Zealand’s network.

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74 Pharmacy Board of Australia Guidelines for dispensing of medicines; Sep 2015; www.pharmacyboard.gov.au
75 Pharmaceutical Defence Ltd; Guide to good dispensing; www.pdl.org.au
76 As noted in their respective sections of this submission, these are professional programmes which have either been evaluated or found to be of net public benefit, or yet to be trialled before implementation.
Table 2 – Cost of Remuneration as % of GDP

<table>
<thead>
<tr>
<th>Country</th>
<th>Cost of Remuneration (m)</th>
<th>Cost of Remuneration Per Capita (US)</th>
<th>Cost of Remuneration as % AWE</th>
<th>Cost of Remuneration Per Capita (US)</th>
<th>GDP* Capita %</th>
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</tbody>
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*AWE 2015 and GDP/Capita in US$ 2015

Source: [http://www.tradingeconomics.com/australia/gdp-per-capita](http://www.tradingeconomics.com/australia/gdp-per-capita), 6CPA, NZ Funding Agreement, NHS England Funding Agreement

**Price disclosure impact on trading terms and dispensing remuneration**

The Federal Government’s price disclosure policy has resulted in significant savings to the Government from the PBS. The express intention of price disclosure is to ensure that the amount the Federal Government pays for PBS listed medicines is close to the price at which they are supplied in the market, based on the information disclosed by suppliers. Price disclosure commenced in 2007, with subsequent changes (acceleration) of the arrangements in 2010, 2014 and in the 2015 PBS Access and Sustainability package.

Chart 6 shows the estimated savings to the Federal Government from price disclosure policy. The Federal Government is estimated to save $20 billion in the five years from 2015-16 from price disclosure, including $2.6 billion in 2015-16 alone, which represents 24% of budgeted PBS spending for 2015-16.

**Chart 6: Federal Government estimated savings from price disclosure policy**

![Price disclosure estimated savings by the Australian Government, $m](image)


The actual level of dispensing remuneration for community pharmacies per PBS script consists of official remuneration, as set out in regulations, and ‘trading terms’ - the discounts and settlement terms from the suppliers and distributors of PBS medicines to community pharmacies.
Chart 7 shows the actual (total) pharmacy dispensing remuneration per subsidised PBS prescription compared to the growth in the volume of these prescriptions. The actual (total) remuneration includes estimates of the trading terms that have been passed onto community pharmacies from suppliers upstream in the pharmaceutical supply chain and hence differs from the official remuneration figures quoted by the Federal Government DoH.

Despite the various dispensing and other fees negotiated through recent CPAs, including the indexation of some fees to the Consumer Price Index (CPI), the level of actual (total) dispensing remuneration per PBS prescription has fallen in recent years and is expected to remain flat during the 6CPA.

While actual (total) dispensing remuneration for community pharmacies has fallen, the volume of prescriptions has risen, to the point where by 2019-20 the level of prescriptions dispensed will be 35% higher than in 2009-10, yet the level of dispensing remuneration per prescription will be, on current trends, around 5% lower than in 2009-10. At the same time, community pharmacies face rising expenses, including in relation to rents and wages and salaries, which the Guild has estimated to be in the vicinity of 5.12% Compound Annual Growth Rate (CAGR) per annum over the past 10 years.

With downward pressure on their actual dispensing remuneration and ongoing cost pressures, community pharmacies are increasingly augmenting their stagnant dispensing remuneration with revenue from OTC medicines, complementary medicines, health support and advice services and broader retail sales related to toiletries, cosmetics and other products.

### Chart 7: Pharmacy remuneration per script adjusted for trading terms

The future viability of the community pharmacy network to act as the distribution channel for the delivery of PBS medicines to Australians depends on an appropriate uplift in the actual (total) remuneration for dispensing. As the Pharmacy Board notes:

“Options for remuneration for dispensing need to support the safe dispensing and quality use of medicines and ensure that pharmacists are able to meet their legal and professional obligations.”
Inadequate resourcing can adversely impact pharmacists’ workloads as well as exposing pharmacists to excessive workplace stress and may put the public at risk.”

In the 6CPA, the Federal Government delinked official pharmacy dispensing remuneration from the price of PBS subsidised medicines through the introduction of the AHI fee, recognising that PBS reforms, such as price disclosure, were negatively impacting the remuneration provided to pharmacies for handling and dispensing PBS medicines.78

While it is critically important that the funding in the 6CPA that the Federal Government has provided the community pharmacy network be delivered in full, the impact of reducing trading terms continues to threaten the viability of services that are currently provided at little or no cost to patients. Chart 7 shows that community pharmacy remuneration (inclusive of trading terms) is expected to be stagnant through the next five years.

As trading terms reach near-zero without appropriate reinvestment by the Federal Government, community pharmacies will be increasingly forced to cut back many valuable services, such as dose administration aids and home deliveries that are currently not fully remunerated on a stand-alone basis. In order for community pharmacies to continue to provide these valued services, as well as high quality dispensing, it is imperative that the Federal Government ensures that there is an appropriate level of re-investment of the savings from PBS reforms back into pharmacy remuneration.

At a very minimum, this re-investment needs to ensure that the actual (total) levels of dispensing remuneration at the beginning of the 6CPA are maintained in real terms at a level that is commensurate with the increased overhead costs in community pharmacy businesses. While it may be argued that such re-investment is already taking place through the PBS listing of new high cost items, the reality is that these new listings represent only a fraction of the $20 billion budget savings forecast over the course of the 6CPA. Additionally, it should be noted that the vast majority of those newly listed high cost items are being dispensed through hospitals.

Finally, appropriate risk sharing arrangements need to be explicitly included in future Community Pharmacy Agreements (as opposed to the 6CPA where risk sharing is at the discretion of the Minister) to ensure that agreed funding commitments are delivered in full.

**Recommendation number 6**

The Guild recommends that:

- in future Community Pharmacy Agreements a mechanism should be put in place to increase the floor on per prescription dispensing remuneration for community pharmacies to take into account the ongoing loss of trading terms as a result of price disclosure.
- in future Community Pharmacy Agreements appropriate risk sharing arrangements need to be explicitly included to ensure that agreed funding commitments to community pharmacies are delivered in full.

**Dispensing repeat prescriptions**

A community pharmacist dispensing a repeat prescription has the same level of obligations for assessment, review and counselling as for original prescriptions. PDL’s *Guide to good dispensing*79

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includes seven routine checks and procedures within the dispensing process and strongly advises pharmacists ‘to observe them on each occasion a prescription is dispensed’.

Dispensing a repeat prescription may in some cases be even more complicated than dispensing a prescription to a patient for the first time, as in addition to ongoing monitoring of adverse effects or interactions, ‘for repeat items, the pharmacist should determine if compliance problems exist and ascertain that the continuation of treatment is appropriate’. In the case of repeat prescriptions, the Pharmacy Board Guidelines advise how ‘counselling provides the opportunity to inquire if the patient is taking the medicine correctly, if the medicine is having the desired outcome or if there are unwanted effects. It offers a further opportunity to detect any errors’.

Variable remuneration for the dispensing of complex and simple prescriptions

There is no simple prescription. Medicines are allocated to the ‘Prescription Only’ scheduling classification because of the inherent safety risks associated with the use of the substance. As the Centre for Medicines Use and Safety at the Faculty of Pharmacy and Pharmaceutical Sciences, Monash University, has noted:

“The level of risk and incidence of medication-related problems correlates with the number of medications used by the patient, the acuity and complexity of their treatment and the level of coordination of their care. Problems can occur due to system failures, iatrogenic issues, poor patient compliance or they may be idiosyncratic. They may include intentional and unintentional over or under-dosing, interactions between medicines and side effects.”

The quality of dispensing requires a certain level of expertise in every situation and Australians expect no less from their community pharmacists. In saying this, there may be dispensing situations in which the patient may benefit from add-on services which complement the dispensing (and counselling) process. The Guild regards these as separate functions which for transparency, can and should be remunerated separately from the dispensing remuneration. These are discussed further under ‘Part Four: Dispensing Related Interventions.

While there are already additional fee arrangements for certain types of PBS medicines – namely Dangerous (Controlled) Drugs, extemporaneously prepared items and chemotherapy compounding – these relate to items for which there are consistent, identifiable additional administrative, professional and/or physical tasks. Indeed, most remuneration arrangements in international jurisdictions have additional fees for these three types of prescriptions. However, the Guild is aware of no examples in other countries where remuneration has been differentiated drug-by-drug throughout the schedule. Such a change would deliver no overall benefit but would likely introduce perverse incentives and distortions in the marketplace, and would be unnecessarily complex to establish, administer, and monitor.

Concerns about potential schemes of variable remuneration for the dispensing of complex and simple prescriptions arise because of their potential administrative complexity and associated monitoring costs, as well as adverse incentives that are potentially created:

- It is very difficult to define qualitative terms, such as ‘level of effort’ in any sense that is sufficiently rigorous to serve as a charging basis. In addition, it is likely that the ‘level of effort’ for the

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80 Pharmaceutical Society of Australia; Dispensing Practice Guidelines; www.psa.org.au [accessed 12/9/2016]
81 Faculty of Pharmacy and Pharmaceutical Sciences, Centre for Medicines Use and Safety, Monash University, Submission to the Standing Committee on Legal and Social Issues - Legislation Committee Inquiry into the roles and opportunities for community pharmacy, June 2014.
pharmacist may depend on the characteristics of the consumer (as well as the medicine), so that indicators that are purely referenced to the type of prescription may not be appropriate.

- In addition, payment systems that are referenced to malleable indicators, say, the length of time spent consulting with a consumer, would inherently incentivise pharmacists to meet that particular indicator, so as to attract a higher payment. Adverse incentive effects of this type may result in higher costs to the Federal Government than expected, and would also require further resources to be expended on monitoring ‘effort’, whichever way it may be defined. Overall, the transactions costs associated with the remuneration arrangements would rise.

For these reasons, variable dispensing remuneration for complex and simple prescriptions is at odds with the quality use of medicines. Where more complex interventions are required to complement the dispensing function, these should be transparently remunerated as a separate service.

**Premium Free Dispensing Incentive (PFDI)**

It has been generally recognised by the Federal Government and by community pharmacies that it is in the interests of all parties, including consumers, for there to be appropriate incentives to encourage the uptake of generic medicines. Increasing the uptake of generic medicines helps to ensure that the PBS remains sustainable. In recent years, community pharmacies have been able to benefit from generic trading terms. Generic medicines also provide increased choice for consumers and many (particularly non-concessional patients) are able to benefit from lower patient contributions when purchasing generic medicines.

The level of uptake of generic medicines in Australia is lower than a number of other comparable countries and the Federal Government should continue to work with community pharmacies to lift the uptake on the basis of the overall benefit both to the cost of the PBS and to the affordability of medicines for consumers. In so doing, it needs to be recognised that PBS reforms have significantly reduced the trading terms on generic medicines, which in turn, means that the financial incentive for community pharmacies to encourage their patients to choose a generic alternative over an originator brand have significantly reduced.

Moreover, should Minimum Order Quantity changes to the CSO standards come into effect, community pharmacies are likely to revise the range of PBS brands stocked to avoid additional charges being levied by CSO wholesalers.

As a result, the Guild believes that it would be increasingly likely that, without an incentive like the PFDI, pharmacies would see little benefit in encouraging generics, which in turn could result in less patient choice and potentially more patients paying a Brand Price Premium on those medicines where such a premium applies to the originator brand.

The Guild believes that the PFDI has helped to increase the uptake of generic medicine use in Australia and that an appropriate incentive should be maintained so that community pharmacies continue to stock and encourage their patients to choose generic medicines. It would make sense to review the effectiveness of the PFDI in the low trading terms environment, but it needs to be ensured that the overall value of the PFDI to community pharmacies as part of their total dispensing remuneration is maintained in real terms. At the same time, consideration should be given to appropriate financial incentives that would encourage community pharmacies to work with their patients and with prescribers in considering the appropriate use of biosimilars as biologics come off patent.

**Optional Co-payment discounts**

As part of the 6CPA PBS Access and Sustainability Package, the Federal Government has allowed community pharmacists the discretion to discount the PBS co-payment by up to $1, with the discount
being funded by the community pharmacy rather than the Government. This measure is estimated by the
Department to save the Government $360 million over the 6CPA by delaying high PBS users from
reaching the PBS Safety Net. Additionally, the financial impost on pharmacies would be a loss of a further
$450 million over the 6CPA.

For many patients, the discount arrangements are confusing. Discounts do not apply to 'early supply' for
some specified medicines and the discount amount is discretionary and for any value up to $1. If they
choose to offer a discount, pharmacists may offer it to selected patients, for preferred brands or for
preferred dispensing times (e.g. not offered after hours) and the offer may be variable. The Guild
understands that while some discount pharmacy chains offer the discount as a promotional exercise, it is
not universal and that uptake has been less than expected by the Federal Government. This is likely
because the cost of any discount is fully borne by the pharmacy. In an economic situation where
pharmacy returns are ever diminishing, it should not be unexpected that many pharmacies choose not to
offer a discount. Whether the savings projected by Treasury are realised or not, the fact remains that any
savings would be achieved at the expense of pharmacists’ remuneration within the allocated $18.9 billion
funding under the 6CPA.

The Guild is also concerned that the PBS co-payment discount is not consistent with the Federal
Government’s NMP in which costs and savings between partners are shared, access processes are
simple and streamlined, cost-shifting minimised, and perverse incentives avoided. Discounting the PBS
cost-sharing commoditises the PBS, devalues the clinical role of the pharmacist, undermines the purpose
of having a consistently applied price signal, and most importantly, is contrary to the concept of
universality of the PBS in which all Australians can access subsidised PBS medicines at the same price
irrespective of where they live. The Guild has a particular concern with discounting PBS prescriptions for
medicines that may be subject to abuse or misuse (e.g. opiates, stimulants, hypnotics).

The Guild considers the optional discounting of PBS patient co-payments to be a fundamentally flawed
policy that should be discontinued. Instead, the Guild supports a thorough review of all PBS Patient Co-
Payments and Safety Net Threshold levels to ensure PBS medicines are affordable to all Australians.

Special handling requirements

There are a number of PBS medicines which require special handling by community pharmacies, in
particular, temperature sensitive medicines requiring refrigeration, cytotoxics and Controlled Drugs and
high cost medicines. While Controlled Drugs are currently remunerated by a Dangerous Drug fee, it is
insufficient to cover the associated costs, including:

- Dangerous Drug handling fees charged by pharmaceutical wholesalers
- Recording and reporting requirements associated with dispensing Controlled Drugs, including the
  need to separately store Controlled Drug prescriptions
- Upgrading Controlled Drug safes to enable greater storage capacity in order to meet the
  increased demand for dispensing PBS prescriptions for Controlled Drugs
- Managing returns of unused Controlled Drugs by consumers

There is currently no specific recognition of the costs of handling or stocking of cytotoxics or items
requiring refrigeration. In order to meet workplace safety standards, the handling of cytotoxics requires
the establishment of appropriate policies and protocols with relevant staff training.83

Pharmacists must store temperature sensitive medicines requiring refrigeration in a dedicated and
approved ‘vaccine refrigerator’. An essential component of good pharmacy practice is routine monitoring

83 Worksafe Victoria; Handling cytotoxic drugs in the workplace; Jan 2003
of community pharmacy refrigeration to ensure temperature sensitive medicines such as vaccines, insulins and biologics are stored at the appropriate temperature. As part of Australian Quality Care Pharmacy Standard, community pharmacies must have a compliant dispensary refrigerator and demonstrate daily monitoring. With the increase in PBS medicines requiring refrigeration, community pharmacies are having to purchase additional refrigerators and dedicate additional storage space. In addition, insurance for refrigerated items come at a premium given there is a greater risk of stock loss associated with power failures and the like.

Given the business and capital costs required for cytoxics, Controlled Drugs and items requiring refrigeration, the Guild believes community pharmacies should receive additional remuneration for dispensing PBS prescriptions for these medicines.

**Recommendation Number 7**

The Guild recommends that:

- community pharmacies should continue to receive the same remuneration for dispensing original and repeat PBS prescriptions for ready-prepared Schedule 4 medicines.

- community pharmacies should continue to receive the same remuneration for dispensing simple and complex PBS prescriptions for ready-prepared Schedule 4 medicines.

- in future Community Pharmacy Agreements dispensing related remuneration, including the Administration, Handling and Infrastructure fee (AHI), dispensing fees (ready-prepared and extemporaneous) and Dangerous Drug fee, should be set to a level that is commensurate with increased overhead costs in community pharmacy businesses.

- additional remuneration be provided for cytoxics and items requiring refrigeration.

- in future Community Pharmacy Agreements the Premium Free Dispensing Incentive (PFDI) should be maintained to encourage community pharmacies to increase the uptake of generic medicines.

- in the interest of PBS universality, the pharmacy funded optional $1 discount should be immediately abolished.

- there should be a thorough review of all PBS Patient Co-Payments and Safety Net Threshold levels to ensure that PBS medicines are affordable for consumers.

**Non-dispensing pharmacy supply arrangements**

**Opiate Dependence Treatment Program**

The Section 100 ODT Program is a joint Federal Government/State initiative that supplies methadone, buprenorphine and buprenorphine + naloxone medicines under the care and supervision of a drug dependence support team as a substitute for illicit opiates to opiate-dependent persons. This program provides eligible patients with a stable dose of an opiate with the intention of providing the opportunity to improve their health and social outcomes.

The effectiveness of ODT programs is reliant on the accessibility and affordability to dependent illicit opiate users. It also relies on access to prescribers, addressing other substance abuse issues such as alcohol, employment status, housing, homelessness and treating underlying mental health disorders. In Australia, treatments are currently administered through a variety of service delivery and funding models with the Federal Government funding the cost of the pharmacotherapy medicines for treatment of opiate dependence and the States and Territories managing supply arrangements to patients, including any subsidies or incentives to community pharmacies for ODT services.
While treatment is provided free of charge in most States and Territories through publicly-funded clinics and public hospitals, there is little uniformity across the States and Territories in the way ODT programs are implemented and delivered from community pharmacies, as seen below:

- **Federal Government** – funds pharmacotherapy
  - Supplied at no-charge to pharmacies (except for wholesaler Controlled Drug administration fee)
- **ACT** – subsidises treatment for 800 patients
  - Government subsidy of $20 per week
  - Mandatory patient co-payment of $15 per week
- **NSW** – subsidises treatment for 20 patients per participating pharmacy per 6 month period
  - Government subsidy of $100 per patient per 6 month period
  - Program enrolment incentive of $1000 per pharmacy
- **TAS** – uncapped incentive program though few pharmacies unwilling to have more than 10 patients as incentives do not compensate the time and work involved
  - Sliding scale for methadone treatment from $565 per year for 1-5 patients to $13,560 per year for 36-59 patients and $27,121 per year for 60 or more patients
  - Incentive for buprenorphine treatment of $90 per patient per month
- **VIC** – subsidises pharmacy service fees for patients under 19 years of age, patients on Youth Justice community orders and patients released from prison for 4 weeks post-release

There is no Government funding for ODT services in the Northern Territory, Queensland, South Australia or Western Australia. In these jurisdictions while the Federal Government covers the cost of the treatment, the cost of the service is covered by the patient and the pharmacy.

The significant variation in services across the country unfairly amounts to inequity between patients according to where they live and also impacts engagement and retention which are key factors in running a program where success means harm minimisation as well as savings in terms of social and criminal impact.

In 2015, the Australian Institute of Health and Welfare (AIHW) found that of the 2,589 dosing points across Australia, 88% are pharmacies and while pharmacists supply against a valid prescription, the process differs to the dispensing and claiming process applicable to other PBS listed medicines.

In those jurisdictions with incentives and subsidies, some of the ODT service costs are also covered by the patients through co-payments. Only the ACT has a standard patient co-payment. In 2009, as part of a research project in the 4CPA, it was found that the average cost to a community pharmacy for providing a range of ODT service models was calculated per occasion of service with a mean range from $4.00 to $18.62 (equating to $28 to $130.34 per week in 2009 or $32.73 to $152.36 in 2016). While the observational study found that the fundamental processes between each pharmacy did not greatly differ,

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84 Victorian Health and Human Services Policy for maintenance pharmacotherapy for opioid dependence
86 A national funding model for pharmacotherapy treatment for opioid dependence in community pharmacy; PwC; 2010; Table 7; https://www.guild.org.au/services-programs/research-and-development/archive-fourth-agreement/2007-08-05
87 Using the Consumer Price Index Inflation Calculator (June 2009 vs June 2016); www.abs.gov.au
the range varied according to whether doses were pre-prepared or not, and whether take-away dosing was involved.

Following a 2002 survey of Guild members, the Guild estimated that $45.00 per patient per week was a representative cost associated with providing an ODT service at the time. Using the CPI Inflation calculator\(^88\), this would equate to $63.79 per patient per week in 2016, which is consistent with the 4CPA project.

Pharmacists have reported to the Guild of occasions where the provision of ODT services is expressly prohibited by lease agreements, occurring more commonly within shopping centres where the landlord has a targeted customer demographic. Other pharmacists have advised that while they are willing to provide ODT services, there are few or no prescribers in the local area that are willing to participate.

Should ODT patients travel to a region where ODT services are not available, the costs and preparatory requirements with establishing the service make it both non-viable and non-practical for a local pharmacy to provide the service, particularly if only for one patient and/or on a temporary basis.

The Guild supports increasing accessibility to ODT services by increasing the eligibility for opiate-dependent Australians to receive treatment and increasing the number of dosing points across Australia. To achieve this, reducing barriers to access such as, affordability and flexibility for patients is critical along with increasing the number of participating prescribers and community pharmacies with appropriate remuneration. The Guild believes this is best achieved by running a national program that ensures equity of access, irrespective of where a person lives.

**Recommendation Number 8**

The Guild recommends that:

- the Federal Government should immediately take responsibility for providing opiate-dependent patients with access to high quality standardised care by:
  - funding a fee for service Opiate Dependence Treatment (ODT) program for eligible community based patients that is delivered through community pharmacy.
  - ensuring consistency in terms of patient contributions so as to reduce financial barriers for eligible patients to access the service.
  - ensuring appropriate remuneration for community pharmacies so as to encourage a greater level of community pharmacy participation.

**National Diabetes Services Scheme**

The NDSS is an initiative of the Federal Government administered by Diabetes Australia with the majority of patient supply Access Points being community pharmacies\(^89\).

Prior to 1 July 2016, despite having to purchase, stock and record supply of NDSS products, community pharmacies were not remunerated for the service provision. Following a survey of Guild members in 2011, the Guild estimated that the average community pharmacy held $5,000 worth of initial stock and the only funding provided was a one-off incentive payment to a maximum of $2,800 (ex GST) consisting of:

1. $2,300 to assist with establishment costs or purchase of products

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\(^88\) Ibid; June 2002 vs June 2016

\(^89\) As at 30 September 2014, 96.7% of Access Points were pharmacies
2. $500 to connect to the NDSS Connect administration system

As part of the 6CPA, the distribution function for test strips, needles, syringes and insulin pump consumables was transferred from Diabetes Australia to pharmaceutical wholesalers for supply to NDSS patients primarily by community pharmacy Access Points. Under section 7.4 of the 6CPA, participating pharmacies receive a payment of $1 for each NDSS product supplied and wholesalers are paid $1 per unit for distribution. While the 6CPA begins to recognise the role of community pharmacy in supplying NDSS products, it continues with a complex administration system that is time consuming and inconsistent with the other major Federal Government supply function provided by community pharmacy, namely the PBS.

Under the new arrangements, pharmacies continue to place orders for NDSS items using the NDSS Connect administration system which then places the order with the pharmacy’s preferred wholesaler for delivery at no charge to the pharmacy, usually within 24 hours. There is no longer an expectation that pharmacies need to keep NDSS stock on hand but can order on demand.

The transfer of the new supply function was expected to occur from 1 July 2016 but unfortunately the implementation did not proceed smoothly and community pharmacy bore the brunt of consumer dissatisfaction. As a result of the problems associated with the delayed implementation in July 2016 and despite CSO wholesalers having NDSS stock on hand, many pharmacies were not able to order stock for their NDSS patients resulting in shortages of many items and access problems for patients. As pharmacies had never previously stocked insulin pump consumables and the new arrangements supported ordering on demand, people using insulin pumps were particularly affected because of the inability for pharmacies to receive timely orders of these products. It has proved particularly problematic for people who are travelling and have forgotten supplies or who leave their re-ordering till their supplies have nearly run out.

The current NDSS arrangement is completely different to how the PBS operates and neither recognises the significant inventory that existing NDSS pharmacies continue to carry nor that NDSS patients may have urgent requirements that would be best met by pharmacies having stock on hand.

With NDSS Connect, community pharmacies have little visibility of the orders and any shortages and little information to guide them in informing and assisting their NDSS patients. As the NDSS arrangements only allow direct (one-for-one) replenishment of items supplied to an NDSS patient, there is no capacity for an existing NDSS pharmacy to reduce or vary its NDSS product inventory to meet changes in local patient needs. Neither can it manage obsolete stock apart from discarding it when it expires, which comes at a cost to the pharmacy which originally purchased the product.

Should a pharmacy wish to add an additional product to its inventory for immediate supply on demand (e.g. insulin pump consumables), the pharmacy must privately purchase the NDSS items at the full wholesale cost. At costs of > $40 for test strips and from $100 to $200 for many insulin pump consumables, a handling fee of only $1 per item (showing a return on investment ranging from approximately 0.5% to 2.5%) provides little financial incentive or economic justification for pharmacies to purchase new NDSS products to keep on hand. As such, any NDSS products not routinely stocked by a pharmacy are ordered on demand with the inherent risks for patients if they have urgent requirements.

The costs involved in preparing a pharmacy, holding stock and training staff to become a NDSS Access Point are substantial. In 2001 the Guild brought to the attention of the Federal Government that the average annual cost to NDSS community pharmacies was $2,841 taking into account direct and indirect revenue and wages and expenses as reported by pharmacists. Based on pharmacy costs and income

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90 As part of the Community Services Obligations (CSO) arrangements under which pharmaceutical wholesalers operate
trends since 2001, the average annual cost to NDSS community pharmacies would now be $8,291. With an income now of $1 per item, based on these figures a pharmacy has to supply almost 700 products a month to break even. It is evident that community pharmacies do not provide this service as a profit making venture and it is critical that the Federal Government continues to assist new NDSS pharmacies with the costs associated with establishing and implementing the service. Given the work involved in establishing the service and the low level of remuneration NDSS pharmacies receive, the Guild is concerned that the Federal DoH is considering discontinuing the start-up incentives of $2,800 when a pharmacy becomes an NDSS Access Point.

The $1 handling fee agreed to as part of the 6CPA was on the understanding that pharmacies would need to keep minimal stock on hand and that any related clinical problems would continue to be managed by Diabetes Australia or the patient’s GP. It is questionable whether this is the best approach for patient care or whether pharmacies should be better remunerated to hold and manage NDSS stock as part of the pharmacy’s inventory to meet their patients’ needs and to also be able to meet any clinical demands within their scope of practice.

Noting that the costs involved in wholesaler distribution and pharmacy inventory management and supply for NDSS products are similar to that for PBS products, the Guild believes this is best achieved by establishing an NDSS supply model with a similar structure to that of the PBS:

- CSO wholesalers purchase stock from the NDSS product manufacturer at the approved ex-manufacturer price (AEMP)
- Community pharmacies order NDSS products directly from CSO wholesalers as per current PBS arrangements
- CSO wholesalers deliver NDSS products to community pharmacies within 24 hours at the approved PTP, inclusive of a wholesaler distribution fee equivalent to that for the PBS
- Community pharmacies supply NDSS products on demand as per the PBS and record the transaction within the pharmacy’s dispense system for transmission via PBS Online
- NDSS patient pays the relevant co-payment to the community pharmacy
- The community pharmacy is reimbursed the price, less any patient co-payment, consisting of:
  - PTP
  - AHI fee equivalent to that for the PBS
  - Recording Fee equivalent to the PBS safety net recording fee
- NDSS records can be linked with the electronic My Health Record or other pertinent systems as required

As with the PBS, pharmacies would be expected to carry an NDSS inventory to meet their local community need and be able to receive deliveries from the wholesalers within 24 hours to meet unanticipated urgent needs.

As the supply of these items do not require a prescription nor the clinical oversight of a pharmacist to assess interactions or contraindications, the supply function is a non-dispensing transaction which can be undertaken by the pharmacy assistant with identified problems referred to the pharmacist. As such, there is no ‘dispensing fee’ as part of the pharmacy remuneration.

From a pharmacy perspective, the NDSS payments would ideally be made by the Federal Department of Human Services – Medicare (Medicare) as part of a combined PBS/NDSS claim within the period of 9-16 days according to the terms of the 6CPA for payment of PBS claims. This would be a significant
improvement on current arrangements in which the NDSS contribution by patients collected by pharmacies is debited on a weekly basis while the handling fees owed to pharmacies are paid monthly in arrears. The administrative burden for CSO wholesalers would also be improved by being paid directly by the pharmacy as per existing account arrangements.

Noting that this arrangement may require legislative changes to enable Medicare to make NDSS payments, as an alternative, Medicare could collect the data through PBS Online for payment by a third-party agent such as Diabetes Australia. Noting that this is likely to delay payments to NDSS pharmacies, this alternative arrangement has the advantage of integrating improved administrative functions associated with NDSS supply with the patient registration functions.

In addition, given the opening hours of community pharmacy and that the majority are NDSS Access Points, it would also be sensible to capitalise on this accessibility to promote the availability of diabetes support services from community pharmacies, including providing an Appliance Use Review\textsuperscript{91} akin to that in the UK for supporting people with diabetes to use their blood glucose monitors and facilitating more community pharmacists to become Diabetes Educators with the ability to provide MBS funded services from the pharmacy.

**Recommendation Number 9**

The Guild recommends that:

- for greater efficiency and patient care, the National Diabetes Services Scheme supply and remuneration model should run parallel to the PBS:
  - NDSS community pharmacies should be able to purchase NDSS products directly from their CSO wholesalers at the approved Price to Pharmacist, inclusive of appropriate wholesaler mark-up.
  - NDSS pharmacies should be able to use their dispense and point-of-sale systems for recording, claiming and stock management.
  - remuneration for NDSS community pharmacies in the next Agreement should be structured to reflect the PBS, inclusive of a commensurate AHI and recording fee.
- the Federal Government should immediately:
  - fund an Appliance Use Review in NDSS community pharmacies to support people with diabetes in the use of their blood glucose monitors.
  - provide funding incentives to NDSS community pharmacies to undertake Diabetes Educator training.

**ProjectSTOP and MedsASSIST**

Project STOP is an initiative of the Guild to address the problem of precursor diversion through Australian community pharmacies. The most common precursor sourced through the community pharmacy channel is pseudoephedrine which can be used in the illegal manufacture of methamphetamines.

MedsASSIST is similar to Project STOP but provides real-time recording and monitoring as a clinical decision support tool for community pharmacists supplying non-prescription analgesics containing codeine. It was developed in response to concerns over patient safety relating to these medicines and as an effective alternative to requiring patients to visit a doctor for a prescription. MedsASSIST focuses on

\textsuperscript{91} UK Appliance Use Review (AUR); [http://psnc.org.uk/services-commissioning/advanced-services/aur/](http://psnc.org.uk/services-commissioning/advanced-services/aur/)
patient care and patient pain management support pathways to help pharmacists identify patients who are at risk of codeine dependence. It facilitates access to suitable referral pathways to support patients to avoid or manage potential substance abuse or misuse, better manage their pain and enhance health outcomes.

Both of these real time monitoring systems give pharmacists the ability to manage diversion issues for the non-prescription supply of pseudoephedrine and misuse of combination codeine analgesics. The implementation of these programs maintains access to these medicines for the majority of the population for minor ailments that might otherwise be available only as a prescription medicine necessitating a visit to a prescriber leading to increased costs.

The Guild believes that the scheduling of codeine combination analgesics as Prescription Only Medicines is a blunt instrument to address the issues of addiction and/or misuse and will only disadvantage people that use these products safely and find them effective, whilst doing little to address the issues of abuse and misuse. The problems associated with abuse or misuse by the minority of people using these OTC medicines is better managed by introducing a recordable medicine schedule. Such a mandate would facilitate the use of real-time monitoring systems to assist health professionals in making clinical decisions. To achieve national consistency for medicine recording, a new appendix can be implemented in the Poisons Standard for adoption or reference by the States and Territories.

### Electronic Reporting and Recording of Controlled Drugs

Electronic Recording and Reporting of Controlled Drugs (ERRCD) was an initiative in the 5CPA to ‘support the development of a system to collect and report data relating to controlled drugs, to address the problems of forgery, abuse, and doctor shopping’.

The initiative was expected to see the development and implementation of software programs providing:

- a nationally consistent Controlled Drug Electronic Register
- a nationally consistent electronic system to collect and report data relating to the dispensing of Controlled Drugs and
- real-time access for prescribers and pharmacists to current information on dispensing events for Controlled Drugs

On 12 February 2012, the then Minister for Health, the Hon Tanya Plibersek MP, announced that a licensing agreement had been signed with the Tasmanian Department of Health and Human Services to use their existing Controlled Drugs monitoring system as the platform for the nationalised ERRCD system to be made available to all States and Territories from July 2012.

It is disappointing that in September 2016 no jurisdiction has yet fully implemented the ERRCD (apart from Tasmania which already operated the system used as the basis for the ERRCD) nor has any dispensing software vendor taken advantage of the Vendor Resource Document to develop an integrated Controlled Drug Electronic Register.

The Guild believes that the Federal Government needs to take responsibility for implementing ERRCD to ensure a standardised approach across the country and that it is implemented in all jurisdictions.

**Recommendation Number 10**

The Guild recommends that:
• the Federal Government take immediate responsibility for the national implementation of a real-time recording system for Controlled Drugs (e.g. Electronic Recording and Reporting of Controlled Drugs – ERRCD).

• dispense software vendors are funded to develop an integrated Controlled Drug electronic register.

• the TGA should immediately introduce a recordable schedule in the Poisons Standard for all drugs at risk of abuse or misuse.

Pharmacy supply of OTC Medicines

Since the ‘Final Report of the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation’ (the ‘Galbally Report’) was presented to the Australian Health Ministers’ Conference (AHMC) in January 2001, there has been a level of uncertainty about the retention of the two OTC medicine schedules – Schedule 2 (Pharmacy Medicines) and Schedule 3 (Pharmacist Only Medicines). Following the Galbally Report, until 2012 the Guild presented evidence to the National Coordinating Committee on Therapeutic Goods (NCCTG) to demonstrate the value in retaining the two OTC medicine schedules. While some evidence was collected through a research project funded under the 4CPA, the remainder had been determined from the data collected under the QCPP Mystery Shopper Program. The operations of the QCPP Mystery Shopper Program were revised specifically to respond to NCCTG requests.

Below is a summary of the Guild’s justification for retaining the OTC schedules:

• The Guild considers the availability of OTC (Schedule 2 and Schedule 3) medicines via community pharmacy to be in the best public health interest of the Australian community. Medicines are not normal items of commerce. If used incorrectly or inappropriately, they have the potential to do significant harm. Given the generally low level of health-literacy of many Australians, access to pharmacist advice for OTC medicines provides protection for consumers. This is particularly so for the more vulnerable groups such as children, the elderly, those from poorer socio-economic backgrounds or those who do not speak or understand English well. The high prevalence of poly-pharmacy also warrants consideration by a pharmacist to ensure there are no interactions between any prescribed, complementary or OTC medicines.

• Appendix 6 provides examples of where pharmacy staff have responded to and managed an individual’s risk with OTC medicine supply.

• The 4CPA Research and Development Project demonstrated that consumer access to OTC medicines was not an issue and that for the main part, consumers were satisfied with the level of pharmacy advice provided and wanted this advice to remain available.

• The extent of pharmacy staff involvement in responding to requests for OTC medicines is promoted by professional supply protocols and determined by the type of request from the consumer. The Mystery Shopper data demonstrated that almost all consumers received some advice in pharmacy and the pharmacy role of supporting consumers with the purchase of OTC medicines is being largely fulfilled. By contrast, there is no information gathering or provision of professional advice available to consumers when purchasing medicines through non-pharmacy outlets.

• Since commencing in October 2002 until February 2013, under the QCPP, the Guild had conducted 31,645 mystery shopper assessments. Below is a summary of evidence gathered to

92 Healthcare Management Advisors, Consumer perceptions of supply or and access to consumer medicines, Department of Health and Ageing, 2008
date as part of the QCPP Mystery Shopper Program that demonstrates the value added by community pharmacy in the supply of Schedule 2 and Schedule 3 medicines. Should the Pharmacy Review Panel require further information about the reports provided to the NCCTG, the Guild would be pleased to assist in this regard.

Key findings identified from the *Quality Improvement in Pharmacy – NCCTG 2012 Report* (reporting on data collected in 2011), included:

- There is greater pharmacy intervention for ‘symptom based requests’ compared to ‘blended product requests’ or ‘direct product requests’
- There is greater information gathering when the pharmacist is referred to by the pharmacy assistant
- The quality of advice given is higher when both pharmacy assistant and pharmacist are involved in the supply
- Improvement in the quality of advice given is related to:
  - improvements in the scope or amount of information gathered (in particular, information associated with risk and inappropriate use of medicines)
  - increasing awareness of the implications of key information factors and their sequelae and the need for pharmacy assistants to refer to and involve the pharmacist
  - improving the decision making skill of the pharmacy staff member through the availability of training, professional protocols and tools and support from the pharmacist
- It should be noted that since the Galbally Report, there have been a number of significant changes to how community pharmacy manages the supply of OTC medicines:
  - Under QCPP, there is a mandatory requirement for pharmacy assistants to complete the training module – ‘Support the sale of Pharmacy and Pharmacist Only Medicines’
  - Since April 2010, OTC medicine refresher training of pharmacy staff has also been mandated for QCPP re-accreditation
  - Community pharmacy has introduced and trained against OTC medicine protocols such as ‘Ask, Assess, Advise’
  - Over 94% of community pharmacies are accredited under QCPP

Based on this evidence, the Guild believes two separate OTC schedules remains appropriate. We also consider that access to OTC medicines via a pharmacy, as opposed to the grocery sector, to be fundamental to the Federal Government’s health reform agenda. Health reform efforts to make better use of the health dollar include the drive for consumers to be central to and take personal responsibility for their health. There is strong international evidence, such as in the UK, that self-care substantially improves the efficiency of the health system, leading to better individual and public health outcomes. Self-care embraces both curative and preventive health. It does not imply that individuals are left to treat themselves in isolation, but rather, are empowered to take personal responsibility for their health through the support of a multidisciplinary team of health care professionals, including pharmacists. Access to both Schedule 2 and Schedule 3 medicines via the pharmacy sector is a fundamental underpinning of the self-care concept.

There are a number of medicines available from a pharmacist in countries such as New Zealand and the UK that require a prescription in Australia. Examples include:

- Azithromycin (UK) – for treatment of chlamydia
• Calcipotriol (NZ) – for treatment of psoriasis
• Oseltamivir (NZ) – for treatment of influenza
• Sumatriptan (NZ) – for treatment of acute migraine
• Trimethoprim (NZ) – for treatment of urinary tract infections
• Sildenafil (NZ) – for erectile dysfunction
• Simvastatin (UK) – for high cholesterol
• Tamsulosin (UK) – for benign prostatic hyperplasia

In some of these cases, there is a requirement for a pharmacist to have completed an accredited training module before they can supply to patients without a prescription. The Guild believes there is greater scope in Australia to implement a Minor Ailments program for a number of Prescription only (Schedule 4) medicines. This would capitalise on the already extensive capability of community pharmacists assisting Australian consumers with non-complex health conditions (minor ailments) that can be managed within a pharmacist’s scope of practice with referral to a doctor or other health care professional when appropriate.

Recommendation Number 11
The Guild recommends that:

• in the interests of accessibility and public safety, the Schedule 2 and Schedule 3 medicine schedules must be retained and expanded.

Dispensing related services
As previously highlighted, dispensing is a complex professional service involving many elements (see Appendix 3). While all prescriptions require professional review and assessment by a pharmacist, some may require additional intervention in order to ensure the best outcomes for the patient.

There are a number of dispensing related services provided by community pharmacists for which there is strong evidence of positive benefits for patients but for which the pharmacy receives little or no remuneration.

As part of the 6CPA, pharmacies receive an incentive payment to ensure that patients receive the highest quality of care, information, advice and service through a quality framework for the provision of DAAs, SS services, and for the documentation of CIs.

However pharmacies are not paid a fee for service by the Federal Government to provide DAAs or SS to consumers, therefore, many charge a patient contribution towards the cost of providing these services, which for the most part does not fully cover costs. Pharmacies are also not paid on a fee for service basis for undertaking CIs, regardless of the level of effort entailed or the benefits to the patient.

Dose Administration Aids (DAAs)
DAAs are a pharmacy service that assist patients to improve health and social outcomes by better managing their medicines. The improved adherence from the DAA service reduces the likelihood of medicine misadventure and the associated use of other high-cost health services such as hospitalisation and/or GP or Emergency Department (ED) attendance.
A patient’s medicines are packed into weekly devices in which the medicines are arranged into individual doses according to the prescribed daily dose schedule. Patients that most benefit from a DAA service are those who are on a number of long-term medicines for chronic health conditions and have unintentional non-adherence – i.e. they may unintentionally forget to take their medicine or forget that they have taken it and take an extra dose.

Australian research has shown improvements in adherence from the use of a DAA ranges from 14.6% to as high as 43%. Likewise, international research has also shown that DAAs can improve adherence for antipsychotics from 64% for usual care to 91% over a period of six months.

For several years, the Federal Government DVA has funded a DAA service for Australian Veterans. Prior to funding the service, the DVA conducted a 12-month randomised controlled trial of DAA usage for community-based veterans. The trial concluded that the benefits of DAA use included better health, lower mortality, improved adherence, and reduction of solid medicines in the patient’s home and improved accuracy of doctor’s records. The DVA DAA service pays pharmacies a weekly service fee of $10 per patient per week and $100 every six months for the pharmacist to assess whether the patient is managing with the DAA with a recommendation to the GP for continuing use. These fees have remained the same since 2008 with no indexation applied.

The Guild believes that the Federal Government should fund a fee for service DAA program under the 6CPA to support at-risk community based patients using long-term medicines prescribed as pharmaceutical benefits. There may be benefit in linking the services with the National Health Priorities and/or other chronic health conditions. The aim would be to facilitate equity of access to a quality assured DAA service for all Australians irrespective of socio-economic background to improve medicine adherence and longer term patient outcomes.

**Staged Supply (SS)**

SS is a service provided by community pharmacies in which dispensed medicines are provided in instalments to at-risk people. A SS service is aimed at improving the safety and efficacy of medicine use in vulnerable patients. The service is particularly valuable for patients with a mental illness, drug dependency or who are otherwise unable to manage their medicines safely. Instalments are supplied at intervals agreed to by the prescriber, patient and pharmacist. This typically ranges from daily to every few days and involves face-to-face contact with the patient.

It is likely that in Australia, the misuse of and trafficking in prescription medicines exceeds that of illicit drugs. Excluding State-based ODT programs, there are no national or State-based funding arrangements to cover pharmacy SS services to eligible patients.

Patients that most benefit from a SS service are those that use analgesic and psychotropic medicines and are at risk of self-harm or addiction-like behaviour (e.g. misuse, abuse, on-selling).

Others that would also benefit from a SS service are patients using high-risk medicines such as clozapine requiring regular, routine therapeutic monitoring for continuation of therapy. (Appendix 4 summarises the processes and remuneration for dispensing clozapine).

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93 Roberts et al 2004; Effectiveness and cost-effectiveness of dose administration aids (DAAs)
94 Schizophrenia Bulletin 2011; Using a Pharmacy-Based Intervention to Improve Antipsychotic Adherence among patients with serious mental illness
SS involves intensive pharmacist monitoring and intervention for particular risks of abuse or intentional misuse or safety risks identified with therapeutic monitoring. This often includes analgesic narcotics and Schedule 8 medicines that require additional recording and documentation. Pharmacies are generally only remunerated in part for this service, predominantly by patient contributions. As such, many pharmacies are reluctant to promote SS services and offer it solely as a community service in response to a particular request from a prescriber or patient.

The Guild believes that the Federal Government should fund a fee for service SS program under the 6CPA for at-risk community based patients, with a particular focus on mental health and chronic pain.

**Clinical Interventions (CIs)**

When dispensing prescriptions or supplying non-prescription medicines, pharmacists routinely conduct valuable CIs to manage or avoid potential medicine related problems. CIs are professional activities which result in the improvement of quality use of medicines for a patient that may involve a change in medicine taking behaviour or compliance, or change of therapy including method of administration, dose, or type of medicine.

CIs have always been an integral part of professional pharmacy practice reducing the need for more expensive and complicated medical interventions in the wider health system. The Australian Commission on Safety and Quality in Healthcare estimates that there are 230,000 medicine-related hospital admissions annually at a cost of $1.2 billion.\(^9\)

Additionally, the rates of prescribing errors in Australian studies are as high as 115 errors per 100 high-risk patients,\(^10\) and the prevalence of inappropriate prescribing in the elderly is 20% with marked variation between therapeutic classes.\(^11\) It is considered that a large proportion of adverse drug events that originate in the community setting may be potentially avoidable, and community pharmacists are ideally placed to detect and resolve these issues for at-risk consumers.\(^12\)

The documentation and analysis of pharmacist CIs in the PROMISe III study found that the average CI was estimated to avoid approximately $360 in health care utilisation and increased the number of quality adjusted life years by approximately 0.01.\(^13\) The study also demonstrated that 40% of the documented CIs resulted in a change in therapy. These changes were predominantly a change of medicine, or a change in dose, with the most common medicine groups requiring interventions being opioids, antibiotics, antidepressants and proton pump inhibitors.

Based on the outcomes of the PROMISe III study, the 5CPA implemented a process change facilitated by a practice incentive payment to encourage pharmacists to record the routine CIs undertaken, particularly as part of the dispensing process. More than 3.6 million CIs were recorded in 2013 alone. Guild data shows that from June 2011 to August 2014, in addition to over 1.5 million interventions to address compliance issues, other frequent interventions have related to addressing drug interactions (133,000), incorrect prescribed strength (51,000), contraindications (15,000), prescribed dose being too high (84,000), incorrect or unclear dosing instructions (267,000) as well as risks of toxicity, allergic reactions and adverse effects (157,000).

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\(^10\) NPS Jun 2009; Medication Safety in the Community: A review of the literature

\(^11\) Inappropriateness of Medication Prescriptions to Elderly Patients in the Primary Care Setting: A systematic Review; Aug 2012


Internationally, there are a range of more complex and problem-focused CIs that have been formalised and appropriately funded. While Canada provides the best example of advancement in dispensing practice and responsibility, pharmacy practice is also being extended in the USA, UK, Ireland and New Zealand. These fee for service interventions focus on opportunities for pharmacists to drive improved patient outcomes in areas that reduce the overall demand on the wider health system.

**Enhanced Clinical Interventions**

**Prescription Adaptation**

Pharmacists regularly collaborate with patients and prescribers to manage medicine-related problems with prescribed medicines. In many circumstances, the outcome is that the prescription is adapted to optimise the therapeutic outcome for the patient.

Reasons for intervening include:

- changing the medicine because of an identified interaction, allergy or adverse effect
- changing the dose of the medicine for identified clinical reasons (e.g. increasing dose to therapeutic levels, reducing a dose due to adverse effects)

As a result of pharmacists intervening in these situations, the therapeutic outcomes for patients are optimised because of the reduction in risk of overuse, underuse or inappropriate use of the prescribed medicine.

Prescription adaptation, whereby the community pharmacist is able to make an adaptation to the dose, formulation or regimen of the prescription is funded in all Canadian Provinces and ranges from CAD$6-$20.\(^{104}\)

**Non-dispensing**

Another outcome is that the pharmacist may choose not to dispense based on their professional judgement. This may be due to therapeutic duplication, a dangerously high dose, treatment failure, or potential overuse/abuse of a medicine.

Non-dispensing can also be used to address other medicine-related priorities such as managing the over-use of antibiotics by encouraging pharmacists not to supply older but valid repeat prescriptions for antibiotics until the prescriber confirms the supply is appropriate. The service also addresses the increasing concerns about over-utilisation and diversion of medicines and reduces wastage of prescribed medicines.

A Non-dispensing service, whereby the community pharmacist is paid not to dispense a prescription based on their professional judgement is funded in Ireland (€3.27) and Alberta, Canada (CAD$20).

The Guild believes that the Federal Government should fund a fee for service Enhanced Clinical Intervention program under the 6CPA for at-risk community based patients focussing on areas such as the over-use of antibiotics and potential overuse/abuse of medicines.

\(^{104}\) A Review of Pharmacy Services in Canada and the Health Economic Evidence; Feb 2016; [https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/Pharmacy%20Services%20Report%201.pdf](https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/Pharmacy%20Services%20Report%201.pdf)
**Recommendation Number 12**

The Guild recommends that immediately:

- the Department of Veterans’ Affairs (DVA) should review both the administration process and the level of remuneration for the DVA Dose Administration Aid (DAA) service and apply annual indexation.
- the 6CPA should be used to fund a fee for service DAA program for eligible community based patients delivered through community pharmacy.
- the 6CPA should be used to fund a fee for service Staged Supply program for eligible community based patients delivered through community pharmacy.
- the 6CPA should be used to fund a fee for service payment for enhanced clinical interventions for eligible community based patients delivered through community pharmacy.

**Medication management services**

Systematic reviews have indicated positive returns on investment when evaluating broader cognitive pharmacist services as a whole, with up to $4 in benefits expected for every $1 invested in clinical pharmacy services.\(^{105}\)

A comprehensive and targeted approach to medicine adherence and medication management can maximise the health and economic dividend from the Federal Government’s investment in the PBS by lifting medicine adherence rates. This, in turn, can significantly reduce wider health costs with suboptimal medicine adherence estimated to cost $3 billion annually.

There is clear evidence that an increased investment in the quality use of medicines through personalised pharmacist care would significantly reduce unnecessary GP consultations, hospital admissions and premature admission to residential care, creating significant savings to the health system and ensuring that taxpayers’ investment in PBS medicines yields the best possible return.

Australia’s meagre investment in medicine adherence and medication management belies the value and importance of the quality use of medicines to individual patients and the cost-effectiveness of the health system.

GPs have an estimated 12 million consultations a year with patients who have experienced an Adverse Drug Event (ADE) in the previous six months.\(^{106}\) With medicine non-adherence costing more than $3 billion a year,\(^{107}\) the current national investment of less than $30 million a year for in-pharmacy and in-home medication management review services is woefully inadequate.

The continuation of current medication management services (HMRs, MedsChecks & Residential Medication Management Reviews (RMMRs)) funded under the 6CPA is subject to cost-effectiveness assessment by an independent health technology assessment body such as the Medical Services Advisory Committee (MSAC). Pending the outcome of these cost-effectiveness analyses, programs may be recommended by the Federal Government for continued funding, expansion or modification.

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\(^{105}\) Avalere Health LLC; Exploring Pharmacists’ Role in a Changing Healthcare Environment; May 2014

\(^{106}\) Ibid

\(^{107}\) IMS Institute for Healthcare Informatics: Responsible use of medicines report, October 2012
The Guild believes that all medication management programs funded by the Federal Government should have well defined eligibility criteria and be well targeted to patients with the greatest clinical need and the least capacity to pay. A comprehensive approach to medication management is required, including a strategy to maximise the quality use of medicines, expressly linked to the objective of delivering better, more cost-effective outcomes across the health system.

The following principles should guide future program development in this area:

- A patient-focussed approach where the ‘right service’ is delivered based on clinical need to a quality standard
- Programs delivered around a model linked to the supply of medicines by community pharmacies
- Integration with the broader primary health care sector, including digital health
- Reasonable co-payments for all fee-for-service medication management services
- Services targeted to those most in need, through well-defined patient eligibility criteria
- Services delivered to a quality standard that meets the Australian Standard 85000:2011
- Consistent program compliance regime, with auditing of services and enforcement
- Service caps where demand is likely to exceed the number of funded services available

**Home Medicines Review Program**

Given the Discussion paper makes statements around issues experienced with the HMR program and poses questions around the future design of the program, the Guild believes it is important for the Review Panel to give consideration to the most efficient use of future taxpayer dollars and ensure future services are provided appropriately to patients in need.

As discussed above, under the 6CPA, the Federal Government has determined that all programs will continue without change until they have been assessed for cost-effectiveness. Currently, a number of medication management programs have capping arrangements in place. These arrangements cap the number of funded medication management services that individual community pharmacies or pharmacists are able to provide and were put in place under the 5CPA to ensure the five year funding allocation was not exceeded. There are no caps on the number of HMR referrals that a GP can generate as they are funded under the MBS, which remains uncapped.

There is evidence to support highly targeted medication reviews being more cost-effective. A Federal Government funded cost-benefit analysis of the HMR program indicated that patients with multiple chronic conditions who are taking multiple medicines (greater than 12 medicines) provide the best value for money in terms of savings to the health care system.108

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However, the report found that while there were savings from avoided GP visits, specialist visits, reduced medical investigations, reduced drug costs and a reduction in hospital admissions – the potential savings vary considerably and in many HMRs the estimated annual economic value of these savings was insufficient to offset the total cost of the HMR. Further, the report recommended that measures to improve the targeting of HMRs to those patients most likely to result in economic benefits should be implemented to ensure the future sustainability of the program.

The Guild agrees with the findings of the report and believes that HMRs should continue to be available for those at-risk patients who stand to derive the greatest clinical benefit from the service.

Currently HMRs are not well targeted. Under MBS item 900, while there are ‘at risk factors’ to guide GPs to target patients for an HMR service, there are currently no patient eligibility criteria for referral other than ‘people living in the community’. The ‘at risk factors’ are not mandatory and only perform an advisory function, and the patient eligibility (i.e. people living in the community) applies to an overwhelming majority of the population.

One of the ‘risk factors’ that guide referral by GPs is ‘currently taking five or more regular medications’. According to ABS data, there are over three million people aged 65 and over. If this demographic information is applied to the number of people aged 65 and over who take six or more medicines, it equates to approximately 456,121 people. If all people who met this one ‘risk factor’ were referred for one HMR per year it would cost in excess of $93 million per annum. The current annual capped budget under the 6CPA is $14.5 million. Thus, the program needs to have appropriately targeted eligibility criteria to ensure consumers who have a demonstrated clinical need are receiving the service when they are most at need.

Whilst well targeted medication reviews have been found to improve the quality use of medicines for patients and to reduce hospital admissions and adverse medication advents, the Guild strongly believes that the best model of practice is one that is collaborative and ensures that there is a link between the patient’s community pharmacy (supply of medicines) and the provision of the medicine related service.

The HMR program provides an example of where the provision of the service was delinked from the community pharmacy through the implementation of a direct referral model. There is evidence that demonstrates that this delinking resulted in the occurrence of a number of purely business driven models that were focussed on volume rather than patient need or improving clinical outcomes.

From the inception of the HMR program in October 2001 until October 2011, HMR referrals were sent to the patient’s usual community pharmacy. Based on recommendations from a qualitative report commissioned in 2008, a ‘direct referral’ model was established that enabled GPs to refer patients directly to accredited pharmacists. This recommendation was based on the perception by some stakeholders that on average they waited about ten days between the GP referral and the provision of the service. In addition, many stakeholders believed that a ten day delay was unacceptable for a patient who may be at risk of medication misadventure. Based on the findings of a recent Federal Government Review, the implementation of the direct referral model has not had an impact on the average time

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109 Australian Demographic Statistics March 2013. Table 7 Estimated resident population by age and sex – at 30 June 2011. ABS.
110 National Health Survey – Use of Medications Australia (Number of Medications Used, By Age of Persons). ABS.
111 Home Medicines Reviews (HMR), which require a referral from the patients General Practitioner (GP), are undertaken by an accredited pharmacist in the patient’s home. GPs are able to refer patients for an unlimited number of HMRs and claim for payment under MBS item 900. Payment for the provision of the HMR service by pharmacists is funded under the Community Pharmacy Agreement via a capped budget.
between GP referral and service, with the average time increasing from a reported average of ten days in 2008 to an average of 25.48 days by 2015.\textsuperscript{113}

The direct referral model correlated with a significant growth in HMR referrals by GPs and HMR services provided by accredited pharmacists. In the financial year ending June 2011, there were 63,088 HMR services claimed, and by 2012-13 there were 115,892 HMR services claimed, representing an increase of 83.7\% from 2010-11\textsuperscript{114}. In the 2012/13 financial year, the provision of HMR services increased to the extent that there was an over expenditure under the 5CPA of $16.56 million. Whilst on face value this could be interpreted as an increase in patient access to services, there is also evidence to suggest that in part the increase was due to business models that were based on maximising financial return.

For example, in February 2013 over 15\% of all reviews were being conducted outside of the patient’s home and there was evidence that HMRs were being channelled to pharmacists who were co-located within general practices. There was also anecdotal evidence that large ‘out-of-town’ corporate providers were establishing business models within local medical centres and providing financial incentives from the HMR fee in return for direct referrals.

A further unintended consequence of the direct referral model resulted in large volumes of HMRs being conducted by a relatively small number of accredited pharmacists. Between March 2012 and February 2013 there were 1,519 pharmacists providing HMR’s. A total of 22 or 1.4\% of the accredited pharmacist providers accounted for 21,602 HMR’s or approximately 20\% of the total number of HMR’s conducted during that period.

The industry expectations of delivering a ‘quality service’ is generally in alignment with a total of no more than 60 HMR’s per month or 15 HMR’s per week. This figure is derived by dividing the nationally accepted maximum working week\textsuperscript{115} (38 hours) by the average time taken to provide the HMR service (up to 3 hours).\textsuperscript{116,117,118} In direct contrast to the industry standard, there was evidence of HMR businesses advertising for accredited pharmacists to conduct ‘up to’ 10 HMRs per day.

The Guild believes that there is a need to reconnect the HMR program with community pharmacies so as to provide a more holistic service for patients and ensure that the critical link between the supply of medicines and their effective management is not lost. This would also ensure that the program provides value for taxpayers and that services are provided appropriately to patients most at need.

**Recommendation Number 13**

The Guild recommends that:

- all Community Pharmacy Agreement professional programs should be delivered and funded through community pharmacy.
• in order to receive Federal Government funding, all pharmacist delivered professional services must be delivered to a quality standard that meets the Australian Standard 85000:2011.

• in order to receive Federal Government funding, all pharmacist delivered professional services must be uploaded to an e-health record to ensure coordinated patient care.

• in order to receive Federal Government funding, all pharmacist delivered professional services should be evaluated for clinical and cost-effectiveness.

• the Home Medicines Review (HMR) program should have well defined eligibility criteria to ensure services are targeted to those with the greatest clinical need and with the least capacity to pay.

• medicine related services delivered by pharmacists in health settings outside the community pharmacy should be funded separately to the Community Pharmacy Agreement and should not duplicate established community pharmacy based medicine related services or fragment patient care by not linking back to the patient’s usual community pharmacy.

**Better utilisation of Community Pharmacy to deliver improved outcomes and efficiency in primary health care**

“The cornerstone of a world-class health system is primary care, with pharmacy one of the key pillars in Australia’s primary health care sector”.

The Hon Sussan Ley MP, Minister for Health and Aged Care. Minister for Sport

Australia’s network of more than 5,500 community pharmacies is a stand-out success in our health system, ensuring that Australians have equitable and affordable access to subsidised medicines through the PBS. An independent geo-spatial analysis found that 87% of Australians live within two and a half km of at least one pharmacy.\(^{119}\)

Every year, Australians make over 350 million visits to their local pharmacies with pharmacists consistently rated among the most trusted health professionals. As highly accessible medicines experts, community pharmacists are well-positioned to play an enhanced role in delivering better, more cost-effective outcomes across the wider health system.

Medicines are the most frequently utilised health treatment, with over 290 million prescriptions dispensed annually. There are a number of clear trends in medicine use in Australia:

• Increased incidence of poly-pharmacy (43% of medicine users over 50 take five or more medicines)\(^{120}\)
• Increasing use of medicines on an ongoing basis to treat chronic health conditions (49% of people aged 65–74 have five or more long-term conditions)\(^{121}\)

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\(^{119}\) ABS Census of Population & Housing, 2011. Pharmacy Guild of Australia; MacroPlan Dimasi.


\(^{121}\) Australian Institute of Health and Welfare (2012). *Australia’s health* 2012. Cat. no. AUS 156. Canberra: AIHW.
• Greater complexity in medicines regimen, with increased likelihood of interactions and adverse reactions (just 10% of older patients can name all their medicines correctly)\textsuperscript{122}

• Relatively low medicine adherence rates of between 50% and 65%, with non-adherence estimated to cost $3 billion annually\textsuperscript{123}

• Significant levels of adverse medicine events, with an estimated 230,000 medicine-related hospital admissions annually at a cost of $1.2 billion\textsuperscript{124}

Around the world, governments are recognising that pharmacists can identify and address health issues which, if left unchecked, may result in significantly greater health costs and patient detriment. Genuine health reform and significant cost savings can be delivered through the better utilisation of community pharmacy.

International experience shows that there are both significant savings, combined with improved health outcomes by following two key principles:

• Removing regulatory restrictions which inhibit health practitioners from practising at the top of their capabilities;

• Allowing patients to choose who provides their primary health care, particularly in the case of chronic disease management.

Many Australians have more frequent interaction with their community pharmacist than with their GP. Studies have demonstrated that on average consumers interact with their pharmacy 12 to 15 times per year, yet only visit their doctor three to four times per year, putting pharmacy in a better position to monitor the progress of patients.

Community pharmacists provide a range of primary health care services beyond dispensing that are crucial to the health of Australians. These services help patients achieve health outcomes and cover, for example, advice to mothers regarding the use of medicines while breastfeeding; sexual health and contraception advice; assessing ailments such as minor wounds and sporting injuries and providing assistance to elderly and other people regarding the health system and their access to social welfare and other community services.\textsuperscript{125}

The Guild believe that an approach to health care which breaks down the traditional silos between doctors, pharmacists and other allied health care providers can enhance health outcomes for consumers and deliver significant productivity benefits without eroding the role of the medical practitioner. Examples of areas where the role of community pharmacists can be broadened to deliver enhanced primary health care services are provided below.

**Minor Ailments Service**

It has been estimated that some 26 million GP consultations a year in Australia subsidised under Medicare are for minor ailments.\textsuperscript{126} Based on the fee for a standard GP consultation this amounts to almost $1 billion per year in Medicare costs. Increased recognition, awareness and enhancement of the valuable role community pharmacies have in providing advice, treatment and triage for minor ailments

\textsuperscript{122} Al Mahdy H & Seymour DG (1990) ‘How much can elderly patients tell us about their medications?’ Postgrad Med J 66:116–121


\textsuperscript{125} Ibid.

\textsuperscript{126} ASMI Minor Ailments Report Sep 2009
would enable patients to get more immediate and less expensive access to treatments while freeing up GP time for treating more complex conditions.

In a number of countries, such as the UK, governments have enabled pharmacies to play an enhanced role in managing minor ailments by raising consumer awareness of the benefits of visiting community pharmacies for advice and treatment, and creating a greater capacity to treat a range of readily identifiable ailments with medicines that had previously been limited to supply on prescription. A 2013 systematic review which included 3,308 publications found:

- A mean price per consultation (excluding cost of medicines) ranging from £1.44 to £15.90, compared to means of £36 for GPs and £111 for emergency department visits;
- Associated savings to the UK's National Health Service (NHS) of £112 million per year;
- No difference in health outcomes, measured by re-consultation and referral rates.

Scotland also has a Minor Ailment Service that allows eligible individuals (mostly over 60s and people on income support) to register with and use a community pharmacy as the first port of call for the treatment of common illnesses. Payments are made on a capitation model that provides a minimum pharmacy payment of £608 per month (for 1 to 250 patients). For pharmacies with more than 1,250 patients the monthly payment is £1,267 plus £0.67 per person beyond 1,250 patients. At the end of March 2015, 913,483 patients were registered for Scotland's Minor Ailment Service, across 1,253 participating pharmacies (an average of 729 patients per pharmacy).

The role of community pharmacy in Australia could be extended to ailments such as uncomplicated eye, ear or urinary tract infections, skin conditions or pain management. This would be supported by the introduction of a recordable pharmacist-only medicine schedule, which could be integrated into the e-health system, and require community pharmacists to refer to the patient's GP.

This service would direct patients with health conditions that can be managed by a pharmacist away from more costly health care options, representing not only a cost-saving, but greater access and convenience for patients. The Pharmacy First minor ailments scheme which operates in Nottingham, has been accessed by more than 250,000 patients who would have otherwise added to the pressure on GP resources.

Pathology Tests

Patients with chronic diseases such as diabetes and cardiovascular disease require periodic ongoing pathology monitoring to assist with guiding their treatment. Given this ongoing need for pathology monitoring, patients often have to visit a GP or specialist on two separate occasions; once to obtain the pathology request, and a second time to discuss the results.

In consultation with the patient’s GP, pharmacists could proactively order a standard range of pathology tests for patients receiving ongoing stable therapy for chronic conditions. The patient would then be able to obtain the test results prior to seeing their GP for a review of their results. A trigger for the pathology test could be the dispensing of the final repeat prescription.

A randomised controlled trial conducted in Canada where pharmacists prescribed medications and ordered pathology tests showed that pharmacist intervention for patients with hypertension resulted in a clinically important and significant reduction in blood pressure.\textsuperscript{135}

According to IBISWorld, the current annual number of pathology tests completed in Australia is approximately 110 million. In 2008, the Australian Association of Pathology Practices reported that 70% of all pathology tests were initiated by GPs, and the Australian Institute for Health and Welfare estimate patients on average have 2.8 tests performed per episode. Assuming that each of these episodes results in a follow-up appointment with a GP to discuss the results, there are a total number of 27.5 million follow-up visits.

Utilising community pharmacists to improve the efficiency of GPs in this way could release capacity in the form of 5.5 million standard consultations per annum. This would provide GPs with additional capacity to treat their existing patients and flexibility to take on more new patients.

**Pharmacist Vaccination Services**

Building on the Queensland Pharmacist Immunisation Pilot (QPIP), and the recommendation in the Parliamentary Inquiry into Community Pharmacy in Victoria to establish a pharmacy immunisation trial, there is a further opportunity for pharmacists to be involved in the delivery of vaccinations listed in the National Immunisation Program (NIP).

Over 10,800 influenza vaccines were delivered during the QPIP, and almost one in five people vaccinated indicated that they would not otherwise have been vaccinated. Consumer satisfaction with the service was extremely high, and the pilot demonstrated that an appropriately trained pharmacist can deliver immunisations safely and effectively in the community setting.\textsuperscript{136}

In many other countries, pharmacies are a leading destination for influenza vaccination, with pharmacists also administering immunisation against other diseases such as shingles and pneumonia.

In Ireland pharmacists receive a government fee of €15 to vaccinate patients over 65 and at-risk patients who have a medical card against seasonal influenza. The vaccines are supplied directly by the Health Service Executive. Pharmacies typically charge private patients €15-30 per vaccination.

In England, pharmacies providing the influenza vaccination service are paid £7.64 per administered dose of vaccine plus an additional fee of £1.50 per vaccination (i.e. a total of £9.14 per administered vaccine). The additional fee is in recognition of costs incurred relating to the provision of the service including training and disposal of clinical waste.

In Alberta (Canada) there is a fee of C$20 per pharmacist-administered vaccination (this includes assessment and administration of publicly funded vaccines and other medications by injection).

Successful vaccination programs rely on the concept of opportunistic vaccination and community pharmacy is perfectly positioned to provide this service. This may increase ‘herd immunity’ and has the

\textsuperscript{135} Tsuyuki et al, Randomized trial of the effect of pharmacist prescribing on improving blood pressure in the community – The Alberta Clinical Trial in optimizing hypertension (RxACTION), 2015.

\textsuperscript{136} Nissen L & Glass B, Pharmacist Vaccination – Influenza Final Report, Queensland University of Technology, 2015.
potential to reduce the number of preventable infections and the associated costs of hospitalisations. This in turn could have further flow-on effects of higher productivity, with reduced sick days for both patients and parents of infected children, an impact on emergency departments and inpatient day beds for the public hospital sector.

Pharmacists are now able to administer influenza vaccinations to adults in community pharmacies in every State and Territory and in Victoria, as part of the NIP. With communicable diseases remaining a significant health problem in all parts of Australia, it is not unreasonable to expect other jurisdictions to consider using community pharmacist vaccinators as part of their NIP strategy. As with GPs and nurse vaccinators, community pharmacists involved in the NIP should also be eligible for vaccination related MBS payments. All vaccinations undertaken in community pharmacies should also be uploaded to the appropriate vaccination register.

**Continued Dispensing**

Continued Dispensing is the supply of an eligible medicine to a consumer under the PBS when there is an immediate need for that medicine but it is not practical to obtain a prescription. Continued Dispensing is permitted when the medicine has been previously prescribed, therapy is stable, there has been prior clinical review to support continuation and the medicine is safe and appropriate for the patient.

Commonwealth legislation was amended to enable Continued Dispensing in 2012, and amendments to relevant State and Territory legislation in all jurisdictions followed.

Continued Dispensing could be extended to other medicines used for chronic health conditions, such as for cardiovascular disease, diabetes, asthma and mental health. The cost to the Federal Government is negligible, but it would address barriers to improved adherence from not being able to have a prescription readily renewed in a timely manner. It would also be of great value in times of catastrophe such as floods, fires and cyclones to ensure patients have ongoing access to their medicines should they be lost during the event. While States and Territories have arrangements in place for emergency supply when a prescriber is not available, such supply is generally limited to a quantity equivalent to 3-days' supply and is not subsidised under the PBS, meaning the patient and/or the pharmacy must bear the associated costs and medicine wastage.

Research indicates there is strong support for continued dispensing arrangements from the community pharmacy sector and from consumers with chronic conditions. In addition, an evaluation of the continued dispensing model noted that additional medicines should be considered for inclusion in the arrangements.

**Prescription Renewal**

At least four million visits to GPs per year involve issuing another prescription for a medicine that a patient is already taking. As part of a collaborative arrangement with the GP and patient, pharmacists could provide ongoing repeat prescriptions to people with stable long term conditions, such as diabetes and high blood pressure, and work with the GP to help patients manage these conditions. The community pharmacy could work to an agreed management plan to monitor the patient’s adherence and response to the prescribed medicine. Doctors in the UK and Canada already authorise

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137 Griffith University (2014). Exploring the health consumers’ perspective on the burden of chronic illness and the role of community pharmacy in chronic illness management. 5CPA &Development Program.


139 Access all areas: New solutions for GP shortages in rural Australia; Grattan Institute; September 2013

pharmacists to renew prescriptions for an agreed period of time, leading to more efficient use of pharmacist and GP time and expertise, and reduced costs to patients.

These Prescription Renewal arrangements will benefit patients who will no longer have to make unnecessary GP appointments; whilst GPs’ time will be freed to deal with more complex cases. This will be particularly important in rural areas where there is less access to GPs. According to the BEACH general practice survey, in 2013-14, 3.1% of GP patient encounters were recorded as ‘managing a prescription’, which was a higher rate than any of the previous nine years.\(^{141}\)

### New Medicines Service (NMS)

An increasing number of Australians are being prescribed medicines on an ongoing basis for chronic health conditions. Maximising their levels of adherence to these medicines at the earliest opportunity enables them to remain healthy and productive and reduces the overall burden on the wider health system.

Ten days after starting a new medicine, 30% of patients are already non-adherent and 50% report a problem with their medicine. At four weeks, the issue remains for 22% of those with a problem and 26% of patients indicate a new problem has emerged. A British study found that at four weeks, just 16% of patients who are prescribed a new medicine are taking it as prescribed, experiencing no problems and receiving as much information as needed.\(^{142}\)

Based on the UK model\(^{143,144}\) a NMS would focus on helping improve a person’s understanding and use of newly prescribed medicines. The UK model has now been fully evaluated. The evaluators concluded:

> "The New Medicine Service (NMS) significantly increased adherence by about 10% and increased numbers of medicines problems identified and dealt with, compared with current practice."\(^{145}\)

Community pharmacies are ideally placed to provide the NMS which would complement existing services by targeting the commencement of a new medicine, which is a proven point of vulnerability. The NMS could also be potentially targeted to biosimilar medicines and injectable devices.

### Pharmacy Health Hubs

Community pharmacies can be more effectively utilised to address health issues arising from the difficulties that some Australians have accessing GP services and by freeing up GPs to treat more complex conditions.

One in five Australians wait for a GP appointment longer than they feel is acceptable.\(^{146}\) Australians living outside of capital cities are particularly affected, being less able to secure a GP appointment the same day (46% versus 64% for those living in a capital city) and having to wait more than five days for an appointment (24% versus 8%). Access to GPs outside normal business hours is also reported as being somewhat difficult or very difficult by 47% of Australians.\(^{147}\) Patients with long term health conditions are

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\(^{142}\) [http://qualitysafety.bmj.com/content/13/3/172.full.html](http://qualitysafety.bmj.com/content/13/3/172.full.html)

\(^{143}\) [https://www.nhs.uk/nhsengland/aboutnhsservices/pharmacists/pages/medicine-service-ga.aspx](https://www.nhs.uk/nhsengland/aboutnhsservices/pharmacists/pages/medicine-service-ga.aspx)

\(^{144}\) [http://psnc.org.uk/services-commissioning/advanced-services/nms/](http://psnc.org.uk/services-commissioning/advanced-services/nms/)


more likely to visit their GP four or more times a year (62%) compared to those with an acute condition (26.8%).

Many rural communities are looking increasingly to their local pharmacies to deliver a wider array of services, in areas such as screening and health checks, vaccinations, pain and wound management, mental health support, smoking cessation, weight loss, Indigenous health, minor ailments and sleep apnoea.

There is an opportunity to establish ‘Pharmacy Health Hubs’ in towns where there are serious shortages of GPs and other health professionals. This initiative would have some similar characteristics to the successful Healthy Living Pharmacies program that has been rolled out in the UK. Under that program, pharmacies develop and implement strategies to overcome identified deficiencies in local public and preventive health services.

Pharmacy Health Hubs could also be used to support national health priorities and public health and prevention campaigns including in the education, prevention and treatment of the health and social issues relating to illicit drugs such as ‘ice’.

The establishment of Pharmacy Health Hubs in areas of demonstrated need would encourage consumers to establish relationships with their local community pharmacy as the centre of a coordinated health network.

**Prevention and Early Intervention**

Australia’s rising health care costs are being driven, in part, by the fact that many Australians are living unhealthy lives that put them at risk of chronic diseases that are very expensive to manage. In addition, while vaccination rates are relatively high by world standards, there are still unnecessary deaths and hospitalisations occurring from vaccine preventable diseases.

Smoking, obesity, alcohol intake, diet and lack of exercise have all been identified as negatively impacting health. Cardiovascular Disease (CVD) is Australia’s most expensive disease group costing nearly $8 billion or 12 per cent of direct health expenditure annually. The primary risk factors for CVD are high blood pressure, smoking and being overweight. It is estimated that mortality rates from CVD can be reduced by 66 per cent by tackling lifestyle issues. It is a similar story with other chronic diseases such as Type 2 Diabetes, Alzheimer’s disease and asthma – all costly for the Federal Government and the community.

Three-in-five adult Australians and one-in-four children are overweight, with obesity rates more than 30 per cent higher in outer regional and remote areas compared with capital cities. About one-third of adult Australians have high blood pressure, more than two-thirds of which is uncontrolled or unmanaged. Nearly 16 per cent of adult Australians still smoke.

If Australia is to address the increasing prevalence and burden of these chronic conditions, there must be a greater emphasis on prevention and early intervention. A survey of 3,000 people that was part of the

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148 ibid
149 http://psnc.org.uk/services-commissioning/locally-commissioned-services/healthy-living-pharmacies/
150 AIHW Australia’s Health 2014
151 ABS 4363:0:55:001 – Australia’s Health Survey 2011-13
153 Ibid
154 ABS 4338.0 Profiles of Health, Australia, 2011-13
Consumer Needs project funded by the Federal Government DoH, found that 49% of participants had visited a pharmacy in the past week.\textsuperscript{155}

As Australia’s most accessible, visited and trusted health destination, community pharmacies can help people to take greater responsibility for their health by promoting healthy lifestyles, checking immunisation status and providing basic health checks to identify those at risk of chronic health conditions for early intervention care and support.

**Transition of care between the hospital and community pharmacy**

The patient transition between the hospital and the community is unfortunately prone to medicine misadventure. This is often related to a lack of communication between the hospital, the patient’s GP and their community pharmacy resulting in missed patient follow-up, inadequate patient education, incomplete medicine reconciliation and the absence of medication management services, such as initiating or updating a DAA, or the provision of services such as a MedsCheck or HMR.

Dispensing, medicine reconciliation, patient education and the provision of medication management services form the core of a pharmacist’s role. Unfortunately it is often unknown to the community pharmacist if one of their patients has been admitted to hospital or discharged. Communication between the hospital, the GP and community pharmacy is variable and can be hospital or pharmacist specific. The hospital may only contact the pharmacist if the hospital has a query regarding a patient’s medicine history or the patient requires a DAA on discharge. Consideration is often not given to whether the community pharmacy:

- needs a prescription for new or changed medicines (particularly problematic for Authority Required prescriptions)
- has to order a medicine (noting wholesaler order cut off times affect delivery times)
- needs GP authorisation for DAA changes

Patients require a prescription to have a medicine dispensed from a pharmacy and after discharge from hospital, the median time for a patient to see their GP is 12 days.\textsuperscript{156} To ensure continuity of medication supply after discharge, community pharmacists need to be able to use the Hospital Medication Chart as a PBS prescription to be able to dispense medicines for people as they leave hospital and return to their community or residential care setting.

The other key problem is the lack of consolidated information about a person’s medicines and the ability to easily share information between care settings and between care providers – namely the hospital, GP and community pharmacy. The ability to use the Hospital Medication Chart as a PBS prescription in conjunction with the development of a useful, consolidated electronic medication profile as part of the patient’s My Health Record is critical to improving patient care, ensuring a smooth transition between the hospital and the community pharmacy and to maintaining links between the patient, the patient’s GP, their community pharmacist and the hospital. This is discussed further under Digital Health (eHealth) and Aged Care sections.

\textsuperscript{155} PricewaterhouseCoopers, Consumer Needs, Fifth Community Pharmacy Agreement R&D Program, 2015.
\textsuperscript{156} EE Roughead et al; Continuity of care: when do patients visit community healthcare providers after leaving hospital? Internal Medicine Journal; Vol 41, Issue 9; pp 662-667; Sept2011
Recommendation Number 14

The Guild recommends that:

- the Federal Government should fund a fee for service minor ailments program in community pharmacy that uses a recordable pharmacist-only medicine schedule.
- the Federal Government should allow community pharmacies to order a standard range of pathology tests in line with best practice for patients receiving ongoing stable therapy for chronic conditions.
- to provide equity and enhanced patient access, community pharmacies involved in the National Immunisation Program (NIP) should be eligible for relevant MBS payments.
- all vaccinations undertaken in community pharmacies should be uploaded to the appropriate vaccination register.
- the Continued Dispensing arrangements for urgent PBS medicine supply should be expanded to include other medicines used to treat chronic health conditions, with a requirement to inform the prescriber.
- the Federal Government should fund a fee for service prescription renewal service in community pharmacy to support patients with stable chronic conditions with a requirement to inform the prescriber.
- the Federal Government should immediately trial a New Medicine Service under the Pharmacy Trial Program to help patients with chronic conditions to understand and use newly prescribed PBS medicines.
- the Federal Government should provide incentives for community pharmacies to become local Health Hubs in areas of demonstrated need.
- the Federal Government should fund a fee for service health check, risk assessment and referral program through community pharmacies.
- transitional care to and from hospitals should use digital health systems, including My Health Records, to maintain links with the patient’s usual community pharmacy and usual GP.

Problems with the supply of high-cost medicines and S100 listed items

High-cost medicines

As the discussion paper notes, expensive medicines, such as the hepatitis C medicines with a wholesale price of up to $22,000, have presented challenges to the supply chain, this in turn affecting consumer access.

Community pharmacy remuneration for high-cost PBS medicines

Table 3 outlines the remuneration received by community pharmacies and CSO wholesalers for high-cost PBS medicines:

<table>
<thead>
<tr>
<th>PBS Listing</th>
<th>Approved Ex-Manufacturer Price (AEMP)</th>
<th>CSO Wholesale Mark-up</th>
<th>$90 Pharmacy Mark-up (as of 1 July 2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 85</td>
<td>&gt; $2,019.77</td>
<td>$69.94</td>
<td>$70.92</td>
</tr>
<tr>
<td>Section 100</td>
<td>&gt; $1,000</td>
<td>$0</td>
<td>$40</td>
</tr>
</tbody>
</table>
Table 3 illustrates that where a medicine is >$2,019.77, e.g. $22,000 as is the case for hepatitis C medicines, the community pharmacy receives $70.92 if the item is S85 or $40 if the item is S100 to cover the administration, handling and infrastructure costs.

**Problems with supply of high-cost PBS medicines**

Community pharmacies face a range of problems that affect their ability to supply high-cost medicines. These are summarised in Table 4.

**Table 4: Problems with the supply of high-cost medicines**

<table>
<thead>
<tr>
<th>Issue</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overdraft interest rates and bank fees</strong></td>
<td>As small businesses, pharmacies are usually financed with a loan from a financial institution such as a bank with a guarantor. This operating loan is invariably an overdraft facility with interest rates of typically 8% to 10%. If the cash flow of a pharmacy is affected due to dispensing high-cost medicines and the pharmacy exceeds its overdraft limits, the pharmacy will incur overdraft interest rates and bank fees at a significant cost to the pharmacy.</td>
</tr>
<tr>
<td><strong>Pay GST to wholesaler and then claim it back from ATO</strong></td>
<td>Medicines only become GST-free at the point of sale. This means that pharmacies first pay GST to wholesaler and claim back from the Australian Tax Office (ATO) via a Business Activity Statement (BAS) that is usually lodged monthly. The higher the cost of the medicine, the higher amount of GST that has to be paid to the wholesaler, the greater the impact on cash-flow. The ability for a pharmacy to claim and receive reimbursement for the GST component before the wholesaler invoice is due directly affects the pharmacy’s cash flow with other subsequent flow on effects (e.g. overdrafts).</td>
</tr>
<tr>
<td><strong>Higher insurance premium</strong></td>
<td>Good business practice means that pharmacies should have adequate insurance to cover their business operations, including the value of the stock on hand. Pharmacies must take additional insurance to cover the high-cost of these medicines.</td>
</tr>
<tr>
<td><strong>Impact on pharmacy premise rental agreements</strong></td>
<td>Supply of high-cost medicines with a low return on investment substantially and artificially inflates pharmacy turnover, falsely indicating that the pharmacy is performing better than it actually is. Some landlords refer to pharmacy turnover to establish parameters to determine rents, resulting in higher rents for pharmacy premises with minimal increase in gross profit.</td>
</tr>
<tr>
<td><strong>CSO wholesaler trading terms</strong></td>
<td>High-cost medicines impact the cash flow of wholesalers as well as pharmacies. As a result, wholesalers have implemented return of goods policies and trading terms for supply of high-cost medicines as part of their risk management strategy. Under these policies, pharmacies may be required to take ownership of the full risk when ordering high-cost medicines if the wholesaler implements a “no returns” policy. Pharmacies are likely to only order these medicines if they have a valid prescription. However, pharmacists are unable to submit the prescription to Medicare for payment unless the patient returns to the pharmacy and signs receipt of the medicine hence there is always a risk of non-fulfilment which increases the risk for pharmacies.</td>
</tr>
</tbody>
</table>
| **Supply of dual listed high-cost medicines**                      | There is a difference in the remuneration arrangements for wholesalers and pharmacies between S100 and S85 medicines. The remuneration for S100 listed medicines does not include a wholesaler mark-up. However, when an item is dual listed on both S85 and S100 (e.g. high-cost hepatitis C medicines), wholesalers are unable to distinguish between an order for an S85 or S100 and as such charge the S85 wholesaler mark-up of $69.94. As S90 Pharmacies only
receive a $40 mark-up with no allowance for wholesaler remuneration, pharmacies incur a loss for supply.

<table>
<thead>
<tr>
<th>S90 and S94 remuneration disparity</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is a disparity between the remuneration received by S90 pharmacies and S94 hospitals. While the AHI for community pharmacies is capped at $70.92, the remuneration to S94 hospitals includes an 11.1% wholesaler mark-up.</td>
</tr>
</tbody>
</table>

As illustrated above, when all additional costs and business risks are considered, it may not be viable for a small business pharmacy to supply high-cost medicines.

**High-cost PBS Schedule**

The Guild believes that a ‘High-cost PBS Schedule’ (the Schedule) be created specifically for listing high-cost medicines that meets the following criteria:

- High-cost defined as medicines with an AEMP > the top tier AHI fee (currently $2019.77)
- S85 and S100 PBS items with AEMP >$2019.77 listed in the Schedule
- CSO distributor pays a maximum of $2019.77 and receives $69.94 wholesaler mark-up for distribution of items listed in the Schedule
- S90 and S94 pharmacies pay a maximum PTP of $2089.71 (AEMP + wholesaler mark-up) for items listed in the Schedule
- S90 Pharmacies receive AHI of $70.92 for supply of all S85 and S100 high-cost medicines
- The balance owed to the manufacturers is paid directly to the manufacturer by the Federal Government – to improve cash flow payments could be made monthly in advance based on past history and subsequently adjusted

**Implement a ‘consignment’ stock solution for community pharmacies**

Another option is for community pharmacies to be able to stock high-cost PBS items on consignment, paying when the medicine is dispensed. Under this proposed model:

- The CSO distributor would supply an agreed amount of inventory of the high-cost item to the pharmacy on consignment, based on previous/expected sales history
- The pharmacy reports on routine stock checks to enable the manufacturer to monitor and reconcile supply and payments
- The pharmacy dispenses the medicine on presentation of a PBS prescription and processes the PBS claim in the usual way
- The stock check report to the manufacturer after the dispense activity triggers an invoice to the pharmacy with sufficient terms to allow the pharmacy’s PBS and GST claims to be made
- The item is replenished on consignment for the pharmacy

Note - with this model there should still be consistent pharmacy and wholesaler remuneration for S85 and S100 prescriptions.

The benefits of these possible solutions are to:

- Consumers
  - Improved access as consumers are better able to receive the medicine at the pharmacy of their choice in a timelier manner - consistent with the NMP.
Reduced risk of break in treatment (and reduced effectiveness) as medicines are easily accessible

- Prescribers
  - Confidence that patients can receive medicines at the pharmacy of their choice
  - Compliance not impacted by access problems

- Community pharmacies
  - Improved capacity to care for pharmacy’s patients with a greater capacity for any pharmacy to supply
  - Improved cash-flow management and reduced business risks
  - Receive consistent mark-up for dispensing S85 and S100 items
  - No loss incurred when S100 item dispensed

- CSO distributors
  - Improved cash-flow management and reduced business risks associated with holding and supplying
  - Recognition of wholesaler costs with consistent mark-up for S85 and S100 medicines

- Federal Government
  - Patients will have improved access to the medicines
  - Greater capacity for any community pharmacy to supply high-cost PBS medicines
  - Greater ability to promote community access through the community pharmacy network

From a consumer perspective, the ideal is for these high-cost medicines to be readily available through the more accessible community pharmacy network. With either solution, the remuneration arrangements for high-cost PBS medicines for S94 hospitals should also be reviewed to address the anomaly in the level of payment provided to a S94 hospital compared to a S90 pharmacy.

**Recommendation Number 15**
The Guild recommends that:

- the Federal Government considers the Guild’s proposals for immediately addressing the problems associated with purchasing and dispensing high-cost PBS medicines by:
  - creating a high-cost PBS Schedule with caps on the amount paid by pharmacies and wholesalers with the balance paid directly to the manufacturer OR
  - implementing a consignment model for payment by pharmacies when the PBS medicine is dispensed.
  - addressing the remuneration anomalies between S90 pharmacies and S94 hospitals.

**Section 100 PBS medicines**
As the Discussion Paper notes, there are a number of PBS medicines subsidised under Section 100 (S100) of the *National Health Act 1953* with each program having unique eligibility and access arrangements. Historically, S100 programs provided PBS access to medicines requiring specialist care and/or supporting arrangements for the supply and administration from within a hospital or specialist clinic.
Currently, there are six programs available under S100[^157]:

1. Highly Specialised Drugs (HSD) Program
2. In-Vitro Fertilisation (IVF) Program
3. Botulinum Toxin Program
4. Growth Hormone Program
5. Opiate Dependence Treatment (ODT) Program
6. Efficient Funding of Chemotherapy (EFC)

There are a number of problems and anomalies with the S100 PBS arrangements that inhibit patient access to these medicines in the community. These problems are summarised below.

**Patient access to S100 listed medicines - public hospital patients versus private hospital patients**

The categories and rules for S100 are complex and continue to expand, diverting doctors and pharmacists' time away from direct patient care, causing confusion and increasing the risk of error. The rules vary according to where the patient is treated (community, hospital outpatient, same-day hospital patient, hospital in the home, overnight patient), if they are being treated for an acute or chronic condition, what type of facility is providing the treatment (hospital, sub-acute or non-acute facility, Aboriginal Health Service), the ownership of the facility (private hospital, public hospital, private practice clinic) and the type of pharmacy dispensing the medicine (public hospital pharmacy, private hospital pharmacy, community pharmacy).

**Complexity of S100 programs**

The complexity of the S100 Programs is particularly exemplified by the S100 HSD Program for which the following rules apply:

- **HSD Public Hospital, non-Complex Authority Required** – Can only be prescribed in a public hospital and can only be dispensed by a S94 public hospital, NOT a S90 community pharmacy or a S94 private hospital
- **HSD Public Hospital, Complex Authority Required** – Can only be prescribed in a public hospital however can be dispensed by a S94 public hospital and in some circumstances a S90 community pharmacy but NOT a S94 private hospital
- **HSD Private Hospital item, non-Complex Authority Required** – Can only be prescribed in a private hospital however can be dispensed by S94 private hospital or S90 community pharmacy but NOT a S94 public hospital
- **HSD Private Hospital item, Complex Authority Required** – Can only be prescribed in a private hospital and can be dispensed by S94 private hospital or S90 community pharmacy but NOT a S94 public hospital
- **HSD Community Access item** (specifically for HIV antiretroviral medicines, hepatitis B medicines and maintenance therapy clozapine) – Can be prescribed in a S94 public, private hospital or in the community and dispensed in S90 community pharmacies and S94 public or private hospitals

Certain S100 prescriptions written by a prescriber in a public hospital cannot be dispensed by a community pharmacy or private hospital, however the same medicine can be prescribed in a private hospital and can be dispensed by a private hospital pharmacy or a community pharmacy but not a public hospital pharmacy.

Given that the clinical indication is identical for S100 prescriptions written in either a public or private hospital, the consequence is that patients who attend a private hospital have better access to PBS listed medicines than those who attend a public hospital. In addition, prescribers that practice in both a public and private setting must write the appropriate script according to where they see the patient.

The Guild has had members report to them of circumstances in which a regular HSD Private patient has been issued a HSD Public prescription after seeing the specialist in a different setting. Neither the original nor the repeats can be dispensed by the community pharmacy. Restricting access to a private or public hospital is particularly troublesome for patients who reside in rural locations and are expected to travel great lengths to receive their medicines.

**Rejected PBS claims**

Noting the complexity of arrangements for S100 HSDs outlined above, the Guild is aware of many community pharmacists who have dispensed an S100 HSD Public prescription in good faith and then had the claim rejected. Though the prescription meets all the necessary requirements, the PBS claim for the prescription is rejected because HSD Public prescriptions cannot be dispensed by community pharmacies. In such circumstances, the pharmacist is unpaid for the full cost of the medicine. Although PBS Online has the capabilities to deliver an instantaneous “REJECTION” message at time of dispensing that alerts the community pharmacist that the medicine cannot be supplied, Medicare has not enabled this function for S100 HSD items. It may be that only after the patient has received a number of repeats that Medicare advises that the claim will not be paid, even though the medicine was supplied to the patient in good faith.

Some Guild members have inadvertently dispensed S100 HSD public hospital prescriptions and having received payment from Medicare, have subsequently had the PBS claim rejected and funds reclaimed. In some instances, the losses have amounted to thousands of dollars with Medicare either requesting full reimbursement from the pharmacy or withholding future PBS claim payments until the full payment has been retrieved.

**S100 medicines and the CSO**

As non-`dual listed`[^158] S100 listed medicines are excluded from the CSO Operational Guidelines, there is no requirement for S100 listed medicines to be supplied through CSO wholesalers or at the AEMP on which the pharmacy remuneration is based.

**Variable distribution**

The ordering arrangements can vary between medicines and manufacturers, with some medicines being supplied by all CSO wholesalers and others by exclusive supply arrangements through select wholesaler/s or other distributors or directly from the manufacturer. As there is no publicly available list detailing any exclusive supply arrangements for S100 listed medicines, if the item cannot be purchased from the pharmacy’s usual wholesaler at the PTP, pharmacists are expected to ‘shop around’, contacting wholesalers and manufacturers to verify ordering arrangements, opening new supplier accounts and managing any account administrative fees, minimum order requirements, postage / courier charges or credit limits. This is administratively burdensome and confusing and diverts the pharmacist’s time away from direct patient care.

[^158]: Dual listed items are listed in both Section 85 and Section 100 of the PBS
**Purchase price for pharmacy**

The PTP for S100 medicines is the AEMP with no allocation for a wholesaler mark-up. As S100 listed medicines are excluded from the CSO, there is no obligation for the S100 medicine distributors (e.g. wholesaler, manufacturer) to sell the medicine to the pharmacy at the PTP. Indeed, as a private business it is expected that wholesalers would make some level of profit for distributing these medicines. However, the outcome is that pharmacists may pay more than the Price to Pharmacy (PTP), affecting the remuneration received by the pharmacy; sometimes resulting in the pharmacy dispensing at a loss. The Guild is regularly contacted by members who have encountered this problem. In one instance, the pharmacist ordered a S100 medicine with a PTP of $2,224.95 but was charged $2,341.70 by the wholesaler, incurring a loss of over $100 for dispensing this prescription, clearly an unsustainable practice for any business. For orders from other distributors, as outlined above, pharmacists may incur other distribution costs further increasing the likelihood of incurring a financial loss for supply.

**S100 remuneration structure**

Dispensing a S100 item is no different to dispensing a S85 item and in fact, often is more administratively burdensome with greater risks of non-payment or financial loss. Moreover, the S100 remuneration does not recognise or remunerate wholesalers for supply or include the wastage factor\(^{159}\) that applies to S85 PBS prescriptions. This is particularly problematic for pharmacists dispensing clozapine prescriptions. While the maximum PBS quantity remains at 200 tablets, prescribers usually can only prescribe sufficient quantity for one month therapy, or less depending on the person’s blood result.

Moreover, because dual-listed S100 medicines (e.g. hepatitis C medicines) are covered by the CSO obligations, wholesalers usually charge the price for the S85 listing, inclusive of the wholesaler mark-up. In these situations, community pharmacies dispense S100 prescriptions for these medicines at a loss.

**S100 listed items that no longer meet the criteria**

As the S100 listing for IVF items, Growth Hormone, clozapine, HIV antiretroviral medicines and hepatitis B medicines has been changed to enhance community access, the Guild believes the criteria for listing as a S100 program no longer applies i.e. ‘because of their clinical use or other special features, are restricted to supply through public and private hospitals having access to appropriate specialist facilities’, and these medicines should be listed in S85.

Medicines listed under the Botulinum Toxin Program can only be dispensed by an S94 public or private hospital. Although botulinum toxin is toxic, there are many toxic substances available on the PBS that are supplied through community pharmacies e.g. chemotherapy. There are many community pharmacies that have been dispensing private prescriptions for botulinum toxin to private hospitals for many years however are unable to dispense PBS subsided botulinum toxin.

The role of the PBS is to provide timely, reliable and affordable access to necessary medicines for all Australians. The TGA is responsible for the regulation of therapeutic goods, including managing any risks associated with individual items. The TGA may impose certain conditions on approval of a medicine, including restrictions regarding prescriber eligibility, as seen with medicines listed in Appendix D of The Poisons Standard.\(^{160}\)

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Recommendation Number 16

The Guild recommends that immediately:

- community pharmacies should be able to dispense and claim any Section 100 (S100) PBS prescription irrespective of where the medicine is prescribed so that patients can access the medicine from their pharmacy of choice.
- S100 PBS medicines should be included in the Community Service Obligation (CSO).
- the S100 PBS medicines remuneration structure should be commensurate with Section 85 (S85) PBS medicines.
- S100 medicines listed under the Botulinum Toxin, IVF and Growth Hormone programs as well as the S100 Highly Specialised Drugs (HSD) Community Access Category should become S85 medicines.
- the S100 HSD Public and Private categories should be amalgamated into one S100 HSD category.

Section 94 Hospital Pharmacy

Disparities between Section 90 pharmacies and Section 94 hospitals

This section refers to a Section 90 PBS Approved Pharmacy as a ‘S90 pharmacy’ and a Section 94 PBS Hospital Authority (public and private) as a ‘S94 hospital’.

Different remuneration arrangements apply for dispensing S85 medicines for S94 hospitals and S90 pharmacies reflecting the fact that while S90 pharmacies are small business entities, hospitals are institutions in which business costs such as staffing, rent, insurance and utilities are covered by State and Territory Governments (public hospitals) and by corporate business entities (private hospitals). Private hospitals may be either ‘for-profit’ or ‘not-for-profit’ organisations and include day hospitals that provide services on a day-only basis and hospitals that provide overnight care. In 2012-13, there were 746 public hospitals (including 17 public psychiatric hospitals) and 592 private hospitals.

The remuneration to wholesalers for the distribution of S85 PBS medicines to S90 pharmacies is covered by the 6CPA wholesale mark-up and is included in the PTP. While S90 pharmacies may also have pricing arrangements negotiated directly with the manufacturer, most commonly for generic medicines, these trading terms are reducing due to price disclosure. As such, privately owned small business S90 pharmacies are reliant on the AHI remuneration to cover the costs for administration, handling and infrastructure.

In contrast, the S94 hospitals have a greater capacity to negotiate the price to hospital for many medicines directly with manufacturers where the arrangement is inclusive of administrative and distribution functions, including wholesaler remuneration. This means, the 11.1% wholesale mark-up paid by the Commonwealth to the S94 hospital does not accurately reflect wholesaler distribution costs paid by the S94 hospital providing S94 hospitals with an unfair commercial advantage over S90 pharmacies, and incentivising S94 hospitals to dispense PBS medicines, including specialised, high-cost and biologic medicines. In addition to this, the Guild understands that there is at least one banner group that owns S94 private hospitals as well as having interests in S90 community pharmacies. The Guild is concerned that such arrangements enables the S94 hospital with the great buying capacity to purchase the medicines as part of the S94 hospital negotiations with manufacturers and supply to their S90 community pharmacies. The other concern is whether such arrangements would enable the S90 pharmacy to collect prescriptions.

and act as the distribution outlet while the prescription is dispensed and claimed from the S94 hospital. Such arrangements would be very lucrative for the group. The Guild believes that S94 private hospital medicine purchasing and supply arrangements should be made more transparent and unfair commercial advantages prohibited.

Table 5 illustrates the disparity in remuneration (exclusive of professional fees) between S90 pharmacies and S94 hospitals (public and private) for higher priced S85 PBS items.

Table 5: Examples of remuneration for S85 PBS listed medicines (based on 1 July 2016)

<table>
<thead>
<tr>
<th>AEMP</th>
<th>S90 Pharmacy (wholesale mark-up + AHI)</th>
<th>S94 Private Hospital (wholesale + private hospital mark-up)</th>
<th>S94 Public Hospital wholesale mark-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1,000</td>
<td>$104.63 ($69.94 + $34.69)</td>
<td>$126.55 ($111.00 + $15.55)</td>
<td>$111.00</td>
</tr>
<tr>
<td>$2,500</td>
<td>$140.86 ($69.94 + $70.92)</td>
<td>$316.39 ($277.50 + $38.89)</td>
<td>$277.50</td>
</tr>
<tr>
<td>$5,000</td>
<td>$140.86 ($69.94 + $70.92)</td>
<td>$632.77 ($555.00 + $77.77)</td>
<td>$555.00</td>
</tr>
<tr>
<td>$10,000</td>
<td>$140.86 ($69.94 + $70.92)</td>
<td>$1,265.54 ($1,110.00 + $155.54)</td>
<td>$1,110.00</td>
</tr>
<tr>
<td>$20,000</td>
<td>$140.86 ($69.94 + $70.92)</td>
<td>$2,531.08 ($2,220.00 + $311.08)</td>
<td>$2,220.00</td>
</tr>
</tbody>
</table>

Unlike S90 pharmacies, S94 private hospitals are not small businesses. They are owned and managed by a corporation, where administration, handling and infrastructure costs incurred by the pharmacy are subsidised through other avenues such as private health insurance funds, privately paying consumers and government funding in addition to PBS dispensing. However, as illustrated in Table 5 for a medicine with an AEMP of $20,000 (e.g. a hepatitis C medicine), a S94 private hospital would receive a pharmacy mark-up of $311.08, in addition to a $2,220 wholesale mark-up.

The Guild understands that there is at least one banner group that owns S94 private hospitals as well as having interests in S90 community pharmacies. The Guild is concerned that such interests enables the S94 hospital with the greater buying capacity to purchase the medicines as part of the S94 hospital negotiations with manufacturers and supply to their S90 community pharmacies. The other concern is whether such arrangements would enable the S90 pharmacy to collect prescriptions and act as the distribution outlet while the prescription is dispensed and claimed from the S94 hospital. With current remuneration levels, such arrangements would be very lucrative for higher priced PBS medicines.

The most recent PBS Report produced by the Federal DoH confirms the trend towards higher spending on more expensive specialised medicines, highlighting the need for the Federal Government to review the S94 hospital remuneration structure. Recognising different business costs may apply to a corporate enterprise, the Guild believes that the S94 wholesale mark-up and pharmacy mark-up arrangements must be reviewed to ensure that the remuneration received is transparent and accountable and remunerates the S94 private hospital with a fair and equitable profit margin to that of community pharmacy.

Impact on competition and consumer outcomes

The considerations that are relevant for assessing whether competition to S90 pharmacies from S94 hospitals would be a beneficial outcome relate to the overall impacts on consumers’ ability to access PBS.

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\(^{162}\) Expenditure and prescriptions twelve months to 30 June 2015; [www.pbs.gov.au](http://www.pbs.gov.au)
medicines, taking into account that the advent of a new supply channel and resulting loss of business for existing S90 pharmacies may challenge the viability of these existing outlets.

In general, whether the advent of additional competition to S90 pharmacies is beneficial for consumer access depends on the consequences for the viability of S90 pharmacies. In and of itself, any additional source of supply of dispensing and related services would improve consumer access to those services. The concern is, however, that the additional supply from S94 hospitals may have adverse effects on existing S90 pharmacies and thereby diminish accessibility in other respects.

Whether, in practice, S94 hospitals would materially displace dispensing through S90 pharmacies is an empirical question. For instance, given the difficulties of parking at most urban hospitals, it seems unlikely that they would attract much dispensing business, apart from those persons who have reasons for visiting the hospital other than to have a prescription filled. Arguably, at least some S94 hospital dispensaries are also not particularly well located to attract ‘walk-in’ customers. Although parking and related problems may not apply to rural and regional Australia, whether the various options canvassed improve access in non-urban areas would depend on the consequences that the additional competition would have for S90 pharmacies in those areas. For instance, the advent of competition from a S94 hospital may cause a S90 pharmacy to close, with an attendant reduction in access to those accustomed to using it.

The Discussion Paper offers no indication as to how, in practice, any purchasing arrangements that may currently exist between S94 hospitals and wholesalers could be extended to S90 pharmacies; for instance, whether S94 hospitals could in some sense be required to purchase medicines on behalf of S90 pharmacies, or whether wholesalers could be required to offer S90 pharmacies the same terms as specific S94 hospitals in an area. Either of these options, if feasible, would seem to represent a heavy-handed intervention in hospital buying arrangements and potentially be complex to implement.

In substance, however, these questions also highlight a potential trade-off between Federal Government objectives in relation to the cost-effectiveness of providing the community with medicines, and broader economic efficiency objectives.

From the point of view of the Federal Government, it may not matter why S94 hospitals (or indeed, discount chains or banner groups) can source supplies at lower wholesale prices than may be the case for S90 pharmacies; the lower the costs of supplies, the lower will be the level of remuneration that the Government will need to make to keep pharmacies financially viable. Until there was a possibility of up to a $1 discount on co-payments, the Federal Government was not a direct or immediate beneficiary of lower wholesale prices for PBS medicines. The initial effect of lower wholesale prices was to increase the margins of the pharmacists who did not offer discounts. Presumably, however, S90 pharmacies paying lower wholesale prices would be more likely to offer the $1 discount, than would S90 pharmacies facing higher wholesale prices. The Federal Government would eventually have some scope for reducing its payments to pharmacies for dispensing, if the whole cost structure of S90 pharmacies were lower.

As a general point, however, if lower wholesale prices are due to the superior bargaining power of S94 hospitals (that is, there is price discrimination in the sense that different prices for the same product are charged to different wholesale customers), then this may merely represent a financial transfer from wholesalers to retailers, rather than reflect a ‘real’ or economic saving. There is then a broader question as to why S94 hospitals (as well as discount chains and banner groups) may pay lower wholesale prices than would apply to an ‘ordinary’ S90 pharmacy:

- Selectively lower wholesale prices may be the result of stronger bargaining power. That is, the lower wholesale prices are the result of a zero sum game in which whatever the S94 hospital or

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163 The only caveat is that the prices be sufficient to permit wholesalers to make normal profits.
S90 pharmacy group gains by way of lower prices is matched exactly by what the wholesaler loses.

- Alternatively, lower wholesale prices may be the result of economies of scale or scope in the wholesaling acquisition, storage, retrieval and delivery processes that lead to genuine savings in resources of labour, capital and so on. Those savings are shared between the wholesaler and the customer (hospitals or large buying groups).

If the source of lower wholesale prices is bargaining power, then this raises the same types of public policy questions that have exercised the Australian Competition and Consumer Commission (ACCC) concerning the large retailers (Coles and Woolworths) in their relationship with their suppliers: the question of the use or abuse of market power in the hands of the buyer of wholesale products.

The ACCC has, to date, not been comfortable in permitting price discrimination arising from greater bargaining power. In economic theory, price discrimination can improve the efficiency of the economy. This is because price discrimination enables a firm to cover its fixed costs with least damage to economic efficiency, by pricing according to the various elasticities of demand. However, the ACCC has tended to reject such claims and to regard price discrimination as potential evidence of the abuse of market power. In contrast, the Productivity Commission has been more willing to accept the economic efficiency argument in favour of price discrimination.

To the extent that the lower wholesale prices paid by S94 hospitals and other large buyers are due to the exercise of market power, it cannot be assumed that similarly lower prices could be extended to a wider market. Taking the situation to the extreme, in which all pharmacists buy wholesale under the same banner and with the same discounted prices for all: there could then be no cross-subsidisation of some wholesale contracts at the expense of others. If, as a result of the shading of wholesale prices, the point is reached where there are no rents left to squeeze from the wholesalers, then further price reductions require real cost savings of some kind. It is not clear how the proposals canvased in the Discussion Paper would contribute to economic efficiency and real cost savings.

In summary, there may well be some savings to the Federal Government from an expansion of S94 hospital supply arrangements, but whether or not these represent gains in economic efficiency depends on whether wholesale prices are lower because of ‘real’ economies, rather than from cross-subsidisation amongst the customers of wholesalers. Thus, it matters greatly what weight is placed on the goal of reducing Federal Government outlays, and the weight placed on economic efficiency.

**Safety Net and S94 hospital discharge prescriptions**

The Guild appreciates that under the current model, S94 hospitals may be encouraged to dispense all of the patients’ medicines upon discharge. The Guild questions whether S94 hospital patients are always provided with a real choice on the dispensing of their prescriptions on discharge – choice of dispensing pharmacy and choice of medicines dispensed. Acknowledging that quality and safety standards may require a S94 hospital to dispense all medicines for hospital in-patients on admission, the Guild believes that on discharge, there should not be any default dispensing of all of a patient’s prescriptions. Patients should have the option to have their prescription filled at their pharmacy of choice, which may be the S94 hospital for convenience or their usual community pharmacy, as well as the choice of which prescriptions (if any) they have dispensed.

The Safety Net early supply rule was put in place as a cost saving measure to discourage consumers from having a PBS prescription filled more often than is required in order to reach the Safety Net. The rule also acts to reduce unnecessary dispensing of repeat supplies and supports good practice for quality use of medicines. The Safety Net early supply rule only applies to some PBS medicines. Under the Safety Net early supply rule, where a repeat supply of a medicine is dispensed within less than a specified
interval (depending on the listing either four days or 20 days) the supply will not count towards the Safety Net threshold, the pharmacist cannot discount the PBS Co-payment and if the consumer has already reached the Safety Net threshold, the patient will be charge the usual pre-Safety Net PBS payment, not the reduced Safety Net amount.

However, the Safety Net early supply rule does not apply to PBS prescriptions dispensed at S94 hospitals. This means that S94 private hospitals are able to supply S85 PBS medicines to in-patients and out-patients (at time of separation). As a result, there is an opportunity for S94 private hospitals to claim and supply a full PBS quantity to the same patient more than once - during their stay and on discharge, increasing revenue. Again acknowledging that quality and safety standards may require a S94 hospital to dispense all medicines for hospital in-patients on admission, the Guild believes that the Safety Net early supply arrangements should apply to S94 hospitals for discharge prescriptions. The Guild also notes that for S90 pharmacies that service a private hospital, the Safety Net early supply rule applies for in-patients on admission, during the stay and on discharge.

**Recommendation Number 17**

The Guild recommends that immediately:

- to encourage community patients (i.e. non in-patients) to have maximum access to medicines through the community pharmacy network, any anomalies in remuneration between Section 90 (S90) community pharmacies and Section 94 (S94) hospital pharmacies should be addressed.
- private hospital medicine purchasing and dispensing arrangements should be transparent and equitable, restricting any unfair commercial advantages between S94 private hospitals and S90 pharmacies in which they have an interest.
- the Federal Government should actively encourage and facilitate maximum patient access to all PBS medicines through community pharmacy, including specialised, high-cost and biologic medicines.
- to facilitate continuity of care, the Hospital Medication Chart should be able to be used as a PBS prescription in community pharmacies.
- the Safety Net early supply rule should apply to S94 hospital discharge prescriptions.

**Rural Pharmacy and the Rural Pharmacy Maintenance Allowance**

The Guild believes that the standard of health care for rural/remote areas should be equal to the standards available in metropolitan areas and is guided by the principle that all Australians have a right to equity and access to community pharmacy services.

Community pharmacists play an important role in the rural/remote primary health care team by providing not only the traditional provision of medicines but a broader and more holistic range of health services and advice to many rural/remote communities. This is of particular importance in areas where other medical advice and services are not readily available. For example, community pharmacists in rural/remote areas are the logical health professional to whom members of the community turn to for advice in the treatment of minor illnesses. Currently 20% of Australia’s 5,587 pharmacies are in rural and remote Australia, some of which are one pharmacy towns.

Whilst they are a critical component of the health care team in rural communities, community pharmacies in these areas do face additional financial challenges, such as dwindling populations and competition
from alternative sources (such as mail order medicine facilities). Issues such as these have the potential to impact the viability of local community pharmacies which can result in a community losing a valuable health resource.

Australia’s suite of Rural Pharmacy Programs is recognised as the most effective rural pharmacy program solution internationally and has helped ensure that pharmacy is one of the few expanding health services in rural and remote Australia. The RPMA is one component of this suite and was implemented to support the community pharmacy network and in turn provide for improved access to PBS medicines and pharmacy services for people in rural and remote regions of Australia. The monthly support allowance provided under the RPMA recognises the additional financial burden of maintaining a pharmacy in these areas.

Reviews conducted as a part of the 3CPA and 4CPA have shown that there is strong support for the RPMA. Many of the rural pharmacies surveyed as a part of these evaluations have indicated that the financial assistance provided by the allowance was a critical factor in their decision to remain in rural practice.\textsuperscript{164}

Comments received by pharmacies participating in the program during this evaluation period include:

- "It would be difficult to stay if this allowance was withdrawn"
- "This pharmacy would not survive without it"
- "There is very limited turnover in rural practice so allowance helps tremendously"
- "Helps to overcome the quiet periods – may otherwise be difficult to maintain business"

The RPMA has not only ensured that pharmacies remain open and available for patients living in rural and remote Australia, it has also provide additional benefits such as:

- Enabling rural pharmacies to provide extended pharmacy services through hiring of additional staff
- Ensuring additional capacity (staffing and locums) and financial assistance for rural pharmacists so that they can engage in quality training and education (often located in metropolitan areas – and now a requirement under AHPRA registration requirements)

Since the implementation of the RPMA, the number of community pharmacies accessing the allowance has risen from approximately 650 pharmacies per year to over 750 pharmacies per year.

The Guild believes that the RPMA should continue, along with the RPWP, as together they contribute to maintaining an equitable distribution of not only pharmacies but also the professional pharmacy workforce. This ensures that patients living in rural and remote Australia can continue to have ready access PBS medicines and community pharmacy services.

The Guild believes that there are a number of improvements that could be made to the RPMA to ensure that it continues to be appropriately targeted to those pharmacies where there is greatest geographical and community need.

\textsuperscript{164} Evaluation of the Rural Pharmacy Initiatives Program, Final report page 185, Human Capital Alliance 2005
**Rural Classification**

The RPMA utilises the PhARIA in order to quantify the degree of remoteness (both geographic and professional) of pharmacies. The PhARIA was designed specifically to aid in the equitable distribution of financial assistance (through rural pharmacy programs administered by the Federal Government DoH) to rural and remote pharmacies.

The PhARIA is a composite index, which incorporates measurements of geographic remoteness, as represented by ARIA+ (quantified geographic remoteness based on the road distance people have to travel to reach a range of services) overlaid with a professional isolation component represented by the road distance to the five closest pharmacies. The locations of more than 13,000 populated localities were used in the development of this index.

There are indications that the Federal Government is considering moving to a more updated model of determining remoteness (and therefore the areas that may require the assistance under the rural programs). Current indications suggest that a move to the Modified Monash Model (MMM) reclassification system may be appropriate as it has improved categorisation of metropolitan, regional, rural and remote areas according to both geographical remoteness and town size – noting that the system was developed to recognise the challenges in attracting health workers to more remote and smaller communities.

Whilst the Guild is supportive of considering a move to an improved classification system, it would insist that any changes to a new system go through extensive modelling against the current arrangements and consultation with Guild representatives to ensure that there are no unintended consequences, gaps or reductions in pharmacy services for those patients in rural and remote Australia.

**Distribution of Allowance Funding**

The RPMA uses a payment matrix which is based on a pharmacy’s claimable RPBS and PBS script volumes and remoteness classifications. This, in theory, means that the greatest assistance is provided to the most remote pharmacies with the lowest prescription volumes.

The format of the matrix has changed little since the inception of the current RPMA program, which was implemented at the beginning of the 3CPA (replacing the existing Isolated Pharmacy Allowance and the Remote Pharmacy Allowance which had been implemented during the 1CPA). It is updated on an annual basis in terms of the script volume categories (based around a current year median script volume) and in 2012 a maximum allowable script volume was added.

The RPMA payment matrix is a potential area for improvement of the RPMA in order to best target those pharmacies that require genuine financial assistance (particularly in relation to the impact of price disclosure) to remain viable and which are providing services to patients in more isolated communities (which may not necessarily be the most remote).

**Recommendation Number 18**

The Guild recommends that:

- the Federal Government continues to invest in the RPMA, with the RPMA matrix reviewed to ensure the allowance continues to be appropriately targeted to pharmacies where there is greatest geographic and community need.
Supply of Medicines and pharmacy services for Aboriginal and Torres Strait Islander Peoples

Aboriginal and Torres Strait Islander Peoples have by far the worst health outcomes and the largest inequity in health care provision of any identifiable group in the Australian population. The life expectancy of Aboriginal and Torres Strait Islander Peoples is around 17 years lower than that of the Australian population, with a mortality rate that is five times higher for adults aged 35-44 years. Indigenous Australians have an obesity rate one and a half times that of non-Indigenous Australians, 3.3 times the rate of diabetes and three times the rate of hospitalisations for respiratory conditions.

There are a number of initiatives by which community pharmacies are working to improve access to PBS medicines and pharmacy services, as well as improving quality use of medicines, by Aboriginal and Torres Strait Islander Peoples. For example, community pharmacies assist the RAAHs in complying with State/Territory legislation by advising and assisting in the establishment of protocols, including those related to the procurement of medicine, storage of medicines, medication compliance, administration of medicines and issues regarding supply, dispensing and record keeping.

S100 Remote Area Aboriginal Health Services Program (S100 RAAHS)

The S100 RAAHS program is a special arrangement for the supply of PBS medicines under S100 of the National Health Act 1953. The program was implemented in 1999 to address the geographical, cultural and financial barriers that Aboriginal and Torres Strait Islander Peoples face in accessing essential PBS medicines.

The S100 RAAHS program utilises the infrastructure of the network of regional and remote area community pharmacies and their expertise in administering the PBS, and RAAHS’s in their delivery of care to Aboriginal and Torres Strait Islander Peoples. The S100 RAAHS enables patients of remote areas AHSs to receive their PBS medicines as they present to an AHS, without the need for a normal prescription and without charge.

The Guild and National Aboriginal Community Controlled Health Organisation (NACCHO) have issued a Joint Position Statement related to the S100 RAAHS program and together have stated that the program has greatly improved access to PBS medicines by Aboriginal and Torres Strait Peoples in remote areas and is one of the most positive developments in Indigenous health service delivery in recent years.

However, as evidenced by numerous reviews, the Program must evolve by focussing more on the quality use of medicines by patients in remote areas, including by providing greater access to medicine reviews for patients with chronic conditions and putting an increased emphasis on medication education that encourages the safe and efficacious use of medicines.

Even with potential improvements there are essential features of the S100 RAAHS program which have ensured its success to date and that must be retained. These include:

- Supply of PBS-medicines to RAAHSs through the existing network of community pharmacies, and at no cost to the patient,
• Utilisation of the existing infrastructure provided at the local RAAHS, without requiring the patient to travel to other venues,
• Provision of a one stop-shop at the RAAHS (patient gets medications and advice about using them at the time of visiting the RAAHS),
• Maintenance of culturally appropriate settings in which the patient is able to access medicines, and;
• The simplicity of eligibility requirements for patients or staff (all clients are eligible without needing to produce Medicare or concession cards, or keep track of safety net totals).

The Guild believes that the S100 RAAHS program has met its primary objective and has increased access to PBS medicines by Aboriginal and Torres Strait Islander Peoples in remote areas and should continue to be funded. This program meets a specific need (that it is providing access to remote areas) and should remain as a program linked to remote areas, irrespective of suggested changes suggested under the Closing the Gap (CTG) PBS Co-payment measure (of which the focus is more about addressing financial barriers).

Whilst the program is currently working well, the Guild believes that it could be enhanced and that there are a number of improvements and enhancements that would assist the S100 RAAHS program to reach its full potential, consistent with the Federal Government’s commitment to CTG.

**Freight costs**

Where the cost of freight to and from the service is borne by RAAHSs and/or community pharmacies, this should be reimbursed. The reimbursement needs to take into account the actual cost of freight of the medicines, and the very nature of providing the medicines in bulk supply to remote areas. This cost can be impacted by the remoteness of the location, distance between the services, the freight services available in the area, and the ability to transport the medicines in a suitable environment, for example, maintaining cold-chain. Currently freight is a significant cost to both the RAAHS and to community pharmacy.

**Recognition of dispensing**

Increasingly, patients whose medicines are supplied under the S100 RAAHS program are having their medicines individually dispensed. In the Northern Territory for example, there is a requirement that certain medicines supplied through RAAHSs are dispensed, rather than bulk supplied. Often, the supplying pharmacist will also ensure that the medicines are packed for the patient using a dose administration aid.

These enhancements to the pharmaceutical care of these remote patients are welcome but it is important that the additional work entailed in the dispensing, rather than the bulk supply, of these medicines is recognised and appropriately remunerated.

During the recent Federal election, both the Prime Minister and the Leader of the Opposition committed to ensuring that there is appropriate remuneration for the provision of dispensing services within the S100 RAAHS program.

**Streamlined electronic claiming**

The current S100 RAHS program claiming process, which uses a paper-based multiple copy claims book, has not changed since the program’s inception. The current claiming process is regarded by all participating pharmacists to be cumbersome, frustrating and time consuming and results in unnecessary and costly delays in payment.
Claims are generally submitted monthly but community pharmacists participating in the program have reported that it can take up to six weeks or longer to receive a payment from Medicare, which increases the financial burden borne by community pharmacies. To address this issue, Medicare should develop an electronic claiming method for S100 RASHP claims that utilises already available technology such as PBS Online and Electronic Funds Transfer.

**Quality Use of Medicines Maximised for Aboriginal and Torres Strait Islander Peoples (QUMAX)**

The QUMAX program is a QUM support initiative developed under the 4CPA and continued in the 5CPA and 6CPA. QUMAX aims to improve health outcomes for Aboriginal and Torres Strait Islander Peoples by providing QUM through a range of support services provided by participating Aboriginal Community Controlled Health Organisations (ACCHOs) and community pharmacies in rural and urban Australia. It is an important program to ensure that patients and AHSs have the support they need to deliver high quality health outcomes.

**S100 Pharmacy Support Allowance**

The Community Pharmacy Agreement also funds the S100 Pharmacy Support Allowance program. This allowance is paid to community pharmacies and approved hospital authorities for the provision of a range of QUM strategies and services to patients of approved RAAHS (note: page 36 of the discussion paper asserts that the funding under this program is accessed by the AHS where it is actually accessed through the community pharmacy). This is a complementary program to the S100 RAAHS program and involves a collaboration between the community pharmacy and the staff of the RAAHS to define and implement local level QUM strategies (contained in an annual QUM work-plan agreed to by both parties) that will benefit staff and patients at that service.

Whilst the Guild is supportive of AHS’s independently employing a pharmacist to provide pharmacy related services within their clinics, it considers that the community pharmacies (which are undertaking the supply arrangements) are ideally placed to provide key services related to the quality use of medicines. This applies in both the remote setting (through the RAAHS) and the regional and urban areas (AHSs) where it is important to continue to build on this relationship between Aboriginal and Torres Strait Islander patients and their community pharmacies. The Guild believes the continuation of the QUMAX and S100 Pharmacy Support Allowance Programs will enable this to happen.

The QUMAX and S100 Pharmacy Support Allowance have been very successful in helping to improve the quality use of medicines for Aboriginal and Torres Strait Islander Peoples but the Guild believes there are a number of improvements that would ensure the programs continue increased health outcomes for patients in AHSs.

**Dose Administration Aids**

(DAAs are devices or systems designed to support at-risk patients (and/or their carers) in the community to better manage their medicine, with the objective of improving adherence and avoiding medicine misadventure and associated hospitalisation. Whilst there is currently a limited amount of funding under the QUMAX program (available only to patients in regional and urban Australia), there would be significant benefits to the patients and their families if DAA services were funded as part of the CTG PBS Co-payment measure along the lines of the DVA’s DAA funding model.

The DVA service builds on other QUM programs in the DVA space which include the Veterans’ Medicines Advice and Therapeutics Education Services. The DVA program aims to assist the veteran community to get the most out of their medicines and to reduce medicine mismanagement. The ongoing coordinated care is provided by the GP and community pharmacist. Increased funding under the S100 Support
Allowance would enable a similar model (coordinated between the community pharmacy and RAAHS) for Aboriginal and Torres Strait Islander patients who would benefit from improved quality use of medicines and medicine adherence. This increase in funding would ensure that community pharmacies are appropriately remunerated for their provision of DAAs to at-risk patients.

**Increased access to community pharmacy services**

The Guild believes a range of models could be devised to provide a higher level of QUM education and services. These need to be flexible and determined by the RAAHS and the community pharmacist jointly to result in an improved service to the patients.

The S100 Pharmacy Allowance should be ‘uncapped’ and be driven by the volume of service and patient need, reflecting differences in the care that is provided in acute situations and in chronic disease management. An increase in funding would enable more onsite community pharmacy visits enabling a wider range (and increased volume) of quality use of medicines activities to be undertaken.

The introduction of an online work-plan and reporting system for activities undertaken as part of the S100 Pharmacy Support Program would also enhance the outcomes for both the community pharmacy and the RAAHS. It would enable quick and effective development of the work-plan between the parties and provide for a platform for up-to-date monitoring against the agreed outcomes.

**Consumer Medicines Information (CMI)**

The addition of pictograms on medicines labels would improve health literacy along with other QUM education provided by health care providers.  

The development of drug information sheets in plain English for the most commonly prescribed medicines would complement the use of pictograms and enhance the benefits of the CTG PBS Co-payment measure. This could be achieved by modifying existing CMIs.

**CTG PBS Co-payment measure**

The cost of medicines is a significant barrier to improving access to medicines for Aboriginal and Torres Strait Islander Peoples. Despite two to three times higher levels of illness, PBS expenditure for Aboriginal and Torres Strait Islander Peoples is about half that of the non-Indigenous average.

The Federal Government introduced the CTG PBS Co-Payment Measure in July 2010 to reduce or remove the patient co-payment for PBS medicines for eligible Aboriginal and Torres Strait Islander patients living with, or at risk of chronic disease. The measure aims to reduce the cost of PBS medicines for Indigenous Australians and assist in the prevention and management of chronic disease in the Primary Health Care setting.

The CTG PBS Co-Payment Measure is funded outside the CPAs and more than 7.5 million scripts have been issued under the scheme since its inception in 2010. Approximately 99% of community pharmacies have dispensed CTG scripts.

As the measure is currently designed, Aboriginal and Torres Strait Islander patients can only access more affordable PBS medicines by attending a registered general practice that participates in the Indigenous Health Incentive (IHI) under the Practice Incentives Program (PIP) or a registered non-remote (urban or rural) Indigenous Health Service. Once patients are registered to participate in the measure, the

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prescriber can annotate the script as a CTG script (either through their prescribing software or manually by writing “CTG” on the script and signing next to the annotation).

Upon presenting a correctly annotated prescription to a community pharmacy for dispensing, eligible patients who would normally pay the full PBS co-payment will pay the concessional rate. Those who would normally pay the concessional price will receive their PBS medicines without the requirement to pay a PBS co-payment. However, premiums for a small number of medicines will still need to be paid by the patient. Prescriptions for all of an eligible patient’s PBS medicines are covered under the measure whether or not the medicines are being used to treat chronic or acute medical conditions.

Despite seeing some improvements through implementation of the CTG PBS Co-payment measure, Aboriginal and Torres Strait Islander Peoples are still comparatively low users of medical services and pharmaceuticals. Medicare benefits paid per Indigenous person are about 67% of the non-Indigenous average, and Indigenous PBS expenditure is 80% of the non-Indigenous average.\textsuperscript{169} In spite of the CTG PBS Co-Payment Measure, over a third of Indigenous Australians either delay or do not fill a prescription due to cost.\textsuperscript{170}

The Guild believes that there are a number of enhancements to the CTG PBS Co-payment measure that need to be addressed to further improve access to medicines by Aboriginal and Torres Strait Islander Peoples.

\textit{Interaction between program and mobility of people living in remote areas}

The mobility of Aboriginal and Torres Strait Islander Peoples living in remote areas needs to be considered along with their need to travel for specialist treatment and hospitalisation. By linking eligibility to the Medicare Card, residents living in remote locations who access medicines through the S100 RAHS program would be able to automatically access CTG prescriptions when travelling in rural and urban locations. This is currently not available and therefore limits an individual’s ability to travel and have timely and affordable access to medicines in the event of travel.

To further aid the mobility of those patients living remote areas, the CTG PBS Co-payment eligibility status should be linked to the patient to address the portability issue so that the patient is eligible regardless of their location or prescriber. This could be done through electronically linking the registration of an eligible patient via the Medicare Card which would not only improve access and efficiency but which would also enable the community pharmacist to call the Medicare helpline to check registration status should a person present without their card. This would also enable the PBS online system to facilitate checking of CTG status. Electronic registration linked to the patient would resolve the access issue when the patient is away from their home base and/or not attending their principal health care provider.

Linking the measure to the Medicare Card will also improve patients’ privacy in community pharmacies and suit those people who are eligible but may be uncomfortable in self-identifying their eligibility if it is not raised by the GP or specialist.

Mechanisms are also needed to enable the suite of PBS medicines programs to complement each other to better meet people’s needs with particular regard to travel between remote and urban areas, and between hospital and home, whilst still maintaining access to their PBS medicines. For example, integrating the CTG PBS measure with existing initiatives such as QUMAX may increase the beneficial impact of the CTG PBS co-payment.

\textsuperscript{169} AIHW. 2013. \textit{Expenditures on health for Aboriginal and Torres Strait Islander Peoples 2010-11}
**PBS Listings for Aboriginal and Torres Strait Islander Peoples**

The PBS listings for Aboriginal and Torres Strait Islander Peoples ([http://www.pbs.gov.au/info/publication/factsheets/shared/pbs-listings-for-aboriginal-and-torres-strait-islander-people](http://www.pbs.gov.au/info/publication/factsheets/shared/pbs-listings-for-aboriginal-and-torres-strait-islander-people)) need to be expanded to better meet their health needs. There is a need to include commonly used medicines under the CTG PBS Co-payment measure, for example, vitamin D and Iron supplements. Inclusion of section 100 HSDs (special supply arrangements) should also be considered as this will improve access for a range of medicines including Clozapine.

**CTG eligibility status and requirement of annotation on the prescription**

When patients present with an unannotated CTG prescription at a pharmacy, they currently have to be sent back to the registered general practice or a registered non-remote AHS or the pharmacist has to contact the prescriber to clarify their intention causing a delay in access to medicines, even when the patient is known to the pharmacy to be eligible and registered for the CTG PBS co-payment measure. The Guild would like community pharmacists to have the ability to annotate prescriptions if patients are already known to be eligible and registered for the CTG PBS Co-payment measure.

Another issue that currently restricts patient access is the fact that AHSs in remote locations cannot provide both CTG prescriptions and medicines under the S100 RAAHS program. These services should be able to provide services at their own discretion based on the needs of the patient whether under the S100 RAAHS program or the CTG-PBS Co-payment measure. Likewise hospitals should be able to issue patients with discharge CTG PBS prescriptions. At the moment prescriptions from hospitals are excluded from this measure, even if the patient is already registered for the measure. This change would assist with the continuity of care for patients regardless of location or health care setting.

The Guild would also like to see the CTG PBS Co-payment measure linked to the patient (as detailed in the section above) as we believe this would overcome issues when medical practices are not registered under the PIP. Any prescriber should be able to annotate a CTG script for an eligible patient regardless of whether or not they are PIP registered.

**Other CTG Improvements**

The Guild believes that the registration process for CTG PBS Co-payment measure should be in real time and online rather than having to mail or fax the forms.

Alternatively, another system to consider is the system used by the DVA where card holders have access to the range of pharmaceutical items available under the RPBS. A similar process could be implemented for the CTG PBS Co-payment measure which would address some of the issues outlined in this section.

The Guild would also like to see information on how medicines are dispensed in different situations for Aboriginal and Torres Strait Islander Peoples readily available to both patients and health professionals. The consolidated provision of this information would assist health professionals in understanding and handling patients’ expectations as they move between different health settings.

**Recommendation Number 19**

The Guild recommends that immediately:

- the eligibility for the Closing the Gap (CTG) PBS Co-payment should be verifiable through the patient’s Medicare Card.
- the Listings on the PBS for Aboriginal and Torres Strait Islander Peoples should be expanded to better meet their health needs.
• Remote Area Aboriginal Health Services (RAAHs) and hospitals should be able to write CTG prescriptions.

• the Federal Government should implement an electronic and online registration process for patients accessing the CTG PBS Co-payment measure in order to improve efficiency and access.

• all PBS medicines, including S100 items, should be available under the CTG PBS Co-payment measure.

• the Federal Government should fund actual freight costs related to the provision of medicines under the S100 RAAHS scheme.

• the Federal Government should fund the full dispensing of medicines supplied under the S100 RAAHs program.

• the Department of Human Services (DHS) should implement an electronic claiming and payment system for community pharmacies delivering the S100 RAAHS program with payment timelines consistent with the broader PBS.

• the Federal Government should fund the provision of DAAs for eligible Aboriginal and Torres Strait Islander Peoples under the CTG PBS Co-payment scheme.

• the Federal Government should increase the level of funding for the S100 Pharmacy Support Allowance to enable multiple site visits from the participating community pharmacy each year to increase the quality use of medicines.

The Australian Pharmaceutical Supply Chain

The reliability and sustainability of the pharmaceutical supply chain in Australia is critical to the achievement of the NMP objectives regarding timely access to the medicines that Australians need, provided at a cost that individuals and the community can afford. The 6CPA failed to recognise the impact of the significant reductions in government medicine reimbursement prices from ongoing PBS reforms on the pharmaceutical supply chain. It is important for consumers that there is a sustainable and reliable supply chain. If manufacturers and wholesalers are not appropriately remunerated for their important role in the supply chain, then the negative impact is likely to flow onto pharmacies and therefore onto patients.

For many years, manufacturers have delivered their products to community pharmacies through pharmaceutical wholesalers which ensured timely access for all patients. However, the medicine supply chain in Australia is becoming increasingly complex and fragmented. A linear model of manufacturers selling to wholesalers who in turn sell to pharmacies does not capture the full picture associated with vertical and horizontal integration along the chain with some manufacturers through logistics and transport companies having exclusive supply arrangements directly to community pharmacies (e.g. Pfizer).

Manufacturing

As a critical element of the PBS supply chain, manufacturers consist of the innovative and generics pharmaceutical industry. In listing a medicine on the PBS, manufacturers prepare a submission for the Pharmaceutical Benefits Advisory Committee (PBAC) providing the clinical evidence and economic justification for Federal Government subsidisation. As part of the application for PBS listing, manufacturers agree to a price for their medicine (the AEMP). As part of the price negotiations, the manufacturer may enter into a risk share arrangements with the Federal Government to ensure the committed funding remains within limits.
For PBS medicines already listed, remuneration for manufacturers must be sufficient to ensure a continued commitment to the Australian market and to guarantee supply. Belinda Wood, the CEO of the Generics and Biosimilar Medicines Association (GBMA) stated at APP2016\textsuperscript{171} that the PBS has now been shown to be sustainable, with its average annual growth now negligible and the Government reaping the rewards. However, from industry’s perspective, she cautioned that ‘the discount well is dry’ with industry experiencing significant loss of revenue, noting at the conference that 68 PBS medicines were now less than $2, with another 149 between $2 and $5 – and $2 life-saving medicines aren’t sustainable. These low prices will lead to increased de-listings, supply interruptions and less choice, increased cost and poorer health outcomes for the customer.

**Pharmaceutical wholesaling**

Pharmaceutical wholesalers rely on the following income streams to support their business operations for the distribution of Federal Government subsidised pharmaceutical products:

1. Direct remuneration by their pharmacy clients for the purchase of PBS and RPBS items
2. Reimbursement by the Federal Government for the distribution of NDSS items
3. Trading-terms offered by manufacturers
4. Payments from the Federal Government as part of the CSO

As part of the 6CPA, pharmaceutical wholesalers are eligible for $2.803 billion in total funding, consisting of:

- $1,799 million to hold and deliver PBS medicines to approved pharmacists
- $28 million for the distribution of NDSS products
- $976 million for the CSO funding pool

**PBS Wholesaler Remuneration**

Pharmaceutical wholesaler remuneration is based on the AEMP agreed between the Federal Government and the manufacturer of PBS, RPBS and NDSS items. As part of the 6CPA, wholesalers are reimbursed as follows:

- For S85 listed PBS and RPBS items –
  - AEMP ≤ $930.06 – 7.52% mark-up
  - AEMP > $930.06 – $69.94 flat fee
- For NDSS items - $1 per unit distribution fee

There is no allocation of any wholesaler mark-up for the distribution of S100 PBS medicines. While distribution costs for these medicines may be covered by the manufacturer as trading terms offered to the wholesaler, there is no guarantee that wholesalers can purchase S100 medicines at prices below AEMP and that cover their distribution costs. Neither is there recognition of the costs associated with distributing PBS medicines requiring monitoring and special handling such as Controlled Drugs, temperature-sensitive medicines requiring refrigeration, cytotoxics and high-cost medicines.

There is also a disparity in the levels of remuneration between wholesalers and community pharmacies with two levels for wholesalers, capping at a PTP of $1,000 and without a remuneration floor. This is in contrast to the three AHI levels for community pharmacies capping at a PTP of $2,089.71 and with a remuneration floor for PBS medicines with a PTP < $180. Despite the cap for wholesalers applying at less than half the PTP that the AHI cap applies for community pharmacies, the amount paid is equivalent - $69.94 for wholesalers versus $70.92 for community pharmacies. So while wholesalers do not have the benefit of a remuneration floor to delink their remuneration from price reductions, they receive higher

remuneration for the administration, handling and infrastructure costs associated with distributing PBS medicines with a PTP greater than $1,000.

Trading terms

Many pharmacies belong to franchise banner groups that provide their members with support such as marketing services and business advice, particularly with regards to negotiating trading terms with pharmaceutical wholesalers and manufacturers. Some banner groups are operated by the major pharmaceutical wholesalers – for example, Australian Pharmaceutical Industries (API) is the parent company of ‘Priceline Pharmacy’ and ‘Soul Pattinson’, Sigma is the parent company for the Amcal and Guardian brands and the EBOS Group (which now owns Symbion) is merging its Chemmart banner group with that of Terry White. There are also some private banner groups such as ‘Full Life’ and ‘My Chemist’. Some pharmacies have formed their own buying groups that they use to try to improve their purchasing capabilities.

The margins for wholesalers and retailers (including community pharmacies) in the supply chain in Australia are illustrated in Charts 8 and 9 below based on ABS analysis for 2005-06 and 2012-13 (the latest year available). Specifically, the analysis is for pharmaceutical, cosmetic and toiletry goods wholesaling and retailing industries according to the ANZSIC 2006 classification system.

Chart 8 shows wholesalers total income increased by approximately 27% from 2005-06 to 2012-13, based on strong growth in wholesaling income. On the expense side, purchases of goods and services (including cost of goods in the form of medicines from pharmaceutical manufacturers) increased by 30.5% over the same period but other expenses did not grow as strongly, resulting in total expenses rising by approximately 25%. The net result was an increase in operating profit before tax of approximately 53% from 2005-06 to 2012-13 and a 1 percentage point rise in the operating profit margin.

Chart 8: Pharmaceutical and toiletry goods wholesaling

<table>
<thead>
<tr>
<th>Year</th>
<th>Wholesale sales of goods</th>
<th>Total Income</th>
<th>Total expenses</th>
<th>Operating profit before tax</th>
<th>Operating profit margin</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005-06</td>
<td>5.0 million</td>
<td>20,000</td>
<td>15,000</td>
<td>5.0 million</td>
<td>6.0%</td>
</tr>
<tr>
<td>2012-13</td>
<td>6.6 million</td>
<td>25,000</td>
<td>18,000</td>
<td>7.0 million</td>
<td>6.0%</td>
</tr>
</tbody>
</table>


Chart 9 shows retailers (including community pharmacy) total income rose approximately 24% from 2004-05 to 2012-13 but on the expense side total expenses rose approximately 25% (including a 23% rise in purchases) which resulted in a drop of operating profit before tax of approximately 4.3%. This translated to a drop in the operating profit margin of approximately 1.6 percentage points.
A detrimental downturn in the profitability of wholesaling of PBS medicines is more often than not passed through to community pharmacy in the form of reduced trading terms – that is the price to pharmacy for PBS-listed medicines as well as other products and/or reduced time to pay for goods purchased from wholesalers.

Moreover, the trading terms pass-through to community pharmacy is neither uniform nor predictable – the trading terms offered to pharmacies may vary depending on the buying power of the pharmacy, which in turn may be, or at least may be perceived to be, a function of whether they are part of a buying or banner group that can negotiate favourable terms. With pharmaceutical wholesaling in Australia dominated by three companies (Sigma, Symbion and API), community pharmacies are largely dependent upon the performance of the full-line wholesalers. The rest of the market is made up of smaller regional based distributors, such as National Pharmacies, which is an accredited distributor for South Australia and Victoria and CH2 which is a subsidiary of Symbion and services public and private hospitals as well as day surgeries and GP clinics.

**Government savings along the supply chain**

The Federal Government’s policies of price disclosure, other regulatory price cuts and arrangements regarding risk-sharing rebates add to the fiscal sustainability of the PBS but this comes at a cost of potential disruption to the supply chain.

**Manufacturing rebates**

Chart 10 shows the Federal Government estimated savings or ‘recoveries’ from pharmaceutical manufacturers as a result of rebates provided by manufacturers through various arrangements that include risk sharing. As noted by Medicines Australia:

“Medicines Australia member companies are contributing to maintain a sustainable PBS through rebates paid to the Government for high-cost drugs. The Commonwealth’s spending on PBS medicines is likely to be even lower if the rebates paid by industry are taken into account.”

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These rebates have grown from $35 million in 2006, to just over $780 million in 2015. Expectations are that these rebates will continue to grow as new high-cost drugs get listed on the PBS.

**Chart 10: Federal Government estimated savings – ‘recoveries’ from pharmaceutical manufacturers**

![Chart showing estimated Australian Government 'recoveries' from pharmaceutical manufacturers, $m from 2006 to 2015.](image)


However, the Guild is concerned that the extent of the industry rebates is not taken into account with regards to PBS expenditure as part of Federal Government economic analyses. In its 2016-17 Federal Budget submission, Medicines Australia highlights how the spending on PBS medicines is likely to be even lower if the rebates are taken into account. While over the past five years the growth in rebate agreements between industry and Federal Government has been increasing, PBS growth has remained flat because the total rebate is not reported in Budget papers. To accurately reflect PBS income and expenditure, the Guild believes that industry rebates for PBS medicines must be accounted for as part of the Federal Budget and other economic analyses. The Guild also supports the call by the medicines industry for this funding to be invested back into the PBS.

**Wholesalers**

The impact of price disclosure policies and other market related factors can be seen in Chart 11 which shows the patchy growth rate of wholesalers’ revenue during a period when PBS listed prescription volumes grew strongly. In other words, lower average prices have been combined with higher volumes passing through wholesalers.

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173 ibid
Without a remuneration floor that delinks the wholesaler remuneration from the price of the PBS subsidised medicine, wholesalers continue to be directly impacted by falling PBS prices. Like pharmacy, pharmaceutical wholesalers have also relied on trading terms to cross-subsidise their costs associated with the core services required for the delivery of PBS and RPBS medicines to community pharmacies in a timely manner. Wholesalers are impacted as a result of the reduction in the prices of PBS medicines brought about by price disclosure by both a reduction in direct remuneration and trading terms reductions. Unlike pharmacies which cannot pass on to PBS patients any changes in business costs, this direct impact on the profitability of the wholesalers in turn has a direct impact on the trading terms offered to their community pharmacy clients.

Given the lack of immunity wholesalers have to PBS price reductions and the differences in the remuneration levels between wholesalers and community pharmacies, the Guild believes the remuneration structure for the distribution of PBS and RPBS medicines by pharmaceutical wholesalers should be revised as follows:

- guaranteed access to any PBS or RPBS listed item from manufacturers in any quantity at no more than the approved ex-manufacturer price
- a floor on wholesaler mark-up to delink wholesaler remuneration from PBS medicine prices
- alignment of the level of remuneration caps with that of community pharmacies
- fees that reflect the actual service costs for distribution of items listed on the PBS, RPBS and NDSS, including S100 medicines
- recognition of the additional costs associated with the distribution of Controlled Drugs, fridge lines and high-cost items
- To implement these changes, the Federal Government must commit to fully expend the wholesaler funding of $2.803 billion (inclusive of CSO and NDSS) committed in the 6CPA.
**PBS price increases**

Australia’s price disclosure system has no automatic mechanism for increasing the price of generic medicines should market conditions change – this is unlike the USA’s NADAC, UK’s Category M, New Zealand’s re-tendering arrangements, South Africa’s Single Exit Price and Ireland’s international benchmarking approach – all of which can (and do) result in prices being adjusted upwards. This is likely to become increasingly important in the future as generic medicines reach a price floor. Already, in the USA in particular, there is widespread evidence that the prices of generics are increasing.\(^{174}\) Sometimes these are temporary spikes in response to short-term market disruption (e.g. a shortage of one brand), but there is also an underlying trend.

**Inventory Devaluation**

In addition, when PBS price reductions come into effect through price disclosure and other regulatory arrangements, manufacturers, wholesalers and pharmacies immediately experience a significant loss due to a reduction in the value of their inventory. Wholesalers have an incentive to keep stock levels to a minimum as more medicines come off patent and are affected by government price drops and pharmacists will also keep limited stock to avoid losing money on stock revaluations.

On several occasions in the past, the Guild has attempted to alleviate the stock value loss that arises on PBS item price reduction dates by proposing a phased implementation of price reductions through the supply chain. The UK Category M model provides a useful exemplar for this process. In the UK:

- For proprietary (i.e. branded) products, a price change up to and including the 8th of the month takes effect for prescriptions dispensed in the following month. For example, if the manufacturer’s list price for a proprietary product changed on the 6th of February, the new reimbursement price would apply to prescriptions dispensed in March. If a manufacturer’s list price changed on the 15th February, the new reimbursement price would apply to prescriptions dispensed in April.

- For non-proprietary (i.e. generic) products, excluding “Category M” products (see below) a price change takes effect one month earlier than the above. For example, if the manufacturer’s list price changed on the 6th of February, the new reimbursement price would apply to prescriptions dispensed in February. If a manufacturer’s list price for a generic drug changed on the 15th February, the new reimbursement price would apply to prescriptions dispensed in March.

Category M products are those that are included in the (currently) £800 million retained buying margin component of the national funding pool. Category M prices are adjusted every quarter based on the Margins Survey.\(^{175}\)

While the DoH provides advance notification of impending price reductions to assist the supply chain to plan for and manage their stock holdings at the time these price reductions are implemented, this does not address the fact that under the 6CPA, community pharmacies are expected to hold sufficient PBS stock to meet community demand. With high cost medicines in particular, overnight price reductions can be to the value of hundreds of dollars and with many medicines, it is critical that the patient’s therapy is uninterrupted. As such, pharmacies have a duty of care to carry minimum stock levels which can significantly de-value overnight and is particularly problematic when reductions occur on weekends or public holidays which delays the pharmacy from re-plenishing. The fulfilment of pharmacy orders also


\(^{175}\) See: http://psnc.org.uk/dispensing-supply/endorsement/how-the-price-change-mechanism-works/ for further details on the above price change process.
requires the wholesaler to have stock to meet demand. Reductions in wholesaler inventory at the time of price reductions can also delay pharmacy replenishment.

While manufacturers, wholesalers and community pharmacists may have informal arrangements to pass on reductions earlier to manage the impact on the day of effect, this is not standardised and varies between manufacturers, wholesalers and pharmacies with the larger corporate banner groups having the greater negotiating power. In the interests of patient care, the Guild believes the Federal Government must work with the whole PBS supply chain to better manage price reductions to guarantee continuity of supply and reduce the overnight impact of inventory devaluation.

**Recommendation Number 20**

The Guild recommends that immediately:

- the Federal Government should manage PBS price disclosure prices reductions, working with community pharmacy, pharmaceutical wholesalers and manufacturers, in a way that maintains continuity of supply while minimising stock value losses, including through consideration of phased implementation of price reductions through the supply chain, as occurs in some comparable international jurisdictions.

- the price disclosure regime should include a mechanism to automatically recognise and adjust ex-manufacturer prices upwards if generic medicines increase in price, as occurs in many comparable international jurisdictions.

- Federal Government budget savings from price disclosure and rebates received from manufactures as a result of risk sharing arrangements should be transparently identified and re-invested as required to maintain the sustainability of the pharmaceutical supply chain in Australia.

- pharmaceutical wholesalers should have access to any PBS and RPBS listed item in any quantity at no more than the approved ex-manufacturer price.

- the wholesaler remuneration structure should include a floor on wholesaler mark-up and align the level of the payment caps with that of community pharmacies and be implemented in a way that ensures that the wholesaler funding committed to in the 6CPA is fully expended at the estimated volume levels.

- pharmaceutical wholesalers should be remunerated by the Federal Government, with appropriate fees that reflect actual service costs for distribution of all items listed on the PBS, RPBS and NDSS (including S100 medicines), recognising additional costs for Controlled Drugs, fridge lines, cytotoxics and high-cost items.

**Community Service Obligation (CSO)**

In the case of items listed on the General Schedule (S85) of the PBS and the RPBS, pharmacy remuneration is based on the approved PTP which includes the AEMP and an allowance for a wholesaler distribution fee as set out in the 6CPA. However, there is no legislation that requires manufacturers to supply items at the AEMP and no legislation that guarantees pharmacies can purchase a PBS or RPBS item at the PTP. In addition, unlike business practices for other commercial retailers, the *National Health Act 1953 (Cth)* expressly prevents a pharmacist from passing on additional business related expenses associated with the ordering and stock-holding of PBS medicines.

For many years a reliable pharmaceutical wholesaler distribution system has meant there has been little need for legislation regarding issues such as timeliness of deliveries from manufacturers to pharmacists nor for intervention regarding delivery costs above the PTP. Instead of legislation, these arrangements were strengthened with the introduction of the CSO in 2006 guaranteeing arrangements were in place
with pharmaceutical wholesalers for all Australians to have access to the full range of S85 PBS and dual-listed\textsuperscript{176} RPBS medicines, via their community pharmacy, regardless of where they live and usually within 24 hours. The Guild remains fully committed to the CSO for the distribution and supply of PBS medicines.

The CSO Funding Pool financially supports pharmaceutical wholesalers to supply the full range of S85 PBS medicines to pharmacies across Australia, regardless of pharmacy location and the relative cost of supply. Under these arrangements, payments are provided directly to pharmaceutical wholesalers who comply with the CSO requirements and service standards\textsuperscript{177}. These payments are over and above those made directly by pharmacists to cover the costs of supply from the wholesaler.

Wholesalers operate on the basis of large volume and relatively small margins so an inadequately funded CSO affects their investment decisions, given that CSO obligations are, by definition, non-commercial activities that would either not be undertaken or, not undertaken at the same level, quality and standard, in the absence of funding. For example, if wholesalers are insufficiently compensated for meeting their CSO obligations, they could be unwilling to devote ongoing resources to CSO provision, putting at risk the viability of the PBS supply chain. Inadequate funding of wholesalers could not only adversely affect the wholesalers themselves but in turn put pressure on the trading terms offered to community pharmacies, putting at risk the viability of the last link in the PBS supply chain.

**CSO Service Standards**

The CSO requirements and service standards apply only to S85 PBS medicines. Non-dual-listed S100 medicines and RPBS items are excluded. As a result, community pharmacists may not be able to purchase a S100 or RPBS listed item at the approved PTP. While DVA has arrangements in place to repay pharmacies the difference for RPBS anomalies this process is administratively burdensome and prolonged for the pharmacy and requires knowledge of the arrangements.

The CSO is included as part of the 6CPA at a value up to $195,222,000 per year without indexation. To access the CSO Funding Pool, the pharmaceutical wholesalers enter into a Deed with the DoH in which they guarantee to adhere to the standards within the **CSO Funding Pool Operational Guidelines** (CSO Guidelines).

The CSO Guidelines changed from 1 July 2015 with the introduction of a Top 1000 High Volume PBS medicine list (Top 1000) for which the Guaranteed Supply Period increased from 24 to 72 hours and Minimum Order Quantities applied. In addition, wholesalers could apply an uncapped surcharge for the delivery to pharmacies of any Top 1000 item required in less than 72 hours or in a quantity less than the Minimum Order Quantity. These changes were introduced at the request of the CSO wholesalers to address the loss in revenue from price disclosure and other Federal Government policies.

While to the Guild’s knowledge, the delivery service to pharmacies to date has remained at the higher standard as per the 5CPA CSO Guidelines, as the wholesale margins of CSO wholesalers shrink, the wholesalers themselves have made it clear that it is only a matter of time before these new arrangements are implemented, to the detriment of community pharmacies.

From 1 July 2016, the distribution of NDSS products ordered via NDSS Connect was also covered by the CSO.

\textsuperscript{176} Dual-listed RPBS medicine is listed on both the PBS and RPBS

Guaranteed Supply Period

Community pharmacists maintain a dispensary inventory to meet the needs of the local community based on the pharmacy’s dispense history. Where a PBS medicine is not stocked because there is no anticipated usage, pharmacies have been able to order the product for delivery within 24 hours. The 72 hour Guaranteed Supply Period fails to provide pharmacies with reasonable flexibility to respond to urgent medicine requests for items not stocked by the pharmacy, in particular:

- in response to specialist orders, dose sensitive treatment, palliative care, hospital discharge prescriptions, travelling patients and
- when there are no alternative brands available that the pharmacy may offer (161 items in the Top 1000 have no alternative brand available for substitution)

Minimum Order Quantities

It is not efficient or cost-effective for pharmacies to stock large quantities of the full range of pharmaceutical items, as this will inevitably lead to costly wastage from expired and unwanted stock on the shelves. A more efficient practice for pharmacists is to assess and monitor their usage patterns and to stock high demand products and those products regularly prescribed by local doctors. Less frequently prescribed items and high-cost items are ordered in smaller quantities or on demand, particularly given the low remuneration for high-cost items.

The introduction of Minimum Order Quantities equivalent to the ‘shelf-pack’ and minimum aggregate order values creates unnecessary inefficiencies in the pharmacy distribution chain by requiring pharmacies to either order stock quantities for some products that would take several months to use or to potentially pay additional fees to order smaller quantities. Shelf pack quantities vary, but 10 to 12 units is typical, and can be as much as 20 or 60 units; if monthly usage for a particular product is four or less, a shelf pack of 12 is equivalent to three months’ worth of stock that the pharmacy would have to carry. This is particularly problematic for fridge lines and Controlled Drugs with limited storage available in pharmacy. The Minimum Order Quantities also makes it difficult to manage stock levels of higher cost items and can lead to increased wastage for medicines with short expiry dates. This arrangement also favours pharmacies with larger prescription volumes which have sufficient product turnover to justify ordering the larger quantities.

Additional Charges

The new CSO Guidelines allow wholesalers the discretion to apply unfettered surcharges or levies on pharmacies for non-compliant orders (e.g. for urgent delivery in less than 72 hours or smaller quantities). Not only does this negate the ability for pharmacies to access medicines at the approved PTP, but there is no transparency or limitations with these arrangements. Given that any fees or levies are a business expense to the pharmacy and cannot be passed on to the consumer, this arrangement generates financial pressures on pharmacies and introduces a disincentive to timely supply, making it difficult for pharmacists to meet the immediate PBS requirements of their patients.

Pharmacists should not be financially disadvantaged when they put the needs of their patients first and the fact the unfettered charges have not impacted pharmacies yet is only a matter of timing. At any time in the future they can be implemented so the CSO wholesalers can maintain their margins and this will affect patients’ access to PBS medicines.

The policy must be fixed by the removal of these changes and a reversion to the more patient-centred CSO standards of the previous CSO Guidelines. Alternatively, the legislation needs to be changed so

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\[178\] A ‘shelf pack’ is the standard manufacturer case quantity of a medicine
that, as with other commercial entities, pharmacists would have the discretion to pass on additional business related costs to the consumer. This is not the Guild’s preferred option as it propagates dispensing as a retail transaction rather than a professional service and directly affects consumers.

**Improved efficiency**

It is understandable that CSO wholesalers would like to improve the ordering efficiencies of their community pharmacy clients. Less frequent orders and shelf pack order quantities would improve the efficiency and lower the picking and handling costs of the wholesalers. Improved ordering efficiency would also have similar benefits for community pharmacists and for this reason, the Guild is supportive. However, it is important not to confuse this desire for improved efficiency with the intent of the CSO which is to ensure that all Australians have timely access to the full range of PBS medicines at a community pharmacy of their choice. The lower CSO services introduced in July 2015 fundamentally undermine the objective of the CSO and will generate financial pressures on pharmacy and introduce a barrier to timely access. To spend nearly $1 billion over five years on a CSO to facilitate timely access to PBS medicines and then allow pharmacies to be charged uncapped fees when they reasonably seek to access PBS medicines in sensible quantities from their suppliers to meet their patients’ needs is contradictory and defeats the whole purpose of the CSO. While the Guild supports improving ordering efficiencies throughout the PBS supply chain, this should be managed externally to the CSO and should not be to the detriment of patient access guaranteed by the CSO.

The introduction of the Top 1000 and the associated lower service standards demonstrates the effect that price disclosure is having on the pharmaceutical supply chain. The Guild believes that if the Federal Government commits to fully expending the funding allocated in the 6CPA to wholesalers and revises the remuneration structure as recommended, CSO wholesalers would accept of retaining the higher service standards without the need to apply additional fees.

**Recommendation Number 21**
The Guild recommends that immediately:

- the CSO should be retained and strengthened to guarantee prompt and efficient supply of all PBS, RPBS and NDSS items (including S100 medicines) to any approved pharmacy in Australia in order to meet the needs of the Australian public.
- whilst supporting improved efficiencies, pharmacies should have access to deliveries within 24 hours with no minimum order requirements in order to meet urgent patient needs.
- pharmacies should have access to any PBS and RPBS listed item in any quantity at no more than the approved Price to Pharmacist (PTP) and without any administrative surcharges.
- with the addressing of wholesaler remuneration, the Top 1,000 list and associated lower service provisions should be discontinued as they undermine the CSO and put at risk patient access to PBS medicines.

**Exclusive Supply**
The Guild’s preferred mode for distribution of PBS medicines is through CSO compliant distributors that the whole community pharmacy network can readily access. When Pfizer implemented its exclusive supply arrangements in early 2011, there were many complaints from pharmacists. This was partly because of implementation issues with the new arrangements and partly because of the potential precedents. Pharmacists were naturally concerned about the additional administration required for ordering and receiving their dispensary stock from different suppliers, which could potentially become unwieldy if the practice escalated. While pharmacies have largely adapted and complaints have reduced
significantly, there are still concerns regarding pharmacists being able to meet unanticipated urgent requests.

Some manufacturers of specialised PBS medicines, including S100 HSDs and other S100 program medicines have exclusive supply arrangements in place, whether directly from the manufacturer, an alternative distributor or through one preferred CSO compliant wholesaler. In such instances, pharmacies that do not have existing accounts with the exclusive distributor have reported a lack of understanding about from where and how these specialised medicines must be ordered along with difficulty in establishing accounts, particularly when urgent supply is required.

The Guild is concerned that one of the four central objectives of NMP is put at risk by exclusive supply arrangements, namely ‘Timely access to the medicines that Australians need, at a cost individuals and the community can afford.’

The CSO sets out agreed service standards for CSO compliant distributors. This is the primary method through which the NMP objective is achieved. It is, however, optional for manufacturers to distribute their products via CSO compliant distributors. If other distribution channels are used, there is no obligation for them to comply with the standards.

While Appendix D of the CSO Guidelines is for a list of PBS medicines subject to exclusive supply arrangements, this is not published. Such lack of transparency makes it difficult for pharmacists to know what PBS medicines are affected so they can implement alternative supply arrangements and is particularly problematic for specialised medicines for which the pharmacist may have less familiarity regarding ordering arrangements.

The Guild believes that all PBS, RPBS and NDSS listed items should be distributed through CSO compliant distributors with guaranteed equitable access for any community pharmacy to meet unanticipated urgent requirements. While manufacturers can also supply through other preferred distribution channels, the Guild believes this should not undermine the ability of pharmacies to access medicines through the CSO distribution network.

Recommendation Number 22
The Guild recommends that immediately:

• as a condition of listing, all PBS medicines should be available for supply from one or more CSO wholesalers, with the obligation on any CSO distributor that enters into an exclusive supply arrangement with a manufacturer to ensure that all pharmacies have equitable access to the medicine in line with the CSO requirements.

Shortages of Medicines
A recent study by The University of Sydney’s Dr Betty Chaar179 noted that medicines shortages in community pharmacy are having a major impact on pharmacists and patients, potentially driving patients to seek their medicine overseas. The study noted that pharmacies in the community are experiencing shortages that are affecting their workload, affecting patient satisfaction, and pharmacists are struggling with the shortages. ‘The TGA should promote (the shortages) website better,’ she says. ‘They should notify doctors clearly that there is a shortage, please don’t prescribe, and try to help out with how we can mitigate the impact.’

The study noted:

- shortages are common and increasing
- multiple causes and impacts on both pharmacists and consumers
- pharmacists devised workarounds, some of which were time-consuming and added heavily to workloads
- a lack of familiarity with the TGA website by consumers and health care professionals
- suggestions for improving notifications, especially to doctors

A recent article in the *Medical Observer* 180 noted the medicine shortages and highlighted concerns expressed by prescribers and pharmacists and organisations such as the Royal Australian College of General Practitioners (RACGP). The article states that ‘doctors and pharmacists are becoming frustrated by medicine shortages, with aggressive PBS pricing taking some of the blame. One week it’s slow-release metformin. The next it’s Bexsero, Zocor or Cavstat. Drug shortages are so common in Australia that the TGA has a special website to keep tabs on them. In August, 160 drugs were listed on the site, with warnings about 11 more to come.’

Whilst the TGA Medicines Shortages Information initiative is welcome, operating to a protocol181 and managing an online database, it relies on voluntary reporting by the manufacturer so unfortunately it is less effective than it could be if the shortages were reported by the CSO wholesalers that know what pharmacies are ordering and what manufacturers can’t supply.

With respect to the supply of PBS items, it is a condition of listing that manufacturers guarantee that they have stock before the item is PBS listed. This is predicated on the manufacturers’ expected market and can be influenced by factors such as whether there is a distinct market leader for a particular item and whether a brand price premium may apply. This is exemplified by the shortage of both strengths of PBS-listed metformin extended release182 since April this year. Despite the Guild notifying the TGA in April and the Federal Government DoH’s Pharmaceutical Benefits Division in May, there is no information in the actual Medicines Shortages database183 (where one would expect an interested party to conduct a search). Rather, the information is communicated as a separate safety alert for which the first notification was on 17 June 2016.184 The last update on 31 August continues to advise of ‘limited availability’ for all products. Given that almost two million prescriptions per year are dispensed for the two strengths of metformin extended release, limited availability is still a significant problem and such notification alone does not adequately indicate the extent of the supply limitations or when supply should again be guaranteed.

Where products are manufactured overseas, the business reality is that precedence is given to production for markets with the highest return on investment. If the value of the product for the Australian market is such that the return on investment is lower than that for other markets, it is understandable that manufacturers give priority to the higher valued markets. The Guild understands that manufacturers require a lead time of four to six months for an overseas order, which can make it difficult for manufacturers to respond to local supply fluctuations.

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**Brand Price Premiums**

Long term shortages are particularly problematic when the shortage involves all base-price brands. This means that the patient is forced to pay the higher price as the law requires pharmacists to charge any applicable brand price premiums and pharmacy staff again bear the brunt of consumer dissatisfaction. An example of this was when Osteomol® was listed on the PBS in November 2014 as a generic alternative to Panadol® Osteo (at that time the highest volume medicine on the PBS). From 1 November 2014 when Osteomol was listed on the PBS, Panadol Osteo had a brand price premium of $1.42.

The Guild understands that Pharmacor, the manufacturer of Osteomol, did not expect to be the only generic brand listed on the PBS at the time nor that there would be a brand premium on Panadol Osteo. Irrespective, from the time it was listed, supply for Osteomol as the base priced product could not keep up with demand and consumers often had no option but to pay the additional $1.42 brand premium for Panadol Osteo. Reports by members to the Guild indicate that pharmacists sometimes waited weeks for backorders of Osteomol to be filled (sometimes only in part).

Given that the majority of patients using this product were concessional patients, an additional $1.42 to the patient co-payment was a significant price increase that by default, often became mandatory. Despite the Guild notifying the Federal Government DoH in late 2014 and throughout 2015 about supply problems with Osteomol and a request to remove the brand price premium for Panadol Osteo until supply of the generic was guaranteed, no action was taken.

**Non-PBS shortages**

It is not only PBS shortages that are problematic. The Federal Government subsidises other supply schemes which involve community pharmacies, including the NDSS and NIP. The Guild is aware of long term shortages during 2015/2016 of whooping cough (pertussis) vaccine for which there is no information on the TGA Medicines Shortages database. The Guild is also aware of NDSS shortages for some insulin pump consumables, but recognises that the Federal Government DoH has been proactively managing this in consultation with Diabetes Australia and the Guild and other relevant stakeholders.

**Responsibility and Management**

While the TGA’s Medicine Shortages Information Initiative provides one means of communicating medicine shortages, it is not clear as to the role of the TGA or the DoH with regards to investigating and managing shortages associated with Federal Government subsidised schemes. For PBS, NDSS or NIP shortages, the Guild would support the relevant section of the Federal DoH taking a more proactive role in managing the situation in collaboration with the TGA. From first being alerted of a potential supply issue, the Guild supports the Federal DoH leading a thorough investigation of the extent and longevity of supply disruption. For PBS and NDSS shortages in particular, we would encourage the Federal DoH to make better use of the information and data available from CSO wholesalers about supply disruptions.

For long term or high-impact shortages, the Federal DoH should further consult with relevant peak bodies to promptly implement risk mitigation practices. If necessary, consideration should be given to enabling price increases as a means to guarantee ongoing supply.

Community pharmacists, prescribers and consumers require and expect a reliable medicine supply and particularly for publicly funded schemes such as the PBS, NDSS and NIP. The Guild believes that for these schemes, the Federal DoH must take a more proactive role in:

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187 High impact shortages are those affecting a large number of people or with potentially significant health consequences
ensuring that manufacturers of listed products have the capability to meet demand, and
responding to and managing disruptions to supply.

**Recommendation Number 23**
The Guild recommends that:

- the Federal Government should immediately work with relevant stakeholders developing and implementing a strategy to proactively prevent and manage supply shortages for the PBS, NDSS and National Immunisation Program (NIP), which would include:
  - more rigorous and ongoing assessment of supply capabilities for newly listed products or brands.
  - a risk assessment of currently listed products to identify potential situations of greatest patient risk should a shortage occur.
  - a management strategy for PBS listed products to guarantee supply including flexibility in pricing to enable price increases if needed.
  - a more stringent approach with manufacturers repeatedly having long-term shortages
  - removal of the Brand Price Premium if base-priced generic alternatives are out of stock or unable to meet demand for extended periods.
  - provision of more complete and timely communication about shortages to health care professionals to enable more effective patient support.

**Digital Health (e-health)**

**Background**
Community pharmacy in Australia leads the way in its willingness to embrace Digital Health and adopt innovative technologies and strategies in its mission to offer the highest standard of pharmacy and health care services.

Whether those innovations are technological, systematic or strategic in nature, community pharmacy has developed the necessary infrastructure and culture to implement innovation efficiently across the network and in such a way as to deliver significant benefits to the public. No other health profession has done more in terms of investing resources to support adoption to the digital health model.

Community pharmacies have been at the forefront in the adoption of technologies and were the first health provider to have their clinical records fully computerised. Pharmacies continue to lead the way in areas such as PBS Online, advanced dispensing systems, the electronic transfer of prescriptions (ETP), and the electronic recording and reporting of patient services.

In this context, supporting and enhancing community pharmacy’s role in digital health should be a priority for government at all levels.

**Enhancing access and supporting QUM**
Community pharmacies will continue to support innovation that enables them to provide high quality health outcomes for patients in a way that is increasingly integrated with the broader health system. However, innovation by any means, including the enhancement of a patient’s access to the health system, should not be at the expense of patient choice or the QUM. The community pharmacy network already delivers the highest levels of accessibility of any part of the health system and this allows it to
exercise its duty of care in supporting patient safety and fulfilling its role as the community’s prime agent and advocate of QUM.

**ETP and the My Health Record**

Community pharmacy supports the concept of the electronic health record (the *My Health Record*) and as the most accessible of all primary health care destinations, has significant untapped potential to support and advocate for its use both with patients and fellow health care providers.

For the *My Health Record* to be successfully adopted across the key junctions in the health care system, such as community pharmacy, it needs to provide significant incentives firstly to engage with the system and then to provide significant value-add for the users of the system. This will require the application of a multi-channel health care engagement model for both community pharmacy and patients while providing a clinical information and support system for community pharmacy to deliver optimal patient care.

A foundational component of community pharmacy’s contribution to the *My Health Record* is through the ETP. With 300 million prescriptions dispensed every year in Australia, and pharmacists dispensing on average 100 to 200 prescriptions a day, ETP is the key mechanism supporting the efficient availability of medication data in the *My Health Record*; continuing to provide the opportunity to strengthen patient safety and confidence in the clinical process of dispensing medication.

ETP achieves this by providing the efficient and secure digital transfer of a patient’s prescription information between the prescriber and dispenser whilst still requiring the original paper (hardcopy) prescription document to be presented at the patient’s chosen community pharmacy.

**Online dispensing, internet pharmacies and paperless prescriptions**

Whilst ETP is a good example of innovation that supports patient care and safety through the patient’s preferred care provider, other internet-based disruptors such as online dispensing and paperless prescriptions, can put these principles at significant risk. Patient choice and the separation of prescribing and dispensing are core tenets of Australia’s medicines system. The requirement for the patient to have a paper prescription for which they have personal control has always been fundamental in upholding these core tenets and any alternative model that is considered, must not undermine the intent, integrity and security of the current system.

It is well recognised that the growth of the internet (web) has provided valuable services to a growing community of users with more and more people accessing online medical services, including for the supply of pharmaceuticals by duly licensed and legally operating internet pharmacies. It is also recognised that such internet-based services complement services provided by the traditional health care system, in particular for people in remote areas with limited access to health services.\(^\text{188}\) However, the web is also exploited and misused to illegally sell prescription medicines to the general public without the required prescription. Information from countries where illegal internet pharmacies have been closely investigated suggests that these pharmacies have a very high volume of transactions.\(^\text{188}\)

Several studies have also explored the public health implications of online pharmacies indicating the negative consequences include dissemination of misleading or unbalanced information about the risks and benefits of medications, over-utilisation of expensive prescription drugs, aggressive promotion of

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pharmaceuticals with questionable safety profiles often at early stages in their product life-cycle, and negative patient-physician interactions.189,190,191,192,193,194

While it is also recognised that the accessibility of medicines may marginally improve through online dispensing and convenience-driven 'innovations' such as 'medicine vending machines', any benefits of this may be largely offset by the further commoditisation of medicines, compromised patient care, increases in adverse drug events and poorer health outcomes. A paperless prescription environment can also present significant risks and negative outcomes such as prescription channelling by prescribers, the loss of consumer choice, and diversion of prescriptions to unapproved and unregistered providers.

When considering the potential introduction of these internet-based disruptive models in any revised policy platform, it is important to recognise, first and foremost, that dispensing a prescription medicine is a service requiring specific clinical expertise supported by tailored professional counselling and advice. The clinical process of dispensing a prescription medicine and conveying of the health and safety requirements of that prescription to the patient is far different to the sale of a retail commodity. The quality use of a medicine applied in the specialised clinical service of dispensing should preferably and wherever possible, be provided face-to-face with the patient by the pharmacist.

**eMedication management**

One of the key problems facing Australian health care professionals is the lack of consolidated medications information and an inability to easily share information between health professionals. When patients move between care settings, the absence of complete and up-to-date medication data can contribute to instances of care becoming high risk, resulting in medication misadventures and unnecessary hospital readmissions.

With appropriate funding, community pharmacists are able to prepare a consolidated medicines list for high risk patients for uploading to and maintaining as part of the **My Health Record**. In fact, such lists are already prepared and maintained by community pharmacists for people that use a DAA. The DAA medicines profile prepared by the community pharmacist includes the medicines packed and not packed, inclusive of PBS, non-PBS and OTC medicines. Given that DAA users are the higher-risk patients who most use medicines, subject to patient consent, one approach would be to pay community pharmacists to upload and maintain the DAA medicines profile to the **My Health Record** as an additional part of their DAA service. This could be done for both residential and community-based patients and would also be of value to ensure continuity of medicine management for DAA users that transfer between care settings as community pharmacists must always refer to the most current DAA profile when preparing a DAA.

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Recommendation Number 24

The Guild recommends that:

- the Australian Digital Health Agency should immediately ensure that community pharmacy dispensing and medicine related services are fully integrated into the *My Health Record* by incentivising community pharmacies to –
  - integrate the *My Health Record* into their systems, practices and workflows and
  - upload and maintain DAA medicine profiles to the *My Health Record* for all community-based and residential DAA patients.

- any possible transition to a paper-optional script environment should expressly prohibit channeling from prescribers; ensure that patients continue to receive the level of pharmacist professional counselling required to deliver Quality Use of Medicine outcomes; and should only be progressed following a thorough investigation into the risks and benefits and international precedents.

Chemotherapy

Community pharmacy serves a vital role in the delivery of chemotherapy medicines to Australians undergoing lifesaving treatment often in rural and remote areas. While much has been done to improve the Section 100 EFC program, the following remain as problems for community pharmacy chemotherapy providers:

- the discrepancy in remuneration
- meeting the urgent chemotherapy needs of regional chemotherapy patients and
- the administration burden associated with claims and prescription reconciliation and ‘owing’ prescriptions

Initial remuneration for the EFC was set at a level that did not cover costs that are unavoidable in the safe and efficient preparation and dispensing of chemotherapy infusions and was cross subsidised by the supplier trading terms available to pharmacies on a small number of off-patent medicines, in particular docetaxel and paclitaxel. Price reductions on 1 December 2012 (76.20 % reduction to docetaxel) and 1 April 2013 (86.94 % reduction to paclitaxel) meant that this cross-subsidy was no longer available.

Following consultation with the Guild and community pharmacy chemotherapy providers, from 1 July 2013 the Federal Government implemented an additional $60 compounding fee to cover the associated costs of compounding chemotherapy infusions. From 1 July 2015, as part of the 6CPA, the additional compounding fee was adjusted to reflect a differentiation in payment according to whether the compounder had a manufacturing licence from the TGA. Table 6 summarises the remuneration arrangements for chemotherapy since December 2011.
Table 6: Summary of Chemotherapy Remuneration since December 2011

<table>
<thead>
<tr>
<th>Component</th>
<th>1/12/2011</th>
<th>1/7/2013</th>
<th>1/7/2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diluent Fee¹</td>
<td>$4.75</td>
<td>$4.91</td>
<td>$5.14</td>
</tr>
<tr>
<td>Wholesale/Distribution Fee¹</td>
<td>$24.00</td>
<td>$24.79</td>
<td>$25.92</td>
</tr>
<tr>
<td>Preparation Fee¹</td>
<td>$40.00</td>
<td>$41.33</td>
<td>$43.22</td>
</tr>
<tr>
<td>Dispensing Fee¹</td>
<td>$6.42</td>
<td>$6.63</td>
<td>$7.02</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>$75.17</td>
<td>$77.66</td>
<td>$81.30</td>
</tr>
<tr>
<td>Additional Fee (Pharmacy)</td>
<td>-</td>
<td>$60.00</td>
<td>-</td>
</tr>
<tr>
<td>Compounding Fee (non-TGA)</td>
<td>-</td>
<td>-</td>
<td>$40.00</td>
</tr>
<tr>
<td>Compounding Fee (TGA)</td>
<td>-</td>
<td>-</td>
<td>$60.00</td>
</tr>
<tr>
<td>Total</td>
<td>$75.17 (cross-subsidised by trading terms)</td>
<td>$137.66</td>
<td>TGA Compounder = $141.30</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Non-TGA Compounder = $121.30</td>
</tr>
</tbody>
</table>

¹ Subject to annual indexation

The two-tiered fee structure originates from a misunderstanding of representations to the DoH about the different business costs of TGA and non-TGA licensed compounders.

- While TGA compounders have higher start up and maintenance costs, they also have higher volume
- Non-TGA compounders must still meet stringent quality controls and have high service costs which are magnified in regional areas (infrastructure, IT, staffing, training, wastage, courier costs, air charter)

The remuneration for chemotherapy also fails to recognise:

- Indexation for the Compounding fee and
- The number of high-cost chemotherapy medicines

Under the terms of the 6CPA, the chemotherapy compounding fee remains fixed, meaning a reduction in effective value each year. In addition, there are several chemotherapy medicines with costs from $2,000 to in excess of $23,000 (Ipilimumab). Examples include:

- trastuzumab, nivolumab, pembrolizumab, panitumumab - > $2,000
- ofatumumab and pertuzumab - > $3,000
- cabazitaxel - > $5,000

The margins earned on dispensing these high-cost medicines, even with a $60 compounding fee, are insufficient to meet the business costs of the chemotherapy pharmacies.

**Regional Chemotherapy Care**

In accordance with the NMP the Guild believes patients should have equal access to chemotherapy treatment irrespective of where they live. This principle of the NMP has been compromised in regional areas or States without a TGA-licensed compounder (e.g. Tasmania) by the two-tiered fee structure affecting the ability for non-TGA compounders in these locations to meet the needs of their patients.
In the absence of a local TGA compounding, regional non-TGA compounders must meet urgent prescriber/patient chemotherapy requests for treatment which for stability or timeliness requires immediate preparation (e.g. patient assessment required prior to ordering treatment).

If it is unfinancial for a local non-TGA compounding to prepare, there are additional patient costs associated with waiting extra days for supply from TGA compounders or travelling to where access is available (accommodation, living expenses, work absence).

**Administration Burden**

**Payment Arrangements**

With the implementation of the 6CPA, the intent by the Federal DoH was that the compounding fee would not be paid to the dispensing pharmacy as part of the PBS claim process, but would be paid separately by an external agent to the compounding directly. This was ostensibly to provide transparency with how chemotherapy treatments were being remunerated.

Given the increased administrative burden associated with this arrangement coupled with either a reduction in remuneration for non-TGA compounders or static remuneration for TGA compounders, chemotherapy compounders negotiated with the Federal DoH and agreed to a compromise in which the compounding fee of $40 is paid by the Department of Human Services (DHS) - Medicare to all pharmacists as part of EFC claims through the PBS Online claiming system and the additional $20 for TGA compounders is paid directly to the compounding via an external agency.

To support this arrangement, pharmacists must also include a Compounder ID and Infusion ID when dispensing PBS chemotherapy prescriptions for transmission to Medicare via PBS Online. This commenced on 1 September 2016 as a transitional arrangement until April 2017 after which it will be mandatory for a PBS claim to be paid.

While TGA compounders and pharmacies have streamlined this process to make it as efficient as possible, it remains administratively burdensome for TGA and non-TGA compounders with no apparent benefit. In particular, the process:

- duplicates the existing PBS Online process
- does not recognise the commercial arrangements that exist between a pharmacy and TGA compounding which covers more than PBS supply and requires the pharmacy to pay for infusions when ordering
- requires additional reconciliation with payment/refund arrangements from different operators
- does no more to address transparency than the agreed changes to PBS Online processing to identify the compounding at time of dispensing

**Owing Prescriptions**

Under State/ Territory and Commonwealth law, a pharmacist must have a paper copy of a prescription that complies with the relevant legal requirements. In situations where urgent supply is required, a prescriber is able to authorise a pharmacist to supply a Prescription Only medicine without a prescription on the proviso that a paper prescription is supplied within a specified period (seven days under Commonwealth law and variable periods up to seven days under State law). These are typically referred to as ‘owing prescriptions’.
A pharmacist requires a prescription that complies with Commonwealth law in order to claim a PBS payment. In addition to the PBS prescriptions used in private practice\(^{195}\) and participating public hospitals\(^{196}\), there are two forms of medicine chart that can also be used as a PBS prescription:

- the Residential Medication Chart\(^{197}\) for use in residential aged care facilities and
- the Hospital Medication Chart\(^{198}\) for use in public and private hospitals

With chemotherapy, there is a lot of duplication in the documentation needed to enable the prescribing, dispensing, claiming and administration of the medicine, creating an administrative burden for all involved. Pharmacists have the added problem that there may be significant delays before a PBS prescription is received for claiming purposes. In some instances, a prescription is provided that covers the State requirements but is not a valid PBS prescription. In such situations, the pharmacy is invariably left with the outstanding debt, including cost of medicine and the professional fees. One of the most common situations where this occurs is for non-streamlined authority chemotherapy medicines when the patient dies before the prescriber writes the prescription. The medicine is ordered and supplied as an ‘owing’ PBS medicine, but the prescriber is unable to obtain PBS phone authorisation after a person dies.

The review of chemotherapy funding arrangements in 2013 highlighted the administrative burden related to medication charting, prescribing and claiming in the hospital setting. Following this, the Federal Government proposed the simplification of a number of administrative processes to reduce the administrative burden faced by prescribers, pharmacists and hospitals when prescribing, dispensing and claiming for PBS medicines. The Federal DoH established the PBS Hospital Medication Chart project to enable prescribing, supply and claiming from a standardised medication chart in the hospital setting. The Commission for Safety and Quality in Health Care was appointed by the Federal DoH to develop the PBS Hospital Medication Chart for use in public and private hospitals and to trial and test the safety and effectiveness of the new chart. Despite the chemotherapy review being the catalyst for the Federal Government to develop the PBS Hospital Medication Chart it is disappointing that the community pharmacy chemotherapy sector was neglected in this project. While the Hospital Medication Chart may resolve the problem of ‘owing’ chemotherapy prescriptions for public and private hospital pharmacies, because it is not able to be used as a PBS prescription in community pharmacies it does not resolve the problem for community pharmacies that dispense prescriptions for public and private chemotherapy clinics.

**Recommendation Number 25**

The Guild recommends that immediately:

- irrespective of TGA licensing arrangements, a flat compounding fee should apply for PBS chemotherapy prescriptions that reflects the service costs.
- the full compounding fee for PBS chemotherapy prescriptions should be paid to the pharmacy as part of the routine PBS claim.


• to manage community-based chemotherapy ordering, supply and PBS claiming, the Hospital Medication Chart should be able to be used as a PBS prescription in community pharmacies.

**Aged Care**

Based on population projections by the ABS, from 2014 to 2064 the population of people aged 65 and over is expected to rise from 3.4 million to 9.6 million people and from 456,000 to 1.9 million for people aged 85 and over. Older people use a relatively high proportion of PBS medicines, with people aged over 65 accounting for approximately 60% of script volume and 53% of the total PBS expenditure in 2010-11. Although there is little focus on aged care within the Discussion Paper, with these trends in mind, the Guild sees community pharmacy support for older Australians as a critical area for discussion.

According to ABS data for 2011, of the 3.1 million Australians aged 65 years and over:

- 65% of older Australians lived in major urban areas and almost a quarter lived in other urban areas such as smaller cities and towns
- 94% lived in private dwellings of which one quarter lived alone, though this was higher for women (32%) than for men (17%)
- the main reasons for living alone were either the death of a spouse or divorce
- of the 180,300 older people who lived in non-private dwellings, 67% lived in residential aged care facilities and 25% lived in non-self-contained accommodation for the retired or aged

**Medicine Use in Older Australians**

The increasing morbidity and disability that accompanies ageing encourages a greater dependence on medicines to cure, slow the progression of, or reduce symptoms of disease. A review of research conducted in Australia between 2006 and 2013 showed the following:

- Community dwelling Australians (≥ 75yo) – 66% reported using five or more medicines and 20% reported using 10 or more
- Residential aged care – 95% of residents are prescribed five or more medicines with an average of seven -10 per resident; 25% of residents prescribed 10 or more medicines
- Australian hospitals – average number of medicines prescribed for older inpatients is nine-10 per patient with an average of five to seven medicine changes made between admission and discharge

**Access to medicines by older Australians**

The 2009/2010 survey of Australians aged 50 years and over showed the following for access to medicines and sources of recommendations:

- Doctors recommended 79.3% of all medicines and 93% of conventional medicines

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204 Op cit – MJA
More occasional medicines were recommended by pharmacists (10.5%)

Complementary medicines were more likely recommended by media or by friends and family

Purchase from pharmacies accounted for 84.8% of all medicines, 94.7% of conventional medicines and 53.2% of complementary medicines

7% of all medicines was purchased from supermarkets, 5.4% from health food shops and 0.7% over the internet

**Medicine-related problems for older Australians**

The medicine-related problems that community pharmacy can assist older Australians with include:

- non-adherence and increased risk of adverse events associated with medicine use
- maintaining accurate and current medicine lists
- continuity of medicine management as part of transitional care
- access issues

Although medicines can play a pivotal role in the quality of life of older people, polypharmacy can contribute to non-adherence and increase the risk of adverse drug reactions. Older Australians have greater problems managing their medicines. The research review reports that up to one-third of older community-dwelling Australians self-report difficulty in removing medicines from packaging, reading medicine labels or using complex dose forms such as puffers and patches. Other self-reported problems include difficulty in swallowing medicines, poor medicine knowledge, difficulty in understanding medicine instructions, confusion about different brands of medicines and difficulty in remembering to take the medicines.

Use of potentially inappropriate medicines by older Australians is another problem and is often overlooked because associated signs and symptoms may be confused with underlying disease or normal aging. A systematic review of US-based studies reported that inappropriate prescribing using the Beers Criteria occurred in 40% of people living in aged care facilities with half as much seen in community-dwelling people 65 years and older. An Australian study of people aged 70 years or older found 20% had been prescribed at least one potentially inappropriate medicine in the previous six months.

**Accurate and current medicine lists**

Prescribers in all settings continue to have problems with accessing current and accurate lists of their patients’ medicines. The research review identified two studies of older people admitted to hospital showing that more than 75% of patients had inaccurate GP medicine lists and unintended discrepancies on their hospital medicine charts.

While the inclusion of PBS data on a person’s My Health Record may be of use to clinicians, there would be greater value if a current medicines list was available that included PBS, non-PBS and OTC medicines, including complementary medicines. Such a list would provide a more complete, reconciled and readily accessible resource than just a list reflecting a person’s PBS dispensing history.

As discussed under the Digital Health section, with appropriate funding, community pharmacists are able to upload and maintain their DAA medicines profiles to the My Health Record for residential and

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205 Op cit – MJA
206 Op cit – Problems with medicine use in older Australians
207 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3571677/
208 Op cit – NPS
209 Op cit – Problems with medicine use in older Australians
community-based patients, many of whom are older, using a number of medicines for multiple morbidities and often transferring between care settings.

**Continuity of medicine management**

Continuity of medicine management is a problem for older Australians moving between care settings:

- From hospital to community
- From hospital to residential care
- From community to residential care
- From residential care to community (following respite stays)

After discharge from hospital to residential care, Australian studies have reported that more than 60% of patients do not have a current medicine chart and up to 40% do not have new medicines available in time for their first scheduled medicine dose, resulting in medicine administration errors in around 20% of patients.\(^{210}\) This is complicated by factors such as:

- Requirements for community pharmacists to prepare a dose administration aid (DAA) based on a patient's current medicine profile
- Access by the community pharmacy to PBS prescriptions for new or changes medicines
- Review and sign-off of a patient's medicine chart by the patient's GP
- Contract arrangements between residential facilities and DAA suppliers located in another city limiting capability for responding to requests for urgent medicine supplies or changes
- Poorer efficiency, additional time and costs associated with use of local community pharmacies to manage urgent supply needs or changes with limited access to patient history

While the Residential Medication Chart provides a prescription for dispensing and claiming for people in the residential aged care facility, community pharmacists also need to be able to use the Hospital Medication Chart as a PBS prescription to be able to dispense medicines for people as they leave hospital and return to their community or residential care setting. In either the community or residential setting, patients need a prescription for the pharmacist to dispense any new or changed medicines. After discharge from hospital, the median time for a patient to see their GP is 12 days.\(^{211}\)

**Access issues**

The quality of older people’s health is linked to their capacity to get transport to health services. The present lack of transport to take older people to health care is a barrier to good health.\(^{212}\) Many community pharmacies offer a home delivery service for their regular patients, whether on a routine or ad hoc basis. This is particularly important for older patients who must rely on either assistance from friends or relatives, public transport or taxis to attend their pharmacy. In the past, this service has mostly been provided free as part of the pharmacy’s customer service. As pharmacy revenue diminishes, pharmacists are having to more and more review their business costs. The Guild is aware that many pharmacies are either ceasing to provide a home delivery service or are implementing service charges. The Guild would

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\(^{210}\) Op cit – Problems with medicine use in older Australians  
\(^{211}\) EE Roughead et al; Continuity of care: when do patients visit community healthcare providers after leaving hospital? Internal Medicine Journal; Vol 41, Issue 9; pp 662-667; Sept2011  
like to see this service maintained and accessible, particularly to those pharmacy patients that most benefit from it.

While it is encouraging to see the Federal Government’s primary health care reforms as part of its Healthier Medicare package establishing ‘Health Care Home’ and tailoring care plans in partnership with patients and families, it is disappointing that the policy direction and communications to date has failed to recognise the important role that community pharmacies can play in these reforms. The Guild has identified a range of structural, policy and regulatory barriers that make it harder for sick and needy patients to access community pharmacy—delivered medicine related care. These barriers run counter to the Federal Government’s preferred coordinated and integrated, multidisciplinary team approach to caring for patients with complex, chronic conditions and make no sense given how crucial medicines and medicine support are to the health and wellbeing of these patients. Examples include:

- Rule 12 of the Private Health Insurance Rules effectively prevents health funds from including pharmacists in chronic disease plans for general (non-hospital) treatment
- Pharmacists are not currently part of the Health Care Home although virtually all the patients in this trial will be very high users of medicines
- The community pharmacist is not acknowledged in the PHN Core Funding Schedule, the PHN Governance Arrangements and the Needs Assessment Guidelines
- Aged Care Assessment Teams and Community Care Providers are often unaware of the services available from community pharmacies for older people, and particular many of the medicine management services for which older people pay

Recommendation Number 26
The Guild recommends that in order to keep older Australians living in their homes for as long as possible the Federal Government should immediately:

- Fund community pharmacists to upload and maintain medicine profiles for community-based and residential patients to the My Health Record.
- Fund pharmacy home delivery services to older Australians.
- Fund the role of community pharmacy in the Health Care Home for older Australians.
- Actively encourage Aged Care Assessment Teams and Community Care Providers to include medication management support in consumer-directed home care packages.

The PBS Administration System
Unquestionably PBS Online has improved the administrative efficiency of PBS claiming and payments as well as assisting the Government with prompt data collection. Because PBS Online is the primary means for transmitting data between pharmacies and Medicare for the payment of PBS claims, virtually 100% of community pharmacies are connected to PBS Online. PBS Online is capable of confirming:

- The concessional eligibility of a patient
- ‘Authority Prescription’ eligibility
- Conflict with the PBS Safety Net early supply rule
- Prescriber eligibility for a PBS prescription

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• patient eligibility for urgent PBS Continued Dispensing supply by a pharmacist

However, despite the advantages provided by PBS Online, a number of administrative problems still remain, as summarised below:

**PBS Online Warnings**

The real-time feedback to pharmacists confirming payment is very useful. In some situations where the dispensing information is unclear the pharmacy may receive a warning. If not actioned, these prescriptions may potentially be rejected. Given the costs of some PBS medicines, it is very important for pharmacists to be aware of any problems with a prescription claim so they can take immediate steps to rectify the problem. However, in some cases, Medicare only provides a warning with a code to indicate a recommended action.

There have been a number of community pharmacists who have been adversely affected by inadvertently dispensing a public hospital prescription for a Section 100 HSD and for which the pharmacist did not receive a claim ‘Rejection’ through PBS Online. These prescriptions can only be dispensed and claimed by a Section 94 public hospital and claims for prescriptions dispensed by a S90 community pharmacy are rejected. The current feedback through PBS Online in this situation is only a ‘Warning’ which has a greater risk of being missed or overlooked. The Guild has had reports from members where they have had PBS claims valued at thousands of dollars being rejected. S100 HSD prescriptions have been problematic because community pharmacists are less familiar with these PBS items and because there are Public Hospital and Private Hospital categories with identical indications and requirements.

**System Outages**

There are two types of system outage that affect PBS Online:

• Planned outages for system maintenance
• Unplanned outages due to a system failure

Planned outages may either be PBS Online specific or be part of a system wide maintenance outage affecting the other administration functions of Medicare. Planned maintenance is usually undertaken on a weekend and during the night as this affects the least number of people using the system. Unfortunately, community pharmacies are more likely to be affected as many have extended trading hours (some operate for 24 hours a day) and open over weekends. Scheduled outages that commence too early (Eastern time) may affect pharmacies open in central and Western Australia whereas outages that commence later have a greater risk of affecting pharmacies in Eastern States if the system is not re-established on schedule.

As implied, unplanned outages are unpredictable and will most likely affect many pharmacies (and their patients) throughout the country if occurring during normal business hours. Prolonged outages are particularly problematic.

Under normal circumstances when PBS Online is operational, if a community pharmacist dispenses a concessional prescription for which the concessional entitlement is not valid, the claim is rejected in real time so the pharmacist can re-dispense the prescription as a general benefit and charge the patient accordingly. This is useful as sometimes, despite a change in their concessional status, patients may present a seemingly valid concessional card still in their possession. When PBS Online is down, if the pharmacist dispenses a prescription for such a patient as a concessional benefit, the claim is rejected and the pharmacist receives no payment.

When PBS Online is down, Medicare recommends that for concessional prescriptions, the pharmacists:
- Contacts the Medicare help line to confirm concessional status
- Dispenses the prescription as a general benefit for the patient to subsequently claim back from Medicare
- Requests the patient to return when PBS Online is operational

None of these actions are practical for either the pharmacist or for patients for which their concessional status has not changed. Given the volume of concessional prescriptions that are done, these recommendations do not consider the impact on the pharmacy workflow. Neither do they recognise that concessional patients may not be able to afford to pay the general co-payment up-front for later reclaiming or that they are able to easily return at a later time (particularly if no time can be advised in the case of unplanned outages).

As the Government is responsible for PBS Online, the Guild believes the Federal Government must take full responsibility when the system is not working by covering any potential risks with PBS prescription claims and honouring the payment for any claimable PBS prescription dispensed.

**Safety Net Reconciliation**

The PBS Safety Net requires patients to maintain their Safety Net records so that the appropriate Safety Net entitlement card may be issued when the threshold is reached. The pharmacist submits the records to DHS-Medicare to substantiate that the Safety Net threshold has been reached. As part of the paperwork, the pharmacist confirms all eligible family members including spouse, dependent children under 16 years of age and dependent students under 25 years of age. For doing this work, the pharmacist is remunerated $9.61 (1 January 2016).

For patients that have a regular pharmacy, the pharmacy’s dispense system maintains the records and links all eligible family members. However, people that use different pharmacies may find that they have exceeded the Safety Net threshold, sometimes substantially. While a refund can be claimed if the patient takes a copy of their records to a Medicare Shopfront, this requires extra administrative work by all involved pharmacies to print and collate their records and is also inconvenient to the patient.

In addition, until Medicare confirms that the threshold has been reached, it may reject a pharmacy’s PBS claim for prescriptions dispensed for a particular Safety Net entitlement. The Guild has been contacted by members who have had PBS claims rejected for Safety Net patients because Medicare records do not indicate that the person has a Safety Net entitlement. This may be due to the lag time from the pharmacy submitting the documentation, or on other occasions reported by members from Medicare ‘losing’ the submitted paperwork.

Given that Medicare has all the relevant PBS Safety Net records submitted through PBS Online, the Guild believes that Medicare not only has the capability but should have the responsibility for managing the Safety Net and advising when the threshold is reached. To assist this, the community pharmacist could:

- Link relevant family members at the beginning of each calendar year
- Confirm status of family members at the beginning of each calendar year and at the time the Safety Net threshold is reached

Such an arrangement would be particularly beneficial to the public, removing the need to collect Safety Net stickers at the time of dispensing and maintaining records, particularly if having to use different pharmacies.
Concessional status on day of death

In July 2015 the Guild wrote to the then Minister for Social Services, the Hon Scott Morrison MP, about pharmacists having PBS claims for concessional prescriptions rejected because the prescription has been dispensed and supplied to a person on the day of their death. While the National Health Act 1953 (Cth) does not prevent a person from receiving a pharmaceutical benefit up until the time they are no longer receiving treatment (in this case death), under the Social Security (Administration) Act 1999 (Cth) a person’s concessional entitlement is end dated for the day before the day of death.

There are often times when a person is being medically cared for up to the hour of their death and at times this care may require the supply of a medicine subsidised under the PBS. As an example, it is not uncommon for a person receiving palliative care to be having PBS pain medicines prescribed and dispensed for them on the day of death.

The Guild has been advised that the Department of Social Services has been working with the DHS and DoH to correct this anomaly with corrective legislation, but 15 months later there is no change. Members are still contacting the Guild advising of rejected claims because the prescription has been dispensed on the day the person has died. Community pharmacists are being put into a very sensitive position and the Guild believes this needs to be urgently addressed.

PBS payments in advance

In this submission the Guild has demonstrated the financial burden placed on community pharmacies supplying medicines and health items under Federal Government subsidised schemes – PBS, RPBS and NDSS, both in terms of capital invested and cash flow. With the PBS and RPBS, this burden is heightened by the increased demand for expensive, specialised medicines through community pharmacies for which the return on investment is negligible, and the fact that while community pharmacies pay GST when purchasing the majority of their inventory, many of the medicines and health products sold by the pharmacy are GST-free. As a result, community pharmacies are GST-claimants with regards to their business activity statements, meaning the GST paid by the pharmacy cannot be used by the business until it is re-claimed.

In New Zealand and the UK, pharmacies are paid by their government medicine schemes monthly in advance, based on past dispensing patterns, with payments subsequently adjusted. This reduces the amount of capital required by the pharmacy and improves the cash flow. The Guild would support the Federal Government undertaking a cost-benefit analysis of reimbursing community pharmacies monthly in-advance on the basis of predicted prescription volumes.

Recommendation Number 27

The Guild recommends that immediately:

- DHS should amend the real-time feedback with PBS Online for S100 HSD prescriptions so that a Rejection rather than a Warning is provided.
- the Federal Government should take full responsibility and honour the payment of all PBS prescriptions dispensed during PBS Online outages when pharmacists do not receive real-time PBS claims feedback.
- DHS should monitor and manage the PBS Safety Net records for automatic issue of a Safety Net entitlement when the threshold is reached.
- the Federal Government should fund community pharmacies for linking and confirming the status of family members as part of the PBS Safety Net process.
• the Federal Government amends the legislation to address the anomaly whereby pharmacies are unable to claim for PBS scripts dispensed at the concessional rate on the day a patient dies.

• the Federal Government should undertake a cost-benefit analysis of moving to a system of reimbursing community pharmacies monthly in-advance on the basis of predicted prescription volume (with subsequent reconciliation) as occurs in international jurisdictions.

**Regulatory Compliance**

In addition to the State and Territory Health Departments, there are a number of Federal Government authorities responsible for regulating elements of relevance to pharmacy practice, of which the primary ones include:

- The DoH – *National Health Act 1953* and related instruments
- The TGA – *Therapeutic Goods Act 1989* and related instruments
- The AHPRA – *Health Practitioner Regulation National Law* and related instruments
- The ACCC – *Consumer Law*

With pharmacy operating in such a complex regulatory environment, the Guild is concerned when it receives reports of alleged regulatory non-compliance by pharmacists. While the Guild does not believe that non-compliance is rife within community pharmacy, the high level of competition and diminishing remuneration for dispensing are factors which can influence the extent of non-compliance. Of particular concern to date has been alleged non-compliance relating to advertising of medicines and pharmacy services and dispensing PBS medicines from non-PBS approved pharmacies.

In order to prevent any escalation of pharmacy non-compliance, the Guild would like to see proper investigation of any alleged breaches with evidence that reports are actioned. Reporting any alleged non-compliance activities is complicated and can be confusing and there is inconsistency between regulators as to how information is shared, if at all. Privacy laws should allow regulators to share information to more appropriately, effectively and efficiently manage any alleged non-compliance reports. Ideally, having one pathway for lodging a complaint would simplify the process, with appropriate systems in place to manage vexatious allegations. Without the evidence through communication by regulators to the profession that reports of non-compliance are actioned, the Guild is concerned it could result in ‘me-too’ activities which not only jeopardises the professional standing of the individual pharmacist/s involved, but can have a negative effect on the profession as a whole and may put consumers at risk.

With pharmacists continuing to be ranked as highly trustworthy in the minds of the public, the Guild does not want to see pharmacy as a profession devalued because of the poor behavior of a few. The Guild supports active investigation by pharmacy regulators of any reports of non-compliance and also supports communication from the regulators to demonstrate that non-compliance is taken seriously and is actioned. Complementing this, the Guild supports the regulators working with the profession to continually raise awareness of the regulatory requirements for pharmacy practice and focusing on areas identified as problematic.

In addition, the process for reporting any alleged regulatory breaches should be simple and clear, including for consumers. Consumers often take to social media or online websites to share negative experiences but may not know their rights or how to direct a query to a regulatory authority.
Recommendation Number 28

The Guild recommends that immediately:

- privacy laws should allow pharmacy regulators to share information to more efficiently and effectively manage matters of pharmacy practice non-compliance.
- all pharmacy regulators should review their policies and procedures with a view to greater sharing of information and referral of complaints, thus enabling one simplified pathway for lodging complaints about pharmacy practice.
- all Commonwealth pharmacy regulators should review their policies and procedures with a view to improving communications about compliance activities and outcomes for greater transparency.
PART FIVE - THE FUTURE OF PHARMACY

Integration of pharmacy with broader health system

If community pharmacy is to reach its full potential as a provider of health solutions to patients, it is critically important that it is better integrated with the broader health system.

In many ways, Australia lags behind other comparable countries in terms of pharmacy integration as well as tackling the need for a more coordinated and collaborative approach to patient care across the health system. As a nation, we have been slow in implementing the enablers such as collaborative care models, e-health enablement and transitional care arrangements. In terms of pharmacy, the UK and Canada in particular, have been much more pro-active in areas such as self-care, minor ailments, the inclusion of pharmacists in patient care teams, and in broadening the role of pharmacy and the scope of pharmacists to drive greater efficiencies and address areas of unmet health needs, including in rural and regional locations.

The reasons why Australia lags behind in terms of integrating pharmacy into the broader health care environment are many and varied. Traditionally, health policy development and implementation has occurred in silos, both within and across jurisdictions. The PBS and community pharmacy have been treated separately from the MBS, and other areas of health policy, including hospitals, population health, private health insurance, e-health, and broader workforce, rural and Aboriginal and Torres Strait Islander health. The systems of primary health care service delivery and remuneration have focused traditionally on individual health providers and practitioners, rather than on delivering overall patient health outcomes. Efforts to open up health service delivery in ways that enhance access, efficiency and coordination, have been seen as threats rather than opportunities to deliver more cost-effective health outcomes. Digital health enablement has been slow, including in relation to the development of collaborative tools, ensuring interoperability between systems and platforms, and the rollout and take-up of e-health by both health providers and patients.

There is some evidence that governments and private health providers are slowly embracing a more integrated approach to health service delivery through a greater focus on transitional care and referral pathways, as well as initiatives like the health care home, the reviews of private health insurance and the MBS, the focus on service delivery through PHNs and the emphasis on consumer-directed care in community based aged care and disabilities. However, there is a real risk that these initiatives will continue to exclude community pharmacy from the broader primary health care system and simply entrench existing siloed approaches to funding and service delivery. Community pharmacies are not included in the health care home. They are not recognised in the PHN core funding schedules. They have not been represented in the major reviews of the MBS and private health insurers or on the Board of the Australian Digital Health Agency. It is very difficult to develop integrated solutions when community pharmacies are not represented in the key policy development and implementation processes.

Pharmacies need to position themselves so they can play a central role in an integrated primary health care environment, sooner rather than later. Their main contribution in this integrated environment will be as medicines experts, as it is increasingly recognised that medicines adherence and medication management are critically important in a coordinated and holistic approach to delivering patient health outcomes. The need for greater integration will be accelerated by specialised and high-cost medicines, the administration and management of which will require increased collaboration, a more individualised patient-centred approach and a demand from funders for the highest levels of adherence. The integration of pharmacy into the broader primary health care system will also be driven by the need for greater efficiency and cost-effectiveness, along with an increased emphasis on prevention, early intervention and wellness as well as the ongoing need for a team-based approach to the support of patients with chronic
and complex diseases. Digital health will be a key enabler of the integration of community pharmacies into the broader health system, making it critically important that medicines that are supplied and patient services that are delivered through community pharmacies are uploaded into the MyHealth Record. Those pharmacies that establish themselves as true health destinations, able to deliver health solutions in a high-quality health-setting, using the skills of highly trained health practitioners who are practising at the top of their profession and utilising the latest digital technologies and collaborative tools and cultures, will lead the way in integrating with the broader health system.

**Pharmacists in General Practice**

Community pharmacy and general practice are integral and central parts of the health care system.

Closer collaboration between community pharmacists and general practice supported by integrated dispense and prescribing systems will improve the quality use of medicines, improve efficiency, reduce wastage and enhance the sustainability of the PBS for the betterment of individual patients as well as the broader Australian community.

Integrating pharmacists into general practice provides both an opportunity to enhance the collaboration between general practice and community pharmacy, and an opportunity to expand the scope of practice for pharmacists to better support people with chronic health conditions, particularly in regions in which there are GP shortages.

The Guild strongly believes that the best way to integrate a pharmacist into the general practice setting is through advancing the scope of practice of pharmacists to work as ‘Pharmacist Prescribers’ to deliver high quality patient care in collaboration with medical practitioners who would continue to have the overall responsibility for diagnosis. In the UK, the role of the pharmacist as a clinician has been strengthened by the development of prescribing rights with independent pharmacist prescribers being recognised as a vital source of clinical care in general practice.\(^{215}\)

The inclusion of a Pharmacist Prescriber into the primary health care team should increase the clinical capacity of general practice and assist in addressing the increasing demands in primary care.

The role of a Pharmacist Prescriber would include strengthening the link between general practice and the community pharmacy as well as improving a patient’s access to the health system and ensure the most cost-effective outcomes.

Importantly, these roles should not duplicate the support that patients already receive from their local community pharmacy but address the gaps in primary health care, particularly with the management of patients with more complex, chronic health conditions. The community pharmacy network is well placed to support GPs by providing common ailments services, supporting patient self-management for chronic conditions, providing preventative health services, and providing medicine reviews.

The Guild believes that for a Pharmacist Prescriber to be most effective within the general practice at maximum efficiency to the health system, they must:

- maintain and strengthen the patient’s relationship with their community pharmacy
- maintain and strengthen the relationship between the general practice and the local community pharmacies

• maintain and strengthen the communication between general practice and the local community pharmacies
• focus on areas of patient care that are not readily available through the local community pharmacy
• ensure efficient use of limited health funding by not duplicating services already being provided in the local community pharmacies
• not dispense medicines from the general practice
• remain professionally independent from the GPs within the practice
• support the general practice with prescribing audits and quality improvement in prescribing practice and medicine education
• be funded from outside the CPAs

Closer collaboration between community pharmacy and general practice can be achieved by enhanced communication and information technology such as secure messaging systems, telemedicine and electronic patient medicine profiles which can be used to ensure all health professionals are involved and the patient remains the centre of the health care system.

Where onsite pharmacist support may be of value, this can be achieved by sessional ‘Outreach Community Pharmacists’, making better use of existing trained pharmacists and infrastructure. These pharmacists, employed by local community pharmacies, could provide support to local general practices on an as needed contract basis. This would maximise efficiency and reduce any duplication of services.

**Recommendation Number 29**

The Guild recommends that immediately:

- the Federal Government should formally recognise in all relevant policies, legislation and regulation, and decision making processes that community pharmacies and pharmacists are primary health care providers.
- the Federal Government should identify and remove any policy, regulatory and funding eligibility barriers that prevent community pharmacies and pharmacists from delivering medicine and related care and support to patients as part of a coordinated and integrated approach to primary health care.

**Pharmacy Data**

Future health decision making will be increasingly data driven. Very large, rich patient, provider and population data sets will be interrogated, often in real time, in ways that will identify areas of unmet health needs, compare the cost-effectiveness of alternative treatment options, assess the outcomes delivered by health providers, and enable health practitioners to personalise care on the basis of a patient's individual attributes, while having access to the world's best health minds at their fingertips.

It is vital that this unprecedented access to patient and aggregated health data is utilised responsibly, while taking the opportunity to unleash its potential for better informed decision making, improved allocation of resources, and more efficient and effective service delivery.

As the primary funders of health care, governments are major holders of health data, but are unlikely to be the most capable and advanced in analysing their own data sets. It is therefore important that
governments provide access to their data to third parties who are best placed to analyse it and apply the analyses in ways that deliver more cost-effective and better targeted health outcomes. This must occur in a way that maintains the privacy and security of patients’ personal health data.

With some 350 million visits and around 300 million prescriptions dispensed annually, community pharmacy is a rich source of health data, which can be used to the benefit of individual patients and the betterment of the overall health system.

Virtually every community pharmacy in Australia operates technologically advanced dispensing and point of sale systems that collect and securely store health and transactional data. These systems connect with the pharmacy supply chain and, in the case of dispensing systems, also with the Federal Government through PBS Online and with prescribers through prescription exchange services.

Community pharmacies have been at the forefront of health data collection, reporting and storage, including through the provision of pharmacy practice incentives that encourage the recording of clinical interventions and pharmacy professional programs. Increasingly, pharmacies are working with medicines companies and other third parties to identify opportunities to deliver better patient outcomes through the intelligent use of pharmacy data in areas like compliance, risk assessment and early intervention and chronic disease management. The benefits of secure electronic recording are embedded in pharmacy quality management with pharmacies working on the premise that if an intervention isn’t electronically recorded, it never occurred.

Community pharmacies are often a patient’s first port of call in the health system and play a key role in navigating patients through the broader system. As such, it is likely that pharmacies will have an earlier understanding of a patient’s health issues and needs. Combining pharmacy data with data from other health providers can provide decision makers with a better understanding of patient pathways through the health system, including points in which they discontinue care or do not transition effectively to the most appropriate care settings. With access to the necessary data, pharmacies can also play a key role in addressing these issues, working in collaboration with other health care professionals.

Finally, consumers themselves are increasingly self-gathering data on their own state-of-health using wearables, impregnated devices and through remote monitoring. As the most accessible health providers with a strong focus on early intervention and health and wellbeing, community pharmacies can play a key role in analysing this health data for patients and providing them with appropriate incentives and support to maintain their health and obtain treatment and support where required.

**Recommendation Number 30**

The Guild recommends that:

- the Federal Government should provide access to its PBS and related health data, with appropriate safeguards to protect patients’ personal health information, to enable enhanced analysis of population health needs and health outcomes.
Pharmacist Workforce

The Review is being conducted at a time when there is significant concern about the future of the pharmacist profession. The Guild shares these concerns as all of our members are registered pharmacists and community pharmacies are by far the largest employer of pharmacists.

These concerns are not confined to Australia; they have also come to the fore in many comparable overseas countries and will be the focus of a major International Pharmaceutical Federation (FIP) workshop that the National President of the Guild is attending in November.

The primary purpose of the Review is not to address broader pharmacist workforce issues. However it needs to be understood that a viable future for community pharmacy and enabling pharmacists to have fulfilling, well remunerated careers practising at the top of their professional skills are intricately linked. Some two-thirds of all registered pharmacists work in and rely upon the viability of the community pharmacy network for their professional livelihoods.

A number of pharmacist practice and remuneration models have been publicly mooted and some are referred to in the Discussion Paper. The Guild believes that it would be inadvisable to see such models as panaceas for the pharmacist profession without fully understanding the repercussions for the wider pharmacist workforce. For example, the provision of certain patient services by pharmacists in GP surgeries that are already delivered through community pharmacies may not result in any net increase in pharmacist opportunities and could disadvantage larger numbers of pharmacists than those who benefit.

Around the world, it is increasingly being recognised that pharmacists can play an enhanced role in the health system, working mainly within their current scope of practice, but also through sensible expansion of their scope where there is evidence of unmet health need and it is demonstrated that pharmacists, with the right training and referral pathways, can meet those unmet needs in a safe and cost-effective way.

The reasons for the current concerns about the future of the pharmacist profession are many and varied. However, there is no doubt Australia is lagging many comparable countries in terms of fully utilising the medicines and wider health expertise of pharmacists, due to a combination of our traditional, siloed approach to health funding and health services delivery and the belligerent opposition of some doctor representatives, in stark contrast to their sister organisations in places like the UK. Second, there is no doubt that PBS reforms have forced many community pharmacies to reduce or not hire additional pharmacist staff and focus on managing their costs rather than identifying ways to expand their businesses into the health services space. Both these phenomena have occurred at the same time that there are record pharmacist graduate numbers with the deregulation of university places.

The answers to the current challenges facing the pharmacist workforce must be evidence-based with a need to resist ad hoc and piecemeal solutions without first having a thorough understanding of their flow-on implications or broader impact. Given that community pharmacies are by far the largest employer of pharmacists, it is highly likely that any successful pharmacist workforce strategy must be underpinned by a sustainable and viable community pharmacy network and a strong commitment by government and other funders to ensuring that community pharmacies have maximum opportunity to establish themselves as health destinations that are integrated with the wider health system.

Such a future workforce strategy should be developed by the broader pharmacy sector and pharmacist profession working together toward common objectives and fully informed by the best available data and evidence relating to future supply and demand as well as the major national and international health and medicines trends. The Pharmacy Faculty at Monash University has provided strong leadership in pharmacist workforce planning in recent years and it would make sense for its work to be built upon and
given the backing of the broader pharmacy sector, possibly working under the umbrella of the APLF. As the vast majority of the pharmacists work either directly for government or deliver clinical services such as dispensing that are funded by government, an investment by the Federal Government in the development of a comprehensive 10 to 20 year pharmacist workforce planning project would provide major impetus to this work.

**Recommendation Number 31:**
The Guild recommends that:

- a comprehensive, evidence-based, industry-led 10 to 20 year pharmacist workforce plan be developed with appropriate investment from the Federal Government.

**Future of Community Pharmacy**
The Review Panel has encouraged submitters to look forward 20 years to envisage the future of community pharmacy. The Guild lauds this long-term approach. The following synopsis envisages what community pharmacies might (and should) look like in 2025 at the end of the Seventh Community Pharmacy Agreement (7CPA). Given that one of the primary purposes of the Review is to inform the 7CPA, this timeframe will provide immediate practical benefit, recognising that longer term trends should, wherever possible, also be identified and taken into account

Any predictions about the future of community pharmacy need to be informed by an understanding of the main contributing factors to change, which include: demographic change; consumer preferences; medicine trends; government and other funding models; technology; pharmacist practice and international comparisons.

Like most western nations, Australia has an ageing population. People are living longer, often with a range of chronic health conditions, the effective management of which entails ongoing medical care, including access to often significant numbers of medicines. Health costs as a percentage of GDP are likely to continue to rise resulting in governments and other health funders to seek efficiencies through improved targeting, an increased emphasis on the most cost-effective means of delivery, and a greater focus on prevention and cost avoidance.

At the same time, it is likely that consumers will continue to want greater control over the management of their personal health needs, from insisting that they have electronic access to their personal health information at their fingertips, to wanting to retain maximum choice about their care, and being given greater flexibility about how they access care and their levels of patient financial contributions.

In a fiscally challenging environment, governments and other health funders will increasingly want to incentivise and fund the achievement of health outcomes and will favour health providers that are able to achieve evidence-based health outcomes at the lowest cost. A more outcomes-based funding approach will be underpinned by an increased focus on coordinated, patient-centred care with health providers collaborating in actual and virtualised health care team environments. It will also have a stronger focus on rewarding those patients who take personal responsibility for their own health and wellbeing.

This more coordinated and integrated approach to health care delivery will be enabled by a variety of technological advances, with a particular focus on remote diagnosis, treatment and monitoring; electronic health records; advanced analysis of health data; and the increasing personalisation of health driven by the patient’s genetic make-up and predictive computing technologies. The traditional siloes between health professions, physical health settings, and health systems and funding sources will gradually fall away, driven by the need for greater efficiency and consumer demand for increased choice.
These future trends pose both challenges and opportunities for community pharmacies.

The overall level of demand for medicines is likely to continue to remain strong, with governments seeking ways to maximise the proportion of these medicines that are dispensed through the less costly and more accessible community pharmacy network rather than more expensive and less accessible hospital settings. Being able to access the pipeline of both new medicines and those that have previously been dispensed through hospital is vital for community pharmacies as the future growth in the PBS will increasingly stem from these higher cost and breakthrough therapies. Pharmacies that demonstrate they have the skills, capacity and clinical settings to dispense and deliver the patient care and support around biologics and other specialised medicines will be in demand by funders, prescribers and patients.

With the predicted growth in the number of Australians living with complex, multiple morbidities, the clinical health role of community pharmacy in maximising medicine adherence and compliance will become increasingly important. Enabled by electronic access to patients’ medicine histories, community pharmacists will play an enhanced role in the active management of medicine regimen, working collaboratively with prescribers and other health professionals. Community pharmacists will play an increasing role in areas like prescription adaptation, de-prescribing, continued dispensing and medicine renewal, pharmaco-vigilance, medicine related point-of-care testing, and personalised medicines support that is tailored to individual patient needs. This more individualised approach to pharmacies’ core medicines expertise will be driven by a combination of outcomes-based funding models and demands by funders for high levels of compliance and adherence to high-cost medicines.

As is occurring in other countries, more and more community pharmacies will specialise in providing medicines and broader health services, support and advice for patients with specific chronic health conditions, addressing the needs of their local communities. Again, this will be undertaken in collaboration with other members of the patient’s health care team and may involve using the community pharmacy infrastructure as a location from which other health professionals deliver patient care, either physically or virtually enabled by communications technologies. Community pharmacies will increasingly establish themselves as a focal points for patients with conditions such as diabetes, offering a combination of medicines and other health products and services, while coordinating care and providing referrals and pathways across the broader health care system. Over time, community pharmacies will become chronic disease hubs, with community pharmacists broadening their skills in areas such as diabetes education, to improve patient access and choice and deliver more cost-effective health options for funders.

The focus of pharmacies on particular chronic health conditions will align closely with consumers’ increasing demand for holistic health solutions. Informed and empowered consumers will seek out health providers that are able to organise and deliver solutions that address their health needs. Pharmacies that understand their patients’ needs and are able to provide comprehensive health solutions will differentiate themselves and flourish. These health solutions are likely to encompass a combination of prescriptions, pharmacy-only medicines, OTC and complementary health products, medicine related services, health and wellbeing support, and remote and in-pharmacy health monitoring.

Like every sector, community pharmacies will continue to be impacted by technological change across all aspects of their businesses. Community pharmacies have consistently been early adopters of technology, from PBS Online, to the electronic transfer of prescriptions, to trialling e-health applications, and the electronic recording and reporting of pharmacist clinical interventions and services. Going forward, pharmacies will continue to embrace technologies that drive greater efficiencies in their businesses and enable them to deliver high quality medicine and broader health solutions to their patients. Consumer medicine support applications will become the norm. The transition to paper-optional scripts will occur over time, but should not be able to be used as a means to reduce competition, undermine patient choice or allow channelling by prescribers. Remote, wireless enabled, monitoring of medicine compliance and patient vital signs will be commonplace as will the use of video-conferencing to enable remote diagnoses.
and treatment. Technological advances in point-of-care and genetic testing will open up opportunities for pharmacies to deliver individualised medicine and broader health solutions. Radio Frequency Identification (RFID) and other logistics technologies will drive greater efficiency and choice in the pharmacy supply chain.

More broadly, the ongoing success of community pharmacies will be linked to their ability to fully integrate with and add value to the broader health care system. Pharmacies are increasingly recognising that in order to remain viable, they must derive revenues from a wider array of funding sources, both public and private. Their future success in accessing these new revenues will depend on their ability to show they can deliver enhanced health outcomes as part of an integrated approach to patient care that is enabled by a combination of inter-professional collaboration and shared access to patient data. Pharmacies will need to establish collaborative cultures, processes and systems, and those that take the lead in this regard will lead the way in patient service innovation.

Community pharmacies that are able to effectively integrate with the broader health system will also become active participants in the delivery of coordinated care plans for patients with chronic health conditions. They will be recognised as the essential first port of call for the medicine related care of patients transitioning between care settings through collaborative arrangements that link rather than separate medicine supply to medicine related patient support. The most successful integrated care models will break down the traditional barriers between health professionals by agnostically directing funding to those health providers that prove themselves to be most cost-effective in delivering measurable health outcomes. Pharmacies that demonstrate the capacity to manage their patients’ medicine and related health needs holistically will become recognised as essential members of the care team in these outcomes based, integrated care models.

As well as playing an enhanced role in chronic disease management and the delivery of broader health solutions, the community pharmacy of the future will increasingly become a preferred location for the treatment of minor ailments, vaccinations, preventive health, health checks and risk assessments, self-care and the tackling of health and lifestyle issues. Because of their accessibility as established and trusted health destinations, community pharmacies will be increasingly turned to by health funders and patients themselves as a preferred entry point into the health system, providing triage and navigating patients through the broader system. This will be even more the case in more isolated and disadvantaged communities where there is not ready access to other health professionals and where governments and other funders are determined to divert patients from other more expensive health settings such as hospitals.

Finally, the Review Panel has asked what the future pharmacy business model or models will look like, including whether they will be retail or health driven. The starting point is that community pharmacies are health providers that operate in a retailing environment. That is one of the strengths and underpins their unique role in the health system. As is the case today, the successful pharmacies of their future will continue to provide a combination of medicines, other products, services, support and advice that meet the needs of their patients. Over the next decade, the health and related needs of patients will change and successful pharmacies, like all good health providers, will truly understand the needs of their patients and be equipped to respond accordingly.

As is the case in other business sectors, individual pharmacies will increasingly seek to differentiate themselves by specialising in niches where there is a community need and they are in a position to use their competitive advantages to meet that need. This is largely a matter for individual pharmacy businesses with the role of government being to ensure that all Australians have timely and affordable access to the PBS through the community pharmacy network along with well-targeted, evidence-based medicine support and other health services, all of which are delivered to a quality standard that is needed to maximise patient health outcomes.
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<tr>
<td>83</td>
<td>Part Four: The Australian Pharmaceutical Supply Chain</td>
</tr>
<tr>
<td>84</td>
<td>Part Four: The Australian Pharmaceutical Supply Chain</td>
</tr>
<tr>
<td>85</td>
<td>Part Four: The Australian Pharmaceutical Supply Chain</td>
</tr>
<tr>
<td>86</td>
<td>Part Four: The Australian Pharmaceutical Supply Chain</td>
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<tr>
<td>87</td>
<td>Part Four: The Australian Pharmaceutical Supply Chain</td>
</tr>
<tr>
<td>88</td>
<td>Part Four: The Australian Pharmaceutical Supply Chain</td>
</tr>
<tr>
<td>89</td>
<td>Part Four: The Australian Pharmaceutical Supply Chain</td>
</tr>
<tr>
<td>90</td>
<td>Part Three: Standards and Quality</td>
</tr>
<tr>
<td>91</td>
<td>Part Four: Regulatory Compliance</td>
</tr>
<tr>
<td>92</td>
<td>Part Four: Digital Health</td>
</tr>
<tr>
<td></td>
<td>Part Five – Pharmacy Data</td>
</tr>
<tr>
<td>93</td>
<td>Part Four: Digital Health</td>
</tr>
<tr>
<td></td>
<td>Part Five – Pharmacy Data</td>
</tr>
<tr>
<td>94</td>
<td>Part Four: Digital Health</td>
</tr>
<tr>
<td></td>
<td>Part Five – Pharmacy Data</td>
</tr>
<tr>
<td>95</td>
<td>Part Three: Demand for pharmacy programs and services</td>
</tr>
<tr>
<td>96</td>
<td>Part One: Regulation of Pharmacy</td>
</tr>
<tr>
<td></td>
<td>Part Three – Consumer Expectations and Attitudes</td>
</tr>
<tr>
<td>97</td>
<td>Part Three: The Community Pharmacy Service Charter</td>
</tr>
<tr>
<td>98</td>
<td>Part Three: Standards and Quality</td>
</tr>
<tr>
<td>99</td>
<td>Part One: The Role of Community Pharmacy</td>
</tr>
<tr>
<td></td>
<td>Part Four: Dispensing related services</td>
</tr>
<tr>
<td>100</td>
<td>Part Four: Dispensing Remuneration</td>
</tr>
<tr>
<td>101</td>
<td>Part Four: Dispensing Remuneration</td>
</tr>
<tr>
<td>102</td>
<td>Part Four: Digital Health</td>
</tr>
<tr>
<td>103</td>
<td>Part Four: Dispensing related services</td>
</tr>
<tr>
<td>104</td>
<td>Part Four: Pharmacy Business Models</td>
</tr>
<tr>
<td>105</td>
<td>Part Three: Overall consumer experience</td>
</tr>
<tr>
<td></td>
<td>Part Four: Pharmacy Business Models</td>
</tr>
<tr>
<td>106</td>
<td>Part Three: Standards and Quality</td>
</tr>
<tr>
<td>107</td>
<td>Part Three: Consumer Expectations and attitudes</td>
</tr>
<tr>
<td>108</td>
<td>Part Four: Optional Co-payment discounts</td>
</tr>
<tr>
<td>109</td>
<td>Part Three: Consumer Expectations and attitudes</td>
</tr>
<tr>
<td>110</td>
<td>Part One: Advertising of Therapeutic Goods (medicines and devices)</td>
</tr>
<tr>
<td>111</td>
<td>Part Four: Pharmacy supply of OTC Medicines</td>
</tr>
<tr>
<td>112</td>
<td>Part Four: Pharmacy supply of OTC Medicines</td>
</tr>
<tr>
<td>113</td>
<td>Part Four: Dispensing Remuneration</td>
</tr>
<tr>
<td>114</td>
<td>Part Three: Complementary Medicines</td>
</tr>
<tr>
<td>115</td>
<td>Part Three: Complementary Medicines</td>
</tr>
<tr>
<td>116</td>
<td>Part Three: Complementary Medicines</td>
</tr>
<tr>
<td>117</td>
<td>Part Three: Complementary Medicines</td>
</tr>
<tr>
<td>118</td>
<td>Part Two: The economic rationale for the community pharmacy model</td>
</tr>
<tr>
<td></td>
<td>Part Four: Pharmacy Business Models</td>
</tr>
<tr>
<td></td>
<td>Part Three: Complementary Medicines</td>
</tr>
<tr>
<td>119</td>
<td>Part Four: Optional Co-payment discounts</td>
</tr>
<tr>
<td>120</td>
<td>Part Four: Optional Co-payment discounts</td>
</tr>
<tr>
<td>121</td>
<td>Part Two: Regulation and remuneration of community pharmacy and it’s outcomes</td>
</tr>
<tr>
<td>122</td>
<td>Part Four: Optional Co-payment discounts</td>
</tr>
<tr>
<td>Page</td>
<td>Section</td>
</tr>
<tr>
<td>------</td>
<td>---------</td>
</tr>
<tr>
<td>123</td>
<td>Part Four: Optional Co-payment discounts</td>
</tr>
<tr>
<td>124</td>
<td>Part Three – Consumer Expectations and Attitudes</td>
</tr>
<tr>
<td>125</td>
<td>Part Three – Consumer Expectations and Attitudes</td>
</tr>
<tr>
<td>126</td>
<td>Part Four: Better Utilisation of Community Pharmacy</td>
</tr>
</tbody>
</table>
| 127  | Part Four: Non dispensing pharmacy supply arrangements  
Part Four: Problems with the Supply of high cost medicines and S100 listed items |
| 130  | Part Four: Access to medicines by older Australians  
Part Four: CTG PBS Co-Payment measure |
| 131  | Part Three – Consumer Expectations and Attitudes |
| 132  | Part Three – Consumer Expectations and Attitudes |
| 133  | Part Four: Chemotherapy |
| 134  | Part Four: Chemotherapy |
| 135  | Part Four: Chemotherapy |
| 136  | Part Four: Chemotherapy |
| 137  | Part Four: Chemotherapy |
| 138  | Part Four: Chemotherapy |
| 139  | Part Three: Standards and Quality  
Part Four: Chemotherapy |
| 140  | Part Four: Chemotherapy |
Appendix 2 - Accessibility – Geospatial evidence

By any comparable measure, community pharmacies in Australia are highly accessible.

The Guild engaged MacroPlan Dimasi to compare pharmacy accessibility to other, similarly essential, services such as medical centres, supermarkets (of different sizes).

The results of that analysis are quite remarkable and demonstrate the success of the current pharmacy model in providing almost universal access to prescription medicines and other pharmacy services.

**Accessibility to vital services, pharmacy, medical centres, supermarkets**

**Table 1 – Accessibility at Grade 1a level (2.5km urban and regional)**

(see Table 17 for details)

<table>
<thead>
<tr>
<th>Region</th>
<th>Pharmacy</th>
<th>Medical Centre</th>
<th>Supermarket</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital Cities</td>
<td>97%</td>
<td>97%</td>
<td>94%</td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>65%</td>
<td>64%</td>
<td>57%</td>
</tr>
<tr>
<td>Total AUS</td>
<td>88%</td>
<td>88%</td>
<td>83%</td>
</tr>
</tbody>
</table>

**Source:** MacroPlan Dimasi Analysis

Note: Grade 1a Accessibility: Proportion of people having access to at least 1 pharmacy/medical centre/supermarket within 2.5km radius in Metropolitan and Regional Areas.

**Table 2 – Accessibility at Grade 1b level (2.5km urban and 5km regional)**

(see Table 18 for details)

<table>
<thead>
<tr>
<th>Region 2.5km(CC)/5.0km(RoA)</th>
<th>Pharmacy</th>
<th>Medical Centre</th>
<th>Supermarket</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital Cities</td>
<td>97%</td>
<td>97%</td>
<td>94%</td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>76%</td>
<td>74%</td>
<td>68%</td>
</tr>
<tr>
<td>Total Australia</td>
<td>91%</td>
<td>91%</td>
<td>87%</td>
</tr>
</tbody>
</table>

**Source:** MacroPlan Dimasi

Note: Grade 1b Accessibility: Proportion of people having access to at least 1 pharmacy/medical centre/supermarket within 2.5km radius in Metropolitan Areas and 5km radius in Regional Areas.

**Accessibility and Choice**

**Table 3 – Accessibility at Grade 2a level (2.5km urban and regional)**

(see Table 19 for details)

<table>
<thead>
<tr>
<th>Region</th>
<th>Pharmacy</th>
<th>Medical Centre</th>
<th>Supermarket</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital Cities</td>
<td>94%</td>
<td>96%</td>
<td>90%</td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>48%</td>
<td>50%</td>
<td>43%</td>
</tr>
<tr>
<td>Total AUS</td>
<td>81%</td>
<td>82%</td>
<td>77%</td>
</tr>
</tbody>
</table>

**Source:** MacroPlan Dimasi Analysis

Note: Grade 2a Accessibility: Proportion of people having access to at least 2 pharmacy/medical centre/supermarket within 2.5km radius in Metropolitan and Regional Areas.

Capital Cities are defined as areas with a Modified Monash Model (MMM) classification of 1. MMM classifications 2-7 are defined as Rest of Australia.
Table 4 – Accessibility at Grade 2b level (2.5km urban and 5km regional)  
(see Table 20 for details)

<table>
<thead>
<tr>
<th>Region</th>
<th>Pharmacy</th>
<th>Medical Centre</th>
<th>Supermarket</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5km(CC)/5.0km(RoA)</td>
<td>94%</td>
<td>96%</td>
<td>90%</td>
</tr>
<tr>
<td>Capital Cities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>76%</td>
<td>74%</td>
<td>68%</td>
</tr>
<tr>
<td>Total AUS</td>
<td>85%</td>
<td>86%</td>
<td>81%</td>
</tr>
</tbody>
</table>

Source: MacroPlan Dimasi

Note: Grade 2b Accessibility: Proportion of people having access to at least 2 pharmacy/medical centre/supermarket within 2.5km radius in Metropolitan Areas and 5km radius in Regional Areas.

The tables 1 - 4 above demonstrate that pharmacy matches medical centres in terms of accessibility.

This is despite the fact there are over 1,500 (27%) more medical centres compared to pharmacies across Australia in total, notwithstanding the very broad definition of 'medical centre'. In areas outside of capital cities, the level of accessibility is slightly higher for pharmacies despite the fact that there are 447 (22%) fewer pharmacies compared to medical centres in those areas.

See Table 14. (Number of Pharmacies, Medical Centres and Supermarkets by Region)

The tables 1 - 4 above show that consumers have not only high level of access but also have choice in their local areas (i.e. high proportion of consumers having access to at least 2 pharmacies within 2.5km/5km radius).

These results indicate that under the current framework, a strong distribution of pharmacies can be achieved in a highly efficient manner.

**After Hours Accessibility**

Pharmacy also compares extremely well in terms of after-hours accessibility compared to other vital services. Table 5 below shows that after-hours pharmacy access on both weekdays and weekends is significantly better than medical centres in both capital cities and the rest of Australia. Pharmacy also compares well to supermarkets (which includes both large and small supermarkets). For instance, in capital cities on weekdays a consumer is about as likely to find a pharmacy within 2.5 km as a supermarket.

---

1 It should be noted that a proportion of the medical centres counted in the analysis are either not open 7 days per week or may not have a qualified GP present on a full-time basis. Therefore the accessibility estimate for medical centres can be regarded as an overestimate. In addition, some medical centres (for instance Aboriginal Health Services) are not subject to commercial pressures as they are funded by the Commonwealth and/or State and Territory Health Governments and are therefore largely immune from locational decisions in a commercial sense.
## Table 5 – After-hours accessibility to vital services, pharmacy, medical centres, supermarkets
(see Table 21 for details)

<table>
<thead>
<tr>
<th>After Hours*</th>
<th>Pharmacy</th>
<th>Medical Centre</th>
<th>Supermarket</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>weekday</td>
<td>weekday</td>
<td>weekday</td>
</tr>
<tr>
<td></td>
<td>weekend</td>
<td>weekend</td>
<td>weekend</td>
</tr>
<tr>
<td>Capital Cities</td>
<td>92%</td>
<td>73%</td>
<td>75%</td>
</tr>
<tr>
<td></td>
<td>75%</td>
<td>40%</td>
<td>94%</td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>45%</td>
<td>32%</td>
<td>34%</td>
</tr>
<tr>
<td></td>
<td>34%</td>
<td>15%</td>
<td>67%</td>
</tr>
<tr>
<td>Total Australia</td>
<td>80%</td>
<td>63%</td>
<td>65%</td>
</tr>
<tr>
<td></td>
<td>65%</td>
<td>34%</td>
<td>87%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>80%</td>
</tr>
</tbody>
</table>

Source: MacroPlan Dimasi

Note: Grade 1b Accessibility: Proportion of people having access to at least 1 pharmacy/medical centre/supermarket within 2.5km radius in Metropolitan Areas and 5km radius in Regional Areas. Modified Monash Model (MMM), Rural and Regional Health boundaries are used for defining regions.

* After Hours weekday: Defined as a facility open after 6pm on Wednesday. After Hours weekend: Defined as a facility open after 6pm on Saturday.

## Table 6 – Correlation Analysis - Pharmacies & Medical Centres within 200m of each other by region
(see Table 15 for details)

<table>
<thead>
<tr>
<th>Region*</th>
<th>Percentage of Pharmacies still open after Medical Centre closes (%)</th>
<th>Percentage of Medical Centres still open after Pharmacy closes (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Weekdays</td>
<td>Weekends</td>
</tr>
<tr>
<td>Capital Cities</td>
<td>73%</td>
<td>45%</td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>72%</td>
<td>31%</td>
</tr>
<tr>
<td>Total AUS</td>
<td>72%</td>
<td>41%</td>
</tr>
</tbody>
</table>

Source: ABS Census 2011; MapInfo; MacroPlan Dimasi

* Greater Capital Cities Statistical Area (GCCSA), ASGS 2011 Edition (ABS cat. no. 1270.0.55.001) boundaries are used for defining regions

The table 6 above shows a correlation analysis between the opening hours of pharmacies and medical centres that are within 200m of each other.

On average across Australia, close to three quarters (72%) of pharmacies are still open on weekdays after the nearest medical centre (within 200m) has closed. On weekends, 41% of pharmacies are still open after hours after the nearest medical centre has closed.

Conversely, just 9% of medical centres are open after the nearest pharmacy has closed. Outside of capital cities, 31% of pharmacies are still open on weekends after the nearest medical centre has closed.

## Table 7 – Correlation Analysis - Pharmacies & Medical Centres (300m in capital cities, 5km in regional area) of each other by region
(see Table 16 for details)

<table>
<thead>
<tr>
<th>Region*</th>
<th>Percentage of Pharmacies still open after Medical Centre closes**</th>
<th>Percentage of Medical Centres still open after Pharmacy closes**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Weekdays</td>
<td>Weekends</td>
</tr>
<tr>
<td>Capital Cities</td>
<td>85%</td>
<td>84%</td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>91%</td>
<td>87%</td>
</tr>
<tr>
<td>Total AUS</td>
<td>88%</td>
<td>85%</td>
</tr>
</tbody>
</table>

Source: MacroPlan Dimasi

* Greater Capital Cities Statistical Area (GCCSA), ASGS 2011 Edition (ABS cat. no. 1270.0.55.001) boundaries are used for defining regions

** Any facility within the defined region - 300m in capital cities and 5km in regional areas
Outside of capital cities, 88% of pharmacies are still open on weekdays after the nearest medical centres (defined as 5km in regional cities) has closed. On weekends, 85% of pharmacies are still open after hours after the nearest medical centre has closed.

In contrast, just 22% of medical centres are open after the nearest pharmacy has closed on weekdays. On weekends 25% of medical centres are open after the nearest pharmacy has closed.

**This is further evidence of the accessibility of pharmacies near medical centres, meeting the needs of patients who may require prescription filled after a visit to the medical centre.**

**Accessibility by Age Profile**

The table 8 below looks at whether there was a difference in accessibility between the over-65s and the under-65s.

**Table 8 – Estimated Accessibility of Pharmacies by Age Profile (kms from residence) - 2016**

<table>
<thead>
<tr>
<th>Region</th>
<th>Up to Age 65</th>
<th>65 &amp; over</th>
<th>Total Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital Cities</td>
<td>0.9</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>6.8</td>
<td>4.2</td>
<td>6.4</td>
</tr>
<tr>
<td>Total AUS</td>
<td>2.9</td>
<td>2.2</td>
<td>2.8</td>
</tr>
</tbody>
</table>

Source: ABS Census of Population & Housing, 2011; MacroPlan Dimasi
Greater Capital Cities Statistical Area (GCCSA), ASGS 2011 Edition (ABS cat. no. 1270.0.55.001) boundaries are used for defining regions

First, in Australia’s capital cities, on average, a resident is located under 1km from the nearest pharmacy. This is an extraordinary level of access to a service that all Australians rely on. Outside the capital cities, country residents are 6.4km on average from the nearest pharmacy. Considering the vastness of the Australian continent and our very low population density, this is an equally extraordinary result. Across Australia, in both the capital cities and the regions, the over-65s enjoy better access to pharmacy than the under-65s.

The difference between the age groups in the regions is significant, with the over-65s (4.2km) being much closer to the nearest pharmacy than the under-65s (6.8km). Given that the level of reliance on a local community pharmacy increases with age this difference in accessibility indicates that the current arrangements are fostering an appropriate distribution of community pharmacies.

**Comparison to the 2014 and 1998 analysis**

The Guild undertook a similar analysis of accessibility by age cohort in 2014 and 1998. The results are remarkably similar and generally improved.

**Table 9 – Estimated Accessibility of Pharmacies by Age Profile (km from residence) – 2014**

<table>
<thead>
<tr>
<th>Region</th>
<th>Up to Age 65</th>
<th>65 &amp; over</th>
<th>Total Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital Cities</td>
<td>1</td>
<td>0.9</td>
<td>1</td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>6.9</td>
<td>4.3</td>
<td>6.5</td>
</tr>
<tr>
<td>Total AUS</td>
<td>3.1</td>
<td>2.3</td>
<td>3</td>
</tr>
</tbody>
</table>

Source: MacroPlan Dimasi 2014
Table 10 – Accessibility by age groups and region (1998 survey) km from residence

<table>
<thead>
<tr>
<th>Region</th>
<th>Up to 54 yrs</th>
<th>55-64 yrs</th>
<th>65+ years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metro</td>
<td>1.1</td>
<td>1</td>
<td>0.9</td>
<td>1.1</td>
</tr>
<tr>
<td>Rural</td>
<td>6.9</td>
<td>6.8</td>
<td>5.3</td>
<td>6.7</td>
</tr>
<tr>
<td>Remote</td>
<td>58.6</td>
<td>58.4</td>
<td>48.7</td>
<td>57.9</td>
</tr>
<tr>
<td>Total AUS</td>
<td>4.7</td>
<td>4.5</td>
<td>3.1</td>
<td>4.5</td>
</tr>
</tbody>
</table>

Source: Pharmacy Accessibility Study 1998 Culevnor & Associates

**Pharmacies and Hospitals accessibility**

Table 11 – Accessibility at Grade 1a level (2.5km urban and regional)
(see Table 27 for details)

<table>
<thead>
<tr>
<th>Region</th>
<th>Pharmacy</th>
<th>Hospitals</th>
<th>Combined Pharmacy and Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital Cities</td>
<td>97%</td>
<td>35%</td>
<td>97%</td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>65%</td>
<td>27%</td>
<td>66%</td>
</tr>
<tr>
<td>Total AUS</td>
<td>88%</td>
<td>32%</td>
<td>88%</td>
</tr>
</tbody>
</table>

Source: MacroPlan Dimasi

Grade 1a Accessibility: Proportion of people having access to at least 1 pharmacy/medical centre/supermarket within 2.5km radius in Metropolitan and Regional Areas.

Capital Cities are defined as areas with a Modified Monash Model (MMM) classification of 1. MMM classifications 2-7 are defined as Rest of Australia

Table 12 – Accessibility at Grade 1b level (2.5km urban and 5km regional)
(see Table 28 for details)

<table>
<thead>
<tr>
<th>Region</th>
<th>Pharmacy</th>
<th>Hospitals</th>
<th>Combined Pharmacy and Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital Cities</td>
<td>97%</td>
<td>35%</td>
<td>97%</td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>76%</td>
<td>44%</td>
<td>76%</td>
</tr>
<tr>
<td>Total AUS</td>
<td>91%</td>
<td>37%</td>
<td>91%</td>
</tr>
</tbody>
</table>

Source: MacroPlan Dimasi

Grade 1b Accessibility: Proportion of people having access to at least 1 pharmacy/hospital within 2.5km radius in Metropolitan Areas and 5km radius in Regional Areas.

Capital Cities are defined as areas with a Modified Monash Model (MMM) classification of 1. MMM classifications 2-7 are defined as Rest of Australia

The tables 9 - 12 above demonstrate that under a hypothetical scenario where all hospitals were to include a community pharmacy, the level of consumer accessibility would remain virtually unchanged. Such a proposal would merely increase the number of community pharmacies in Australia, without any discernable improvement to consumer access.
### 13. Estimated Accessibility of Pharmacies by Age Profile

Average distance (km) per person by age group

<table>
<thead>
<tr>
<th>Region*</th>
<th>Up to age 65</th>
<th>65 &amp; over</th>
<th>Total</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall (km)</td>
<td>After Hours**</td>
<td>Overall (km)</td>
<td>After Hours**</td>
</tr>
<tr>
<td></td>
<td>Weekdays (km)</td>
<td>Weekends(km)</td>
<td>Weekdays (km)</td>
<td>Weekends(km)</td>
</tr>
<tr>
<td>Sydney</td>
<td>0.8</td>
<td>1.1</td>
<td>2.2</td>
<td>0.8</td>
</tr>
<tr>
<td>Rest of NSW</td>
<td>3.9</td>
<td>19.5</td>
<td>29.8</td>
<td>3.4</td>
</tr>
<tr>
<td>Total NSW</td>
<td>1.9</td>
<td>7.5</td>
<td>11.8</td>
<td>1.9</td>
</tr>
<tr>
<td>Melbourne</td>
<td>0.9</td>
<td>1.4</td>
<td>2.4</td>
<td>0.9</td>
</tr>
<tr>
<td>Rest of VIC</td>
<td>4.0</td>
<td>17.1</td>
<td>40.0</td>
<td>3.5</td>
</tr>
<tr>
<td>Total VIC</td>
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</tr>
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<tr>
<td>Rest of QLD</td>
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<tr>
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<td>20.6</td>
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<tr>
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<td>3.0</td>
</tr>
<tr>
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<td>2.3</td>
<td>4.9</td>
<td>1.7</td>
</tr>
<tr>
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<td>247.1</td>
<td>251.2</td>
<td>83.9</td>
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<td>110.7</td>
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<tr>
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<td>3.0</td>
<td>0.9</td>
</tr>
<tr>
<td>Capital Cities</td>
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<td>2.6</td>
<td>0.9</td>
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<td>Rest of Australia</td>
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<td>15.7</td>
<td>2.2</td>
</tr>
</tbody>
</table>

As at April 2016
Source: ABS Census of Population & Housing, 2011; MacroPlan Dimasi

* Greater Capital Cities Statistical Area (GCCSA), ASGS 2011 Edition (ABS cat. no. 1270.0.55.001) boundaries are used for defining regions

**After hours Weekday: Defined as a facility open after 6pm on Wednesday

**After hours Weekend: Defined as a facility open after 6pm on Saturday

Table details the average accessibility (distance – km) of pharmacies for people by GCCSA regions for people aged under 65 years, over 65 and overall. It furthers narrows down the accessibility by after hours on weekdays and weekends.
## 14. Number of Pharmacies, Medical Centres & Supermarkets by Region

<table>
<thead>
<tr>
<th>Region</th>
<th>Overall</th>
<th>Pharmacy</th>
<th>Medical Centres</th>
<th>All Supermarket</th>
<th>Large Supermarket</th>
<th>Small Supermarket</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall</td>
<td>After Hours**</td>
<td>Overall</td>
<td>After Hours**</td>
<td>Overall</td>
<td>After Hours**</td>
</tr>
<tr>
<td></td>
<td>Weekdays</td>
<td>Weekends</td>
<td>Weekdays</td>
<td>Weekends</td>
<td>Weekdays</td>
<td>Weekends</td>
</tr>
<tr>
<td>Sydney</td>
<td>1,214</td>
<td>723</td>
<td>250</td>
<td>1,798</td>
<td>279</td>
<td>73</td>
</tr>
<tr>
<td>Rest of NSW</td>
<td>706</td>
<td>164</td>
<td>74</td>
<td>882</td>
<td>68</td>
<td>11</td>
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<tr>
<td>Total NSW</td>
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<td>887</td>
<td>324</td>
<td>2,679</td>
<td>347</td>
<td>84</td>
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<tr>
<td>Melbourne</td>
<td>996</td>
<td>566</td>
<td>192</td>
<td>1,324</td>
<td>301</td>
<td>79</td>
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<tr>
<td>Rest of VIC</td>
<td>346</td>
<td>80</td>
<td>24</td>
<td>415</td>
<td>60</td>
<td>10</td>
</tr>
<tr>
<td>Total VIC</td>
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<td>646</td>
<td>216</td>
<td>1,740</td>
<td>361</td>
<td>89</td>
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<tr>
<td>Brisbane</td>
<td>520</td>
<td>240</td>
<td>64</td>
<td>653</td>
<td>98</td>
<td>26</td>
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<tr>
<td>Rest of QLD</td>
<td>636</td>
<td>176</td>
<td>64</td>
<td>783</td>
<td>54</td>
<td>18</td>
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<tr>
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<td>1,436</td>
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<tr>
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<td>335</td>
<td>174</td>
<td>77</td>
<td>379</td>
<td>55</td>
<td>18</td>
</tr>
<tr>
<td>Rest of SA</td>
<td>129</td>
<td>17</td>
<td>30</td>
<td>131</td>
<td>11</td>
<td>3</td>
</tr>
<tr>
<td>Total SA</td>
<td>464</td>
<td>191</td>
<td>107</td>
<td>510</td>
<td>66</td>
<td>21</td>
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<tr>
<td>Perth</td>
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<td>148</td>
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<tr>
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<td>19</td>
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<tr>
<td>Total WA</td>
<td>615</td>
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<td>167</td>
<td>628</td>
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<tr>
<td>Hobart</td>
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<td>12</td>
<td>72</td>
<td>4</td>
<td>2</td>
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<tr>
<td>Rest of TAS</td>
<td>89</td>
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<td>26</td>
<td>159</td>
<td>17</td>
<td>3</td>
</tr>
<tr>
<td>Darwin</td>
<td>26</td>
<td>16</td>
<td>4</td>
<td>39</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Rest of NT</td>
<td>8</td>
<td>1</td>
<td>1</td>
<td>37</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Total NT</td>
<td>34</td>
<td>17</td>
<td>9</td>
<td>76</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>Total ACT</td>
<td>75</td>
<td>49</td>
<td>12</td>
<td>86</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Capital Cities</td>
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<td>2,075</td>
<td>759</td>
<td>4,804</td>
<td>832</td>
<td>224</td>
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<tr>
<td>Rest of Australia</td>
<td>2,063</td>
<td>481</td>
<td>226</td>
<td>2,510</td>
<td>232</td>
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<tr>
<td>Total AUS</td>
<td>5,762</td>
<td>2,556</td>
<td>985</td>
<td>7,314</td>
<td>1,064</td>
<td>295</td>
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</tbody>
</table>

As at April 2016

Source: ABS Census of Population & Housing, 2011; MacroPlan Dimasi

* Greater Capital Cities Statistical Area (GCCSA), ASGS 2011 Edition (ABS cat. no. 1270.0.55.001) boundaries are used for defining regions
** After hours weekday: Defined as a facility open after 6pm on Wednesday
** After hours weekend: Defined as a facility open after 6pm on Saturday

Lists the actual number of facilities by GCCSA regions. For example: Sydney has 1,214 pharmacies. Out of these, only 723 open after 6pm on weekdays while 250 open after 6pm on weekends.
## 15. Correlation Analysis - Pharmacies & Medical Centres
Pharmacies/Medical Centres within 200m of each other by region

<table>
<thead>
<tr>
<th>Region*</th>
<th>Percentage of Pharmacies still open after Medical Centre closes (%)</th>
<th>Percentage of Medical Centres still open after Pharmacy closes (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Weekdays</td>
<td>Weekends</td>
</tr>
<tr>
<td>Sydney</td>
<td>70%</td>
<td>41%</td>
</tr>
<tr>
<td>Rest of NSW</td>
<td>71%</td>
<td>23%</td>
</tr>
<tr>
<td>Total NSW</td>
<td>71%</td>
<td>36%</td>
</tr>
<tr>
<td>Melbourne</td>
<td>76%</td>
<td>56%</td>
</tr>
<tr>
<td>Rest of VIC</td>
<td>73%</td>
<td>36%</td>
</tr>
<tr>
<td>Total VIC</td>
<td>75%</td>
<td>52%</td>
</tr>
<tr>
<td>Brisbane</td>
<td>71%</td>
<td>33%</td>
</tr>
<tr>
<td>Rest of QLD</td>
<td>76%</td>
<td>38%</td>
</tr>
<tr>
<td>Total QLD</td>
<td>73%</td>
<td>36%</td>
</tr>
<tr>
<td>Adelaide</td>
<td>77%</td>
<td>47%</td>
</tr>
<tr>
<td>Rest of SA</td>
<td>76%</td>
<td>36%</td>
</tr>
<tr>
<td>Total SA</td>
<td>77%</td>
<td>45%</td>
</tr>
<tr>
<td>Perth</td>
<td>73%</td>
<td>49%</td>
</tr>
<tr>
<td>Rest of WA</td>
<td>63%</td>
<td>28%</td>
</tr>
<tr>
<td>Total WA</td>
<td>72%</td>
<td>46%</td>
</tr>
<tr>
<td>Hobart</td>
<td>72%</td>
<td>24%</td>
</tr>
<tr>
<td>Rest of TAS</td>
<td>41%</td>
<td>36%</td>
</tr>
<tr>
<td>Total TAS</td>
<td>58%</td>
<td>29%</td>
</tr>
<tr>
<td>Darwin</td>
<td>75%</td>
<td>33%</td>
</tr>
<tr>
<td>Rest of NT</td>
<td>100%</td>
<td>0%</td>
</tr>
<tr>
<td>Total NT</td>
<td>77%</td>
<td>31%</td>
</tr>
<tr>
<td>Total ACT</td>
<td>73%</td>
<td>51%</td>
</tr>
<tr>
<td>Capital Cities</td>
<td>73%</td>
<td>45%</td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>72%</td>
<td>31%</td>
</tr>
<tr>
<td>Total AUS</td>
<td>72%</td>
<td>41%</td>
</tr>
</tbody>
</table>

As at April 2016
* Greater Capital Cities Statistical Area (GCCSA), ASGS 2011 Edition (ABS cat. no. 1270.0.55.001) boundaries are used for defining regions
Source: ABS Census 2011; MapInfo; The Pharmacy Guild of Australia; MacroPlan Dimasi

This list entails the percentage of:
- a) Pharmacy which are still open after the closest medical centres within 200m closes down on weekdays and weekends
- b) Medical Centres which is still open after the closest pharmacies within 200m closes down on weekdays and weekends
### 16. Correlation Analysis - Pharmacies & Medical Centres

Pharmacies/Medical Centres within (300m in capital cities, 5km in regional area) of each other by region

<table>
<thead>
<tr>
<th>Region*</th>
<th>Percentage of Pharmacies still open after Medical Centre closes**</th>
<th>Percentage of Medical Centres still open after Pharmacy closes**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Weekdays</td>
<td>Weekends</td>
</tr>
<tr>
<td>Sydney</td>
<td>87%</td>
<td>83%</td>
</tr>
<tr>
<td>Rest of NSW</td>
<td>92%</td>
<td>87%</td>
</tr>
<tr>
<td>Total NSW</td>
<td>89%</td>
<td>84%</td>
</tr>
<tr>
<td>Melbourne</td>
<td>86%</td>
<td>83%</td>
</tr>
<tr>
<td>Rest of VIC</td>
<td>94%</td>
<td>88%</td>
</tr>
<tr>
<td>Total VIC</td>
<td>88%</td>
<td>85%</td>
</tr>
<tr>
<td>Brisbane</td>
<td>82%</td>
<td>83%</td>
</tr>
<tr>
<td>Rest of QLD</td>
<td>94%</td>
<td>90%</td>
</tr>
<tr>
<td>Total QLD</td>
<td>89%</td>
<td>87%</td>
</tr>
<tr>
<td>Adelaide</td>
<td>83%</td>
<td>82%</td>
</tr>
<tr>
<td>Rest of SA</td>
<td>87%</td>
<td>76%</td>
</tr>
<tr>
<td>Total SA</td>
<td>85%</td>
<td>80%</td>
</tr>
<tr>
<td>Perth</td>
<td>81%</td>
<td>87%</td>
</tr>
<tr>
<td>Rest of WA</td>
<td>79%</td>
<td>92%</td>
</tr>
<tr>
<td>Total WA</td>
<td>80%</td>
<td>88%</td>
</tr>
<tr>
<td>Hobart</td>
<td>82%</td>
<td>94%</td>
</tr>
<tr>
<td>Rest of TAS</td>
<td>80%</td>
<td>71%</td>
</tr>
<tr>
<td>Total TAS</td>
<td>81%</td>
<td>79%</td>
</tr>
<tr>
<td>Darwin</td>
<td>100%</td>
<td>94%</td>
</tr>
<tr>
<td>Rest of NT</td>
<td>86%</td>
<td>86%</td>
</tr>
<tr>
<td>Total NT</td>
<td>96%</td>
<td>91%</td>
</tr>
<tr>
<td>Total ACT</td>
<td>82%</td>
<td>82%</td>
</tr>
<tr>
<td>Capital Cities</td>
<td>85%</td>
<td>84%</td>
</tr>
<tr>
<td>Rest of Australia</td>
<td>91%</td>
<td>87%</td>
</tr>
<tr>
<td>Total AUS</td>
<td>88%</td>
<td>85%</td>
</tr>
</tbody>
</table>

As at April 2016

* Greater Capital Cities Statistical Area (GCCSA), ASGS 2011 Edition (ABS cat. no. 1270.0.55.001) boundaries are used for defining regions

** Any facility within the defined region - 300m in capital cities and 5km in regional areas

This tables shows:

a) Percentage of any pharmacy which is still open after medical centres are closed within – 300m in capital cities & 5km in regional cities

b) Percentage of any medical centre which is still open after pharmacies are closed within – 300m in capital cities & 5km in regional cities
### 17. Grade 1a Accessibility*

#### Accessibility within 2.5 km radius

<table>
<thead>
<tr>
<th>State</th>
<th>Modified Monash Model Classification **</th>
<th>Pharmacy</th>
<th>Medical Centre</th>
<th>Supermarket</th>
<th>Large Supermarket</th>
<th>Small Supermarket</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NSW</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
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<td>98%</td>
<td>94%</td>
<td>88%</td>
<td>86%</td>
</tr>
<tr>
<td>2</td>
<td></td>
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<td>44%</td>
<td>36%</td>
<td>32%</td>
</tr>
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<td>60%</td>
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</tr>
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<tr>
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<td>77%</td>
<td>75%</td>
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<td>98%</td>
<td>98%</td>
<td>96%</td>
<td>92%</td>
<td>86%</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>71%</td>
<td>72%</td>
<td>68%</td>
<td>59%</td>
<td>44%</td>
</tr>
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<td></td>
<td>80%</td>
<td>80%</td>
<td>77%</td>
<td>70%</td>
<td>64%</td>
</tr>
<tr>
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<td>63%</td>
</tr>
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<tr>
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<td>60%</td>
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<td>9%</td>
<td>11%</td>
</tr>
<tr>
<td><strong>Total VIC</strong></td>
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<td>82%</td>
<td>76%</td>
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<td>61%</td>
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Source: Rural and Regional Health Australia (RRHA); ABS Census of Population & Housing, 2011; Pharmacy Guild of Australia; MacroPlan Dimasi

*Note: Grade 1a Accessibility Methodology: Proportion of people having access to at least 1 pharmacy/medical centre/supermarket within 2.5 km radius in Metropolitan & Regional Areas

**Modified Monash Model (MMM). Rural & Regional Health Australia boundaries are used for defining regions

MMM classification 1 is defined as capital cities while classifications 2-7 are defined as Rest of Australia.
## 18. Grade 1b Accessibility*

**Accessibility within 2.5 km radius in Metro Areas, 5 km in Regional Areas**

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Source: Rural and Regional Health Australia (RRHA); ABS Census of Population & Housing, 2011; Pharmacy Guild of Australia; MacroPlan Dimasi

*Note: Grade 10 Accessibility Methodology: Proportion of people having access to at least 1 pharmacy/medical centre/supermarket within 2.5 km radius in Metropolitan Areas, 5 km in Regional Areas

** Modified Monash Model (MMM), Rural & Regional Health Australia boundaries are used for defining regions

MMM classification 1 is defined as capital cities while classifications 2-7 are defined as Rest of Australia.
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Source: Rural and Regional Health Australia (RRHA); ABS Census of Population & Housing, 2011; Pharmacy Guild of Australia; MacroPlan Dimasi

*Note: Grade 2a Accessibility Methodology: Proportion of people having access to at least 2 pharmacy/medical centre/supermarket; within 2.5 km radius in Metropolitan & Regional Areas.

** Modified Monash Model (MMM), Rural & Regional Health Australia boundaries are used for defining regions.

GCCSA regions are used for this analysis. MMM classification 1 is defined as capital cities while classifications 2-7 are defined as Rest of Australia.
## 20. Grade 2b Accessibility*

### Accessibility within 2.5 km radius in Metro Areas, 5 km in Regional Areas**

<table>
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<th>State</th>
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<th>Medical Centre</th>
<th>Supermarket</th>
<th>Large Supermarket</th>
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Source: Rural and Regional Health Australia (RRHA); ABS Census of Population & Housing, 2011; Pharmacy Guild of Australia; MacroPlan Dimasi

*Note: Grade 2b Accessibility Methodology: Proportion of people having access to at least 2 pharmacy/medical centre/supermarket, within 2.5 km radius in Metropolitan Areas & 5 km Regional Areas

** Modified Monash Model (MMM), Rural & Regional Health Australia boundaries are used for defining regions.
<table>
<thead>
<tr>
<th>State</th>
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<th>Medical Centre After Hours***</th>
<th>Supermarket After Hours***</th>
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<th>Small Supermarket After Hours***</th>
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</table>
| Source: ABS Census of Population & Housing, 2011; Pharmacy Guild of Australia; MacroPlan Dimasi
*Note: Grade 1b Accessibility Methodology: Proportion of people having access to at least 1 supermarket/pharmacy/medical centres/banks; within 2.5 km radius in Metropolitan Areas & 5 km in Regional Areas
** Modified Monash Model (MMM), Rural & Regional Health Australia boundaries are used for defining regions
***After hours weekday: Defined as a facility open after 6pm on Wednesday
***After hours weekend: Defined as a facility open after 6pm on Saturday

<table>
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</table>

Source: ABS Census of Population & Housing, 2011; Pharmacy Guild of Australia; MacroPlan Dimasi

*Note: Grade 2a Accessibility Methodology: Proportion of people having access to at least 2 supermarket/medical centres/banks; within 2.5 km radius in Metropolitan & Regional Areas

**Modified Monash Model (MMM), Rural & Regional Health Australia boundaries are used for defining regions

***After hours weekday: Defined as a facility open after 6pm on Wednesday

***After hours weekend: Defined as a facility open after 6pm on Saturday
<table>
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<th>ACT</th>
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Source: ABS Census of Population & Housing, 2011; Pharmacy Guild of Australia; MacroPlan Dimasi

*Note: Grade 2b Accessibility Methodology: Proportion of people having access to at least 2 supermarkets/pharmacy/medical centres/banks; within 2.5 km radius in Metropolitan Areas & 5 km in Regional Areas

**Modified Monash Model (MMM), Rural & Regional Health Australia boundaries are used for defining regions

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***After hours weekend: Defined as a facility open after 6pm on Saturday
### 25. Estimated Accessibility for Advantaged & Disadvantaged Areas**, 2011

**Average distance (km) per person by Regions**

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* Greater Capital Cities Statistical Area (GCCSA); ASGS 2011 Edition (ABS cat. no. 1270.0.55.001) boundaries are used for defining regions

** Relative Advantaged Regions: Regions with SEIFA IRSAD Decile > 5 (Regions with decile’s 6-10)

** Relative Disadvantaged Regions: Regions with SEIFA IRSAD Decile < 6 (Regions with decile’s 1-5)

As at April 2016

Source: SEIFA Index of Relative Socio Economic Adv. & Disadvantage (IRSAD), ABS Census 2011; The Pharmacy Guild of Australia; MacroPlan Dimasi

Large Supermarket: 2,000 sq.m +
Small Supermarket: 500 – 1,999 sq.m
## 26. Number of Pharmacies & Hospitals by Region

<table>
<thead>
<tr>
<th>Region*</th>
<th>Pharmacy</th>
<th>Hospitals</th>
</tr>
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*Greater Capital Cities Statistical Area (GCCSA), ASGS 2011 Edition (ABS cat. no. 1270.0.55.001)
*Greater Capital Cities Statistical Area (GCCSA), ASGS 2011 Edition (ABS cat. no. 1270.0.55.001)
boundaries are used for defining regions

As at April 2016
Source: ABS Census of Population & Housing, 2011; Pharmacy Guild of Australia; MacroPlan Dimasi
Grade 1a Accessibility (with MMM breakdown) : Monash Modified Model regions are used for this analysis. MMM classification 1 is defined as capital cities while classifications 2-7 are defined as Rest of Australia.
## 28. Grade 1b Accessibility*

Accessibility within 2.5 km radius in Metro Areas, 5 km in Regional Areas**

<table>
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<tr>
<th>State</th>
<th>Modified Monash Model Classification**</th>
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<td>91%</td>
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</table>

Source: Rural and Regional Health Australia (RRHA); ABS Census of Population & Housing; 2011; Pharmacy Guild of Australia; MacroPlan Dimasi

*Note: Grade 1a Accessibility Methodology: Proportion of people having access to at least 1 pharmacy/hospital within 2.5 km radius in Metropolitan Areas & 5 km radius in Regional Areas

** Modified Monash Model (MMM), Rural & Regional Health Australia boundaries are used for defining regions

Grade 1b Accessibility (with MMM breakdown): MMM classification 1 is defined as capital cities while classifications 2-7 are defined as Rest of Australia.
Appendix 3 - Dispensing Fact Sheet
Dispensing your prescription medicine: more than sticking a label on a bottle

Pharmacy is the health profession responsible for ensuring the safe and effective use of medicines.

In recent times, the scope of pharmacy practice has extended beyond the supply of medicines to include a range of professional health services such as medicine reviews, chronic disease management and wound management support. Many pharmacies also provide preventive health services including smoking cessation and weight management support. However, the traditional dispensing of prescribed medicines still remains the important priority for most pharmacists.

Dispensing is an integral service provided by pharmacists as part of the Medication Management Cycle. The separation of prescribing and dispensing of medicines provides a safety mechanism as it ensures independent review of a prescription occurs prior to the commencement of treatment.

**Medication Management Cycle**

- **Review**
  - Transfer of verified information
  - Monitor for response
  - Administration of medicine (measurement, preparation, administration and recording)
- **Prescribe**
  - Decision to prescribe medicine
  - Record modifying codes/prescribed
  - Review of medicine order
  - Issue medicine
  - Provision of medicine information
- **Dispense**
  - Data collection and reporting
  - Audit review of quality and safety
- **Administer**

In addition to the labelling and supply of a medicine according to legal requirements, dispensing involves the clinical interpretation and evaluation of the prescription.

This includes assessing the prescribed dosage to ensure it is safe and appropriate; checking for allergies, contra-indications and drug interactions, at the point of medicine selection or preparation.

The provision of medicine information to the consumer or their carer, to ensure the safe and effective use of the product, completes the dispensing process.

Pharmacists must dispense accurately, reflect the prescriber's intentions and be consistent with the needs and safety of the consumer.

As a complete process, dispensing requires the professional and clinical review by a pharmacist. Some steps in the dispensing process can be completed by appropriately trained pharmacy assistants under direct pharmacist supervision.

Counselling is an essential element of the dispensing process, ensuring patients or their carers have sufficient information to enable an understanding of their medicines and the intended therapeutic effect, and to minimise the risk of adverse effects.

As a result of dispensing, patients or their carers should:
- receive clearly and correctly labelled medicines
- understand how and when to use the prescribed medicines
- understand how to store the medicines
- have access to a pharmacist for professional counselling or advice

The flow-chart on the following page demonstrates that there is more to the dispensing process than sticking a label on a bottle.
Appendix 4 - Dispensing clozapine
The requirements and process for dispensing clozapine are different to that of other medicines listed on the PBS. Given that clozapine has potentially serious adverse effects such as agranulocytosis and neutropenia, there are restrictions on the prescribing and dispensing of clozapine as part of the product registration for supply in Australia. The product sponsors for the two brands must maintain a Clozapine Patient Management System (CPMS) and prescribers and pharmacists must follow strict protocols for prescribing and dispensing.

Requirements for dispensing a clozapine prescription

- All prescribers and clinics must be registered with the relevant
- The pharmacy premises must be registered with the relevant CPMS
- Each pharmacist working at the pharmacy must be individually registered with the relevant CPMS
- Although the two brands of clozapine are “a” flagged in the Schedule of Pharmaceutical Benefits, it is recommended that the brands not be interchanged as the patient’s history in the respective patient monitoring systems will not be complete.

Note – registration with both systems is required if prescribing or dispensing both brands of clozapine.

Process for dispensing a clozapine prescription

- Prescription presented to pharmacy by patient or sent via the Clozapine Co-ordinator
- Blood results are normally hand written on prescriptions by doctor
- Pharmacist confirms blood results are less than 48 hours old.
- Pharmacist reviews blood results to see if they are in the acceptable range.
- The quantity of tablets dispensed is 28 days as this corresponds to the blood tests.
- Pharmacist must log into the web-based Clozapine Patient Management System (CPMS) – each pharmacist working at a pharmacy has their own log-in details and password.
- Confirm prescriber and clinic are registered with the CPMS
- Search for the patient via their identifying CPMS number and review their status.
- Pharmacist must review the blood results on the website entered by doctor/clinic for the corresponding prescription date.
- If pharmacist is sure the patient is in green zone and blood results are ok then submit dispensing details on eCPMS for patient (include daily dose and quantity of supply).
- Manage dose adjustments as per protocol.
- If blood results are not provided the pharmacist must contact doctor for copy of latest blood results and enter on eCPMS prior to dispensing on eCPMS.
- If blood results are a concern then pharmacist refers to protocol for next step and contacts doctor for instruction.
- Once this process is carried out only then can the pharmacist dispense the medicine using the dispensary software, checking for adherence or other medicine-related issues.
- When dispensed, the pharmacist must confirm acceptance of the PBS claim via real-time feedback in the dispense software via PBS Online.
- Supply medication to patient/carer with appropriate counselling and reminders about appointments (blood tests/specialist/GP/mental health unit).

Given the nature of the medicine and the condition it is used to treat many patients have clozapine packed in a Dose Administration Aid (DAA).

The quantity of clozapine supplied to each patient will vary depending on the patient’s dose and should be for a maximum of 28 days as this coincides with the need for a blood test every 28 days. However, the manufacture only supplies clozapine in 100 tablet packs so there is always a need to break packs. With S85 PBS items, when a pharmacist is required to break a pack there is a “wastage” factor applied to the pharmacy remuneration. This wastage factor does not apply to S100 PBS medicines.

Costs and remuneration for dispensing clozapine
Pharmacists that dispense clozapine as a Section 100 (S100) PBS prescription are only remunerated for dispensing the prescription. They receive no remuneration for the additional work in therapeutic monitoring and data entry and because of the structure of the S100 remuneration model, the wastage factor that pharmacists are paid for dispensing less than the PBS maximum quantity does not apply.

Key points of consideration:
- Dosage – initial dose of 12.5mg – 25mg per day titrated up to 300mg per day
- Quantity dispensed – variable; initially 7 days supply then up to 28 days supply when stabilised
- Wholesaler markup – Nil
- Wastage factor for dispensing less than maximum quantity – Nil
- PBS maximum quantity = 200 tablets (manufacturer pack = 100 tablets)
- Dispensing fee = $7.03

The table below indicates the cost per pack to the pharmacy for purchasing clozapine tablets and the mark-up that would apply if a maximum quantity could be dispensed versus a more likely dispensed quantity of 28.

<table>
<thead>
<tr>
<th>Tablet Strength</th>
<th>Price to Pharmacist (100 tabs)</th>
<th>Pharmacy mark-up (Max PBS Qty - 200 tabs)</th>
<th>Pharmacy mark-up (28 tabs)</th>
</tr>
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<tbody>
<tr>
<td>25mg</td>
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</table>
Appendix 5 – A comprehensive list of pharmacy services
Primary health care services provided by community pharmacies

Across the country, participating community pharmacies provide a wide range of services in their undertaking to improve the health of all Australians. Some of these services are listed below. Programs and services provided by community pharmacies are supported by the accredited Quality Care Pharmacy Program quality assurance platform. Over 94% of the 5,500 community pharmacies in Australia are either accredited or undergoing accreditation/re-accreditation under the QCPP.

Medicines management and Quality Use of Medicines activities

- MedsCheck/Diabetes MedsCheck
- MedsIndex and adherance support
- Staged supply
- S100 Remote Aboriginal Health Services Program
- Chemotherapy medicines preparation
- Compounded medicines
- New to Therapy services
- Home Medicines Reviews
- Dose Administration Aids
- Pharmacovigilance including adverse event reporting
- Product recalls and safety alerts
- Consumer Medicines Information
- Residential Medication Management Reviews
- Emergency contraception provision and counselling
- Complementary medicines advice

Disease management, monitoring and support

- Respiratory (asthma and chronic obstructive pulmonary disease) services
- Diabetes management services including National Diabetes Services Scheme
- Cardiovascular disease services
- Dementia management support
- Pain management services
- Arthritis management support
- Mental health support services
- Aged care services
- Continence Aids Payment Scheme
- Sleep apnoea services
- INR (anticoagulant therapy) monitoring
- Palliation support services

Public/population health activities

- Immunisation services
- Project STOP pseudoephedrine sales monitoring
- MedsASSIST codeine sales monitoring and support
- Closing the Gap Pharmaceutical Benefits Scheme Co-payment measure
- Needle and Syringe Programs
- Opioid Dependence Treatment
- Maternal and Child Health clinics
- Health aids and equipment provision
- Adverse event reporting, product recalls and safety alerts
- Return of Unwanted Medicines
- Absence from Work Certificates
- Home delivery services

Minor ailments

- Pharmacy and Pharmacist Only medicines
- Skin care support and products (dermatitis, eczema, acne)
- Wound care support and products
- First Aid support and products

Wellness, screening and prevention services

- Blood pressure and cardiovascular disease risk assessment
- Diabetes risk assessment
- Smoking Cessation support and products
- Point of Care Testing cholesterol and blood glucose
- Self-test screening: bowel cancer and chlamydia
- Bone density testing (external provider)
- Weight management and nutrition services
- Compression garment fitting for deep vein thrombosis
- Lifestyle advice and support
- Travel health support

Note: this is neither an exhaustive list of services nor a list of services available from every pharmacy. To locate pharmacies providing specific services, go to findapharmacy.com.au

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Appendix 6 - Examples of pharmacist intervention with OTC medicine supply
The examples below of de-identified pharmacist intervention with OTC medicine supply were collected from Guild members and included in the Guild’s submission to the Scheduling Review undertaken by the Department of Health and Ageing, April 2012.

- 22YO female requests a salbutamol inhaler (Schedule 3). On questioning, patient is using inhaler 3 times a day and stopped preventer therapy. Advised on use of preventer and reliever and referred back to GP for review.

- Early 20s female identified as repeat purchaser of laxative (exempt from scheduling). Patient is very thin and purchasing a bottle of 90 tablets every 1-2 weeks. Risk of laxative misuse identified. Patient counselled about risks with laxative overuse and educated on diet and exercise. Alternative interim laxative recommended (lactulose) with referral to GP.

- Elderly man recommended paracetamol (Schedule 2) by doctor. Requests anti-inflammatory because it is not working. On questioning, identify potential under dose. Counselling on correct dose of paracetamol for ongoing pain relief. Patient reported back that pain management had improved.

- Female in 30s requests oral thrush treatment. On questioning, identified new asthma preventer therapy (Schedule 4) with risk of oral thrush as side-effect. Oral thrush treatment provided with directions + advice on how to manage risk of oral thrush from preventer treatment by rinsing mouth after use and using a spacer.

- Regular patient on several medicines for heart, blood-pressure and diabetes requests remedy for pain relief. On questioning, identified patient has been using ibuprofen purchased from supermarket (exempt from scheduling), without any effect. Cardiovascular risks associated with ibuprofen identified. Alternative analgesic recommended.

- Young adult male identified as frequently purchasing salbutamol inhaler (Schedule 3) without use of preventer therapy. Pharmacist intervened and counselled patient on asthma medicine use with referral to GP. Patient returned later that day with prescription for asthma preventer therapy (Schedule 4).

- Adult female requests pseudoephedrine (Schedule 3) for hay fever. Identified as using product when required for hay fever but not finding it effective. Recommended fexofenadine antihistamine tablets and fluticasone nasal spray. Re-presented to pharmacy a few weeks later advising that hay fever was now controlled.

- Middle aged woman requests anti-inflammatory for recent unexplained muscle pain. Previously used OTC oral diclofenac but condition had worsened over past week and needing more frequent pain relief. Questioning identified recent increase in atorvastatin (Schedule 4) dose at time when muscle pain noticed. Potential side-effect from atorvastatin identified. Patient referred to GP for assessment.

- 40YO male requests OTC antihistamine. Appeared to be disorientated and incoherent and had visible rash. Questioning identified swelling of throat, tongue and difficulty breathing. Escort to near-by general practice where patient administered adrenalin and monitored. Confirmed anaphylactic response.

- Patient requests decongestant/antihistamine eye drop (Schedule 2) on recommendation of friend. Pharmacy policy requires first time eye drop users to be counselled by pharmacist. Identified patient has glaucoma; caution required with decongestant/antihistamine products. Potential adverse outcome identified and avoided.

- Adult male re-presenting every 10-14 days for salbutamol inhaler (Schedule 3). Pharmacist intervention identified non-use of preventer therapy and potential interaction between cardio-
vascular medicines and salbutamol. Pharmacist worked with patient to review use of salbutamol and patient referred to GP for assessment.

- Adult female regularly requesting ibuprofen + codeine (Schedule 3) for pain relief. Contact with other pharmacies identified misuse/abuse potential. Pharmacist intervention identified patient taking 16-20 tablets a day. Pharmacist worked with patient's doctor to arrange a dosing chart so pain management is monitored by patient, doctor and pharmacist working together. Since intervention, patient has not exceeded prescribed amount and sees her doctor and specialist more regularly.