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Foreword

As the peak organisation representing all pharmacists in Australia, PSA is committed to ensuring a viable and robust community pharmacy network. We acknowledge the Review Panel’s clear statements that the recommendations from this review will be consumer-focused and directed towards achieving the objectives of the National Medicines Policy (NMP). In order for these objectives to be realised, Australia needs a community pharmacy network that is sustainable into the future.

The significance of this Review and any resulting reforms should not be underestimated, as the community pharmacy sector employs approximately 80% of all pharmacists working in Australia. In drafting this submission, PSA has taken into account the views of our members, the broader profession, and the views of consumers – for whom our vision of delivering excellence in pharmacists care exists.

In responding to PSA’s call for feedback on our Review Consultation Framework, pharmacists raised with us a number of issues of concern including: the impact of discounting on pharmacy business viability, pharmacist remuneration levels and future career prospects. Many of our members are seeking opportunities that allow them to innovate, to further develop and diversify their practice, including access to community pharmacy ownership.

PSA is cognisant that up to 60% of the pharmacist workforce is comprised of early-career pharmacists, who represent the highest proportion of community pharmacy employees, and the lowest proportion of pharmacy owners. Regardless of the role they hold, early-career pharmacists are the group who stand to be impacted the most by any reforms.

PSA’s submission does not rely solely on the views and contributions of individuals within our profession, however. Our full response to the Discussion Paper has been extensively informed by local and international evidence – where available - in key areas being considered by the Review Panel. The positions articulated in this submission have been given significant consideration and many have been formed over a number of years through both extensive consultation with the profession and as a result of previous sector reviews and reforms.

PSA is aware that the Review Panel has heard from many individuals and stakeholders as part of their consultation process. We trust that the Panel has processes in place to ensure that the many opinions and anecdotes expressed to the Panel are weighted appropriately against a robust, consultative, evidence-informed submission from the pharmacists’ peak body. We are confident that through the Panel’s own consultations, they will now be aware of the full approved scope of practice and evidence for pharmacists’ expertise, and recognise that as a workforce, Australian pharmacists are underutilised. This Review presents an opportunity to explore how the contribution of pharmacists in the Australian health system can be optimised. We look forward to meeting again with the Panel to further discuss how PSA can assist in enabling this.

Joe Demarte
PSA National President

* Registered pharmacists with less than 10 years of experience post-graduation (Pharmacy Board of Australia. Registration Data – March 2016 At: http://www.pharmacyboard.gov.au/About/Statistics.aspx )
** Duckett, S., Breadon, P. and Ginnivan, L., 2013, Access all areas: new solutions for GP shortages in rural Australia, Grattan Institute, Melbourne
Medicines should not be viewed as ordinary items of commerce.

An underpinning principle of PSA’s consideration of, and response to the issues raised in the Review, is that altering regulation or practice in one area of the National Medicines Policy (NMP) may have consequences – both intended and unintended - for other areas.

Cost or social circumstances should not be a barrier for consumers to access health services provided by pharmacists. PSA believes that evidence-based, cost-effective community pharmacy services which meet consumer needs should be appropriately supported by the Government.

Discretionary discounting by pharmacies, whether done independently or through the Government’s $1 discount measure, undermines the universality of the Pharmaceutical Benefits Scheme (PBS) and actively works against the objectives of the NMP.

Characterising the PBS copayment as a “price signal” is inappropriate and should be rejected as health care is not a commodity nor are medicines ordinary items of commerce; they are essential products and services without which a much greater burden is placed on the health care system and taxpayers.

PSA believes that the Government should invest in primary health care services which make best use of the available pharmacy workforce, and provide cost effective solutions to meet local health needs.

To help address existing and significant inequalities in health status, Government should consider developing an overarching universal medicines access program for Aboriginal and Torres Strait Islander people.

All community pharmacies should aim to meet the health care needs of their local community through the provision of quality services and advice. PSA does not believe a ‘one size fits all’ approach is appropriate to determine appropriate service provision or pharmacy trading hours.

Pharmacist services remunerated by Government should allow for flexibility in terms of service setting to most appropriately meet consumers’ needs.

A more appropriate payment model for pharmacist services is one which recognises and remunerates pharmacists based on the complexity of the presenting consumer’s situation and/or services provided.

The current remuneration structure for the supply of high cost PBS drugs through community pharmacy should be considered carefully by Government to ensure that access is not compromised.

PSA would urge the Review Panel to carefully consider the international evidence available on the unintended effects of loosening community pharmacy regulations (including location rules, ownership and the State & Territory legislative restrictions on the co-location of pharmacies and supermarkets), particularly from jurisdictions where re-regulation has been required after a period of time to address the consequences of such changes.

Throughout this document the pharmacist delivered services to which we have referred and proposed are all well within the scope of practice of all registered pharmacists in Australia. Curricula for pharmacy courses at all universities are mapped to the National Competency Standards Framework for Pharmacists in Australia.
About PSA

The Federal Government recently awarded the Pharmaceutical Society of Australia (PSA) with national peak health body status. The Government rewarded PSA’s advisory, policy formulation, education and representation of pharmacists as part of the Health Peak and Advisory Bodies Program (HPAB).

PSA proudly represents Australia’s 29,000 pharmacists working in all sectors and locations.

PSA’s core functions relevant to pharmacists include: providing high quality continuing professional development, education and practice support to pharmacists; developing and advocating standards and guidelines to inform and enhance pharmacists’ practice; and representing pharmacists’ role as frontline health professionals.
Context of Submission

PSA has been encouraged by the Review panel to go beyond the Review’s Terms of Reference in drafting this submission, viewing the questions and the implications of reform in the context of not only the National Medicines Policy but the wider health reform agenda being pursued by Government, as depicted below. A number of these key pieces of reform that are either underway or awaiting Government response, will invariably be impacted by, or have an impact on the Review.

Figure 1: Wider Health Reform Agenda

- Reform of Federation: https://federation.dpmc.gov.au/
- Review of 6CPA Professional Pharmacy Programmes: In progress: no public details available.

* Indicates that the review is ongoing and/or recommendations are with government
In considering the most effective way to interpret and respond to the Review’s Discussion Paper, PSA has mapped each of the 140 questions posed by the Review Panel, to the four central objectives which underpin the NMP (below and Fig 2):

- **Access to Medicines**: 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**.

PSA’s responses to the questions have been grouped accordingly. One of the challenges identified in this process is that there are no standard measures or metrics across sectors or the health system as a whole, for assessing performance against the goals of the NMP. It also became clear in mapping the questions that the pillars of the NMP do not stand alone – many issues raised and questions posed by the Panel relate to multiple elements.

An underpinning principle of PSA’s consideration of and response to the issues raised is to recognise that altering regulation or practice in one area may have consequences – both intended and unintended - for other areas.

A further challenge in responding to the questions is the lack of publicly available data on many of the aspects covered by the review. Therefore PSA’s responses to some questions and the positions expressed should be interpreted with this caveat in mind.
Access to Medicines

The questions posed by the Panel, identified as being underpinned by the Access to Medicines pillar of the NMP, present a number of common themes and issues for consideration by both PSA and the broader pharmacy sector.

The two overarching themes present in these questions are the accessibility of pharmacies - with a major focus on the Pharmacy Location Rules, and accessibility of medicines, focusing on both supply arrangements and consumer affordability.

Accessibility of Pharmacies

Community pharmacies are uniquely placed within Australian communities, with the value of the community pharmacy network to both consumers and the health system well documented.

Recent research indicates that the majority of consumers have no issues accessing community pharmacies, and that most consumers “were most satisfied with their recent visit to a pharmacy”. The ease of consumer access reflects, in part, the impact of the pharmacy location arrangements (the ‘location rules’). The objectives of the location rules as stated are 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; and
• continued development of an effective efficient and well-distributed community pharmacy network in Australia.

Under the current location provisions, access to pharmacies by all segments of the population is extremely high. This access is of inestimable value in terms of delivering safe and reliable health care services, and as Australia’s population ages, will prove invaluable in meeting the needs of older consumers.

Accessibility of pharmacies, and indeed all health care services, is also determined by such factors as mobility, the age structure of a community, and the incidence of vehicle ownership. Accessibility is therefore likely to be worse in areas with low incomes, and/or a high proportion of people with disabilities or those experiencing social disadvantage.
Accessibility to Medicines

The questions posed by the Review touch on the key aspects of the accessibility of medicines – both the physical supply and timely provision of medicines, and the affordability of medicines to consumers and the broader health system.

Over the last two decades, a number of programs have been initiated by the Australian Government to improve access to medicines for Aboriginal and Torres Strait Islander people. Despite having two-to-three times higher levels of illness, underuse of medicines is evident in Australian Aboriginal and Torres Strait Islander populations.6 Poor adherence to prescribed medicines is well documented and associated with adverse health outcomes in all population groups.7

These programs also assist with financial burden of chronic disease medicines in urban and rural settings. The medicine access schemes for Aboriginal and Torres Strait Islander people vary according to geographical location. Program-specific rules can make navigation between programs difficult for both Aboriginal and Torres Strait Islander people and health professionals; PSA has addressed these concerns in its response to the relevant questions.

Ultimately, all Australians should have timely access to the medicines that they need, at a cost individuals and the community can afford. PSA is committed to working with the Review panel, the Government and the broader pharmacy sector to achieve this.
Relevant Discussion Paper Questions

01 In your opinion, is the ratio of community pharmacies to population optimal? What data would you use to support this opinion?

PSA believes that the ratio of community pharmacies to the population is optimal, or near optimal. As detailed in the Review’s Discussion Paper, the distribution of pharmacies across Australia is proportional to the distribution of the population in each State and Territory.

PricewaterhouseCoopers (PwC) undertook research with the aim of measuring community pharmacy’s impact on consumer health outcomes. As part of that research, PwC found that 98.5 per cent of consumers reported having no issues accessing community pharmacy.*

Furthermore, the most recent OECD Report indicates that in Australia, the number of pharmacies per 100,000 people is close to the OECD average, and compares favourably to many other developed countries including the United Kingdom, the United States of America, Switzerland and Finland.

PSA does note, however, that access to pharmacies and medicines in rural and remote regions of Australia could be improved, and recommendations for this are addressed herein.

10 Is the current system of dispensing of medicines in Australia, that focuses predominantly on community pharmacies operating as small businesses, the best way to achieve the objectives of the NMP? Should there be alternative approaches for the dispensing of PBS medicines beyond a community pharmacy, such as through hospitals or different pharmacy arrangements? If so, what could these alternative approaches look like?

Achieving the objectives of the NMP is not the role of community pharmacy alone. It should also be noted that the NMP relates to far more than just the dispensing of medicines.

PSA understands that alternative approaches to dispensing, such as hospital and other outpost arrangements already exist.

At present there are no available metrics through which to objectively measure whether or not the objectives of the NMP are being met. PSA strongly encourages the Review Panel to consider this in their recommendations.

11 Is the 6CPA achieving appropriate ‘access to medicines’ as defined in the NMP? If so, why? If not, why not and how could access be improved?

PSA believes it is important to recognise that the 6CPA only commenced on 1 July 2015, and that thus far there has been no evaluation of its impact on access to medicines, nor has there been any indication of how its impact will be measured or evaluated.

Indications from arrangements in the 5CPA are that access to medicines is extremely high. It is therefore difficult to envisage significant improvements to access given that available data indicate access is close to 100%.

*The project surveyed 3,000 consumers in the community
To what degree is it appropriate that community pharmacies be protected from the normal operations of consumer choice and ‘protected’ in their business operations? Is such protection required to achieve the NMP objective of access to medicines? If so, why? If not, why not?

The assumption inherent in this question is that regulations restricting both ownership and location of pharmacies are ‘protective’, presumably in the context of both competition and regular commerce.

The provision of medicines is a core activity for pharmacists, and should not be thought of as merely a supply function – it is performed in the context of having the highest possible regard for patient safety and promoting the judicious use of medicines. Given the high incidence of medication misadventure it would be irresponsible to categorise medicines as ordinary items of commerce.

The prices paid by consumers for prescription medicines are controlled by Government, not as a ‘protective’ mechanism for pharmacies, but to ensure universal access to medicines – one of the key objectives of the PBS and NMP. As such, PSA does not believe that these measures limit consumer choice, and in fact believes that they are beneficial to consumers by ensuring equitable access to medicines, regardless of personal circumstances.

It should also be noted that significant competition does already exist in the community pharmacy sector, both outside of PBS medicines and now within the PBS, as a result of the $1 discount.

European experience indicates that the removal of such ‘protections’, has resulted in a reduction in competition and concentrations of ownership in some jurisdictions. Indeed, in some countries, namely Estonia and Hungary, legislation regarding the establishment and ownership of pharmacies has been re-established after years of liberalisation.

Currently community pharmacists have discretion over some charges. For subsidised PBS prescriptions, should community pharmacists be able to charge consumers above the ‘dispensed price’ for a medicine in some circumstances? Should community pharmacists be allowed to discount medicines in some circumstances? If so, what limits should apply to pharmacist pricing discretion? If not, why not?

Discretionary discounting by pharmacies, whether done independently or through the Government’s $1 discount measure, undermines the universality of the PBS and the objectives of the NMP.

Medicines affordability is a significant issue which must be dealt with in an appropriate, consistent and national manner. Discounting PBS prescriptions not only undermines the principles of universal access and equality which underpin the PBS, it also results in the commodification of medicines. PSA believes that this is undesirable as it may contribute to medicines being viewed as ordinary items of commerce, undermining the rigour underpinning the extensive regulatory processes that therapeutic goods are subjected to for the safety and benefit of consumers.
Given that very high cost drugs are likely to become more common on the PBS, should this remuneration structure for hospitals change to more closely reflect the remuneration structure of community pharmacy?

In community pharmacy, the remuneration structure for very high cost drugs through the PBS is already proving to be problematic. The recent inclusion of Hepatitis C treatments on the PBS, welcomed by PSA as an important initiative to increase access to life-saving medicines, provides a useful example. The lack of a consultative approach to implementation of this measure has unfortunately resulted in a number of issues for the community pharmacy sector and subsequently, consumer access.

Feedback from pharmacists indicates that the remuneration received for dispensing these high-cost medicines does not cover the inherent financial risks nor the impact that stocking them can have on the cash flow of a community pharmacy. Perhaps of most concern, is that a recent poll indicated that up to one third of community pharmacies would elect not to stock these items.

Together, these issues could have potentially serious repercussions for consumer access, continuity of treatment and outcomes, particularly for those in rural and remote settings. If not resolved, these issues are likely to worsen as more high-cost therapies move onto the PBS.

Given these issues, PSA believes that the remuneration structure for high cost drugs on the PBS available through community pharmacies should be addressed prior to consideration of any changes to the remuneration structure for hospitals.

PSA has received feedback which suggests that one option to mitigate some of the burden associated with the supply of high cost drugs through community pharmacy may be to remove the GST from these medicines.

Should both direct consumer remuneration and government-based remuneration be applied for particular services or access arrangements?

Arrangements involving a patient co-payment could be considered for evidence-based pharmacist services which are shown to be cost-effective and meet community need. Requiring consumers to pay in full for these services is likely to create further health inequalities as those who can afford to pay will be able to access the services while others – often those most in need – will miss out.

PSA believes that Government at all levels, including through Primary Health Networks (PHNs), should invest in primary health care services which make best use of the available pharmacist workforce, and provide cost effective solutions to meet local health needs.

Would the removal of pharmacy location rules in urban areas with their retention in other areas, particularly rural and remote areas, increase or decrease access and affordability for pharmaceuticals to the public? Why and for what reasons?

As PSA understands, after review of Australian and international literature, there are insufficient data available to answer these questions. Current international experience suggests that the removal of all regulatory arrangements (including both location and ownership provisions) favours urban populations. However, it is not known what impact partial removal of these regulations has, and for these reasons it is difficult for PSA to provide an informed comment.

PSA would have concerns about the implementation of any such changes, with arrangements needing to be made in order to avoid unintended consequences. PSA would urge the Review Panel to carefully consider the international evidence available on the unintended effects of loosening community pharmacy regulations, particularly from jurisdictions where re-regulation has been required after a period of time to address the consequences of such changes.
Would the removal of the location rules in urban areas with their retention in other areas, particularly rural and remote areas, discriminate against rural and regional consumers or benefit those consumers relative to consumers in urban areas? Why or why not?

For similar reasons outlined in response to Question 43, PSA believes there are insufficient data to inform comment on this question. Again, PSA would urge the Review Panel to carefully consider the international evidence available on the unintended effects of changes to community pharmacy regulations, particularly in jurisdictions where re-regulation has been required to address the consequences of such changes.

It has been suggested to the Review that this creates unintended consequences in locking pharmacies into specific shopping centres and transferring effective ownership of the pharmacy approval number to the shopping centre. Is this a reasonable assessment of the effect of the location rule regarding short distance relocation from a shopping centre? Should this rule be modified, and if so, why? If not, why not?

Other than anecdotal evidence, there are limited data available to provide informed comment support either the retention of, or changes to, this rule. In order to fully assess the potential consequences of changes to this rule, both positive and unintended, further investigation and modelling must be undertaken.

PSA notes that decisions made by the Australian Community Pharmacy Authority (the body which considers applications for approval to supply pharmaceutical benefits at particular premises) are not made public, and therefore believes that further data and information would need to be made available in order for stakeholders to provide an informed response.

PSA suggests that the Review Panel seek advice from the ACPA on this issue to ensure that recommendations are not made on the basis of anecdotal evidence alone.

The current pharmacy location rules do not preclude a pharmacist from operating more than one pharmacy within a particular area. To the extent that this may allow an approved pharmacist to restrict local competition by opening a second pharmacy in the same area, should the rules be amended to support choice and value for money for consumers?

The assumption inherent in this question is that consumer choice is restricted. However, at least anecdotally, PSA is aware of proprietors owning two pharmacies that operate significantly different business models – providing consumer choice. That being said, PSA also recognises that it is important that the arrangements in these cases are transparent and readily accessible to consumers.

PSA also recognises that the flexibility of the location rules in instances such as these may be considered by the Review Panel.
Recognising that restrictions on co-location of pharmacies and supermarkets exist under state and territory legislation, would the removal of this restriction from the pharmacy location rules be desirable or undesirable?

PSA supports the retention of State and Territory legislative restrictions on the co-location of pharmacies and supermarkets.

The physical setting and atmosphere of supermarkets are not regarded as places where consumers seek personal health care advice. Supermarkets, in particular larger outlets, operate in a setting which generally promotes features such as convenience, unrestricted access, one-stop-shop locations for the purchase of groceries and other ordinary items of commerce.

PSA does not believe supermarkets provide an environment conducive for consumer-centred care, promotion of health literacy, opportunistic interventions, interdisciplinary collaboration or effective operation of the health care team. Surrounded by an environment which highlights price and convenience, if a pharmacy is located in a supermarket, it follows that consumers will also approach or initiate their health care interaction with a high priority on these factors. PSA believes this will impede the pharmacist-consumer interaction and potentially impact on public safety and the quality use of medicines (QUM).

Having a pharmacy located in a supermarket also has the potential for consumers to develop the notion that potent, scheduled medicines are safe enough to be allowed to be located within an unregulated environment. PSA believes it is undesirable and in fact unsafe to portray this type of message as it can dilute and possibly undermine the rigour underpinning the extensive regulatory and scheduling requirements that therapeutic goods are subjected to for the safety and benefit of consumers, as outlined in the NMP.

PSA believes a pharmacy located in a supermarket is regarded as being part of the same business premises. Therefore, even though pharmacists may not be directly involved in the sale of these goods, the environment is inconsistent with pharmacists being able to meet their professional obligations as detailed in Section 5 of the National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007 which requires that an approved pharmacist must comply with the Pharmaceutical Society of Australia’s Code of Ethics and Professional Practice Standards in their dealings with each individual patient.16

PSA’s Code of Ethics states that pharmacists must not sell or supply a product where it “may impose a hazard to the patient’s health or condition.”17 The sale of tobacco products by pharmacists is also inconsistent with professional behaviour expected of pharmacists. Tobacco products and alcoholic beverages are some of the highest selling items in supermarkets (including co-located outlets owned by them).

Would it be desirable if remote s100 Aboriginal Health Services were also able to write CTG scripts?

Allowing doctors working in remote s100 Aboriginal Health Services to write CTG scripts would be desirable. Currently, Aboriginal Health Services in urban and rural areas, or certain accredited General Practices are able to provide CTG prescriptions.18 Allowing remote s100 AHSs to provide CTG scripts would only improve access to medicines for Aboriginal and Torres Strait Islander peoples, providing continuity of access to medicines, especially for people who travel frequently between urban, rural and remote settings.

As stated previously, PSA believes that eligibility for medication access programs and services should be based on consumer need, not their location.
Could the arrangements for s100 and CTG co-payments be merged to allow Indigenous people who travel to access both s100 while they are at home and CTG co-payments when they travel?

Program specific rules can make navigation between CTG and s100 difficult for both Aboriginal and Torres Strait Islander people and health professionals. Allowing remote s100 AHSs to write CTG prescriptions (as above), and hospitals to provide CTG prescriptions to eligible out-patients would go some way to improving access for Aboriginal and Torres Strait Islander people who travel between urban, rural and remote areas.

Merging CTG and s100 arrangements requires further information and consideration. PSA would urge the Government to consider developing overarching universal medicines access program for Aboriginal and Torres Strait Islander people.

Should hospitals be allowed to write CTG co-payment scripts for out-patients?

Hospitals should be able to provide CTG prescriptions to out-patients who are eligible and registered for the CTG program for the same reasons as articulated above.

Should s100 and RPBS items be included in normal wholesale arrangements and in the CSO? If so, why? If not, how do the current arrangements support consumer access to all PBS and RPBS items?

s100 and RPBS items should be included in normal wholesale arrangements and in the CSO. From a consumer perspective, the categorisation of their medicine as s100, PBS or RPBS is irrelevant in terms of them accessing the medicine in a timely manner. These items should be included in the same arrangements as the PBS to ensure that the NMP objective of access to medicines is fully realised.

Have recent changes to the CSO, such as the extension of the guaranteed supply period and introduction of minimum order quantities, had an impact on consumer access or choice? If so, what evidence is available to demonstrate this?

PSA believes it is important to recognise that the changes to the CSO as a part of the 6CPA only commenced on 1 July 2015, and that thus far there have been no evaluations of their impact on access to medicines, nor has there been any indication of how the impact will be measured or evaluated.

Anecdotally, however, PSA is aware of instances in which the changes to the CSO have had a negative impact on consumer access to medicines through extended timeframes for supply to pharmacies.
Has the $1 discount had an impact on the access and affordability of PBS medicines? Has the introduction of the $1 discount been a successful implementation of policy?

PSA believes that the $1 discount, introduced as one of the Government’s PBS Savings measures, works against the universality of the PBS. Practically, for both consumers and pharmacists there are wide-reaching consequences. For pharmacies which may already be struggling financially, absorbing the cost of the $1 discount on all PBS prescriptions may cause them to become unviable, or result in a reduction of pharmacy services. Consumers may face hardship in having to travel greater distances to access a pharmacy offering the discount and/or by changing pharmacies to access the discount, existing relationships may be lost, fragmenting care and leading to poorer health outcomes.

Data provided to the Senate Community Affairs Committee as part of an answer to Estimates Questions on Notice, indicate that of the 24.1 million eligible PBS prescriptions dispensed nationally in January and February 2016, only 7.1 million (30%) had a discount applied, while 17.0 million (71%) prescriptions had no discount applied – despite approximately 79% of approved pharmacies offering discounted prescriptions, at least for some customers. These statistics further demonstrate that the impact of the measure is highly variable, further compromising equity of access. PSA believes that this demonstrates that both the concept and implementation of the $1 discount as a policy measure, while expected to save $400 million over five years, will be highly unlikely to have the desired impact, as cautioned by PSA when its introduction was first announced.

What examples can you provide of variation in prices for regular PBS prescriptions?

We do not believe it is helpful to list arbitrary examples in this submission. In order to appreciate the variability in prices offered for regular PBS prescriptions, PSA strongly encourages the Panel secretariat to undertake a comprehensive review of the prices for PBS medicines detailed on the websites of all major pharmacy groups and independent pharmacies.

Is the PBS Safety Net adequate to address the needs of low income consumers who face high pharmaceutical costs and other medical-related costs? If not, what other strategies can be employed to ensure access to cost-effective health care is protected and promoted?

The PBS Safety Net, prior to the introduction of the Government’s raft of PBS Savings Measures, broadly addressed the needs of low income consumers with regards to high cost medicines and other pharmaceutical costs. It is anticipated that the combined impact of the $1 discount, changes to the availability of OTC items on the PBS and the increase of the Safety Net threshold will result in a proportion of current SN card holders not reaching the Safety Net, leaving them financially worse off. Previous experience has shown that greater out of pocket costs (even small increases) may cause consumers to cease taking important therapies or delay treatment, with serious health consequences and flow-on effects to the health system.
What is the objective of the co-payment? Is it to ensure patients use PBS medicines appropriately, by setting a price signal? If so, is this objective enhanced or undermined by allowing co-payment discounts?

The original intent of the PBS co-payment was to create a value for medicines, and ensure that they would not be seen as ordinary items of commerce, in line with Government’s key medicines policy framework, the NMP and QUM principles. PSA believes that the objective of the consumer co-payment – ensuring appropriate and judicious use of PBS medicines, is undermined by allowing co-payment discounts, and sends the message to the community that medicines are no different to other products which do not require regulatory controls.

Furthermore, the description and use of the PBS co-payment as a “price signal” is inappropriate as price signals work by encouraging consumers to think about whatever it is they are about to buy, and whether it’s worth the cost. Price signals assume consumer knowledge of the product, and its value. This economic device has been found to be inappropriate for primary care as health care is not a commodity, nor are medicines ordinary items of commerce; they are essential products and services that can create much greater downstream costs if not used in the right way.

Is it reasonable for consumers to expect access to medicines outside of standard business hours? If so, why? What arrangements could be made to improve consumer access?

It is reasonable for consumers to expect access to medicines outside of standard business hours to some degree. However, as previously stated, not all pharmacies, particularly those experiencing financial pressure as a result of the Government’s PBS savings measures are able to offer or maintain the service levels required to offer extended trading hours.

The Victorian Government’s pilot of 24-hour pharmacies will provide an important insight into the viability and utilisation of services and medicines access outside of standard business hours.
Quality, Safety and Efficacy of Medicines

The Review discussion paper poses a number of questions relating to the second objective of the National Medicines Policy which is medicines meeting appropriate standards of quality, safety and efficacy. However, as noted earlier, many of the questions relate to multiple elements of the NMP.

PSA’s position and recommendations regarding minimum usage requirements, the supply of complementary and alternative medicines through pharmacy, and chemotherapy compounding, particularly in the context of remuneration and supply arrangements, will be covered in further detail in the relevant sections of this submission.

Relevant Discussion Paper Questions

Are there other issues with the production and delivery of chemotherapy medicines which the Panel should be aware of?

Question 139 of the discussion paper correctly states that “Chemotherapy patients benefit from the ability of local chemotherapy manufacturing facilities to provide more timely medications to local patients” and recognises that these local facilities do not usually hold a TGA license.

However, PSA has received feedback from pharmacist members which indicates that the new two-tiered fee structure for chemotherapy compounding, implemented on 1 July 2015, has disadvantaged pharmacies which are not TGA licenced. Additionally, the feedback indicates that the “one size fits all” approach of the new structure may disproportionately affect rural and remote consumers who rely on local manufacturers for timely access to compounded chemotherapy.

PSA acknowledges that the new fee structure was implemented to reflect the additional costs associated with TGA licensing, however, it also recognises that the new funding model encourages the centralisation of chemotherapy compounding to TGA licensed facilities, and that some States and Territories, namely Tasmania and the Northern Territory, lack any TGA licensed compounders.

PSA would encourage the Panel to consider the impact of the two-tiered remuneration structure on the viability of local facilities and make recommendations to ensure that all Australians have timely and convenient access to medicines which are safe, efficacious and of high quality.
Quality use of Medicines

A significant proportion of the questions posed by the Review Panel have implications on the third objective of the National Medicines Policy – the quality use of medicines.

Medicines are the most common treatment used in health care and contribute to significant improvements in health when used appropriately. However, medication misadventure, medication errors and adverse drug reactions result in poorer health outcomes for Australians and significant unnecessary expenditure in the health system. Drug utilisation data indicate that prescription medication use in Australia is steadily increasing. Over 80% of Australians aged 65 years and over, and 70% of Australians aged 45-64 regularly use pharmaceuticals, with these proportions expected to further increase. However, 30–50% of prescribed medicines for long term conditions are not taken as recommended.

Australia spends over $19 billion on medicines every year. By comparison, very little is spent on medication safety and not enough focus is placed on reducing the occurrence and severity of medication errors.

All medicines have the potential for side effects and can interact with other medicines. Each year 230,000 people are admitted to hospital, and many more people experience reduced quality of life, as a result of side effects of their medicines. This comes at a cost to the health system of more than $1.2 billion. Much of this personal and financial burden is preventable, with increasing evidence of the impact that pharmacists can have on medication safety and adherence, and the resulting savings to the health system.

Optimising the management of long-term conditions through quality use of medicines has been shown to reduce or delay the incidence of hospitalisation in patients with chronic diseases and to reduce the need for, and spending on, expensive hospital admissions and medical services.
In your opinion, should there be a maximum ratio of retail space to professional area within pharmacies to maintain the atmosphere of a health care setting for community pharmacies receiving remuneration for dispensing PBS medicines?

There are no data available to indicate the ideal ratio of retail space to professional area within a pharmacy. In the absence of any measures of achievement of the National Medicines Policy objectives for different pharmacy types, it is difficult to provide an informed comment on what an ideal ratio should be, nor if it is even useful to prescribe such a measure. Internationally, and indeed in Australia, models with vastly different ratios of retail:professional space coexist.

PSA’s Health Destination program has demonstrated that pharmacies of different sizes, layout, location and staff numbers, can all be supported to increase consumer engagement and effectively deliver health care services.

PSA believes that a community pharmacy should be regarded as a place where consumers can confidently establish an ongoing therapeutic relationship with the pharmacy health care team. Health care focused interactions within a pharmacy should occur as a partnership between the consumer and pharmacist. Such interactions would be sub-optimal from a QUM perspective, unless the environment is conducive for, and the consumer is receptive to, the provision of health advice.

PSA encourages all pharmacies to ensure that a professional and appropriate pharmacy environment is provided for consumers, however, we also recognise that legislating or monitoring the ratio of perceived retail space to professional services space is both impractical and challenging to enforce. It would also serve no purpose if the intended outcomes of such restrictions were not clearly articulated in the context of the NMP and broader health system.
As medicine specialists, what are the professional programs and services that pharmacists should or could be providing to consumers in order to best serve the consumers?

Australians are missing out on evidence-based pharmacist care. Compared to much of the developed world, Australia is lagging behind in implementing innovative care models which make best use of the unique skills and expertise of pharmacists to prevent and manage chronic and complex conditions.

Pharmacists in Australia are one of the largest, most trusted and most accessible groups of health professionals. Similarly, community pharmacies in Australia have provided, and will continue to provide a vital network for primary and preventative community-based health care. Whilst pharmacists’ unique skills and expertise have been historically underutilised, there is a significant opportunity, within the current health reform environment, to ensure that pharmacists’ skills are better utilised to contribute to improved health outcomes for all Australians.

PSA has continued to advocate for pharmacists’ important contribution in the following areas to be recognised and appropriately remunerated;

- Prevention: ie. Evidence-based screening and risk assessment;
- Public Health: ie. Immunisation;
- Primary Care: ie. Triage, referral and the management of minor ailments;
- Optimising Medicines Use: ie. Medication management services, medication reviews, medicines information and adherence services;
- Effective Care Transitions: ie. Medication reconciliation and care coordination;
- Collaborative models of care: ie. Health Care Homes, Pharmacists in General Practice and Pharmacists in Aboriginal Health Services.

PSA wishes to reiterate to the Panel that despite uninformed commentary to the contrary, all of the above services are well within the current approved scope of practice for pharmacists and covered within the Competency Standards required of all registered pharmacists.31

Should there be limitations on some of the retail products that community pharmacies are allowed to sell? For instance, is it confusing for patients if non-evidence based therapies are sold alongside prescription medicines?

PSA’s Code of Ethics states that pharmacists must not sell or supply a product where it “may impose a hazard to the patient’s health or condition”. 32 Specifically, PSA does not support the sale of homeopathy products in pharmacy and believes that pharmacists must use their professional judgement to prevent the supply of products with no reliable evidence or evidence of no effect.33

Is it appropriate that the PBS links the remuneration for the provision of professional advice to the sale of medicines?

Dispensing is often wrongly perceived as an administrative task, as illustrated by the description in this question which limits it to the “sale” of a medicine. Dispensing more accurately represents a key consumer entry point into community pharmacy services. The dispensing and supply of medicines encompass multiple components of professional activities and should be recognised and remunerated as a health service and not a retail transaction.

PSA believes that remuneration for medicines supply and dispensing activities must be based on pre-established transparent criteria so that the important contribution pharmacists make to health is more visible to consumers, payers and policy makers.34
Would it be preferable when a medicine is dispensed if advice given to consumers is remunerated separately; for example, through a MBS payment? Would this be likely to increase the value consumers place on this advice?

PSA believes that a MBS payment is an appropriate remuneration mechanism for the provision of medication management services provided by pharmacists, in the same way that GPs and other health professionals’ clinical services are recognised. Medicines advice is just one such service, and an MBS payment would allow it to be delivered based on consumer need and the complexity of the presenting consumer’s situation and/or service provided.

Remunerating pharmacists through the MBS also brings pharmacists into line with other health professionals. Pharmacists are currently the only AHPRA registered allied health practitioners not eligible to provide services through the MBS. Considering the evidence for pharmacists’ interventions on certain chronic disease markers, compared to a number of practitioners and items that are remunerated on the MBS, the exclusion of pharmacists should be viewed as an oversight and rectified by Government. This would accord with recommendations from both the MBS Review and the Primary Health Care Advisory Group.

If an MBS payment for professional pharmacy advice was introduced, what level of service should be provided? Should the level of payment be linked to the complexity of particular medicines? Should it be linked to particular patient groups with higher health needs?

PSA advocates for a payment model which recognises and remunerates the pharmacist based on the complexity of the presenting consumer’s situation and/or service provided, rather than the complexity of the medicines supplied. This accords with recommendations from the 2001 Galbally Review, which advocated a focus on the consumer rather than on the risk profile of the product itself. Furthermore, it allows for services to be provided along a continuum, with the level of service being determined according to complexity and need (see Appendix 1).

What are appropriate ways for pharmacies to identify and supply the health services most needed by their local communities?

To ensure that the services being provided by local pharmacies are based on community and consumer need, a local needs assessment should be completed.

PSA’s Health Destination Pharmacy program supports pharmacies to identify and meet the health needs of their local communities, by providing detailed information on health issues, opportunities, needs and demographics in the local area.

Data which may help local pharmacies identify the health needs of their community can also be found through the Primary Health Networks and www.myhealthycommunities.gov.au.
How should government design the provision and remuneration of new programs that are offered through community pharmacy to ensure robust provision, value for taxpayers and appropriate supply for patients in need?
For instance, should all patients be entitled to an annual HMR? Should HMRs be linked to a health event, such as following hospital discharge? Should they only occur following referral from a medical practitioner?

PSA strongly believes that the provision of all health services should be based on patient need. This principle should apply for pharmacist services offered in all settings, including community pharmacy.

Services should be able to be conducted at a location of the patient’s choice, in a setting which meets their care needs at the time. This allows for flexibility to ensure that the service is not only delivered in a setting which is appropriate for the consumer, but that it is accessed by them in a timely manner, particularly when they are transitioning between health care settings. This is particularly important, as it is well-recognised that many adverse health events, particularly those relating to medicines, such as medication misadventure leading to potentially preventable hospital admission or readmission, occur during these transition periods.

Pharmacists can have a significant impact during critical transition periods and their involvement has been shown to decrease readmissions and future episodes of care. The proposal in this question to open up HMRs to all patients, while at the same time restricting the provision of service to an annual review, is incongruent with the principle of health service delivery based on consumer need.

Research and evaluations conducted in successive Community Pharmacy Agreements over more than a decade have made evidence-informed recommendations regarding better targeting of HMRs, investment in transitions of care periods and greater flexibility in terms of service setting to enable care to be provided where it is required. PSA has strongly encouraged Government to take these recommendations into account in the design and remuneration of pharmacy programs, as detailed in PSA’s 6CPA Discussion Paper.

Furthermore, PSA believes that it is important to note that HMRs and RMMRs were subject to funding limitations as a result of finite CPA budgets - even before the latest round of caps imposed on 1 March 2014. In direct contrast to this arrangement, GPs referring patients for either a HMR or RMMR are able to claim via items 900 and 903 on the MBS – for which funding is not limited. This has set up a funding inequality which then creates a mismatch between the demand and supply of patient services. In the simplest of terms, supply of MMR services is not able to meet demand due to business rules driven by funding constraints rather than clinical need (on the pharmacy side), and consumers who need these services the most may be missing out.

PSA recognises that while HMR & RMMRs are funded through the 6CPA there may be no opportunity for pharmacists to be remunerated for these services through the MBS, however, ultimately medication management services provided by pharmacists should be remunerated through the MBS, to not only ensure availability but also consistency in remuneration models between professions.
What pharmacy services should be fully or partially Government funded and what is best left to market or jurisdiction demands?

As previously stated, PSA believes that a patient co-payment could be considered for evidence-based services which are shown to be cost-effective and meet consumers’ clinical need, but that requiring consumers to pay in full for these services has the potential to create further health inequalities.

PSA strongly believes that access to pharmacy services, just like access to medicines, should not be restricted by the consumer’s ability to pay – and that evidence-based health services should not be left to market forces.

PSA believes that the Government should invest in primary health care services which make best use of the available workforce, and provide cost effective solutions to meet consumer needs. Pharmacists are currently underutilised in this regard.

Is there a role for pharmacists to work with patients and other health professionals, possibly relating to individual medicines or specific conditions, to better create the data to analyse the health outcomes for that particular patient or group of patients, including through the use of a patient’s existing My Health Record?

The measurement of health outcomes is complex and requires a robust evaluation framework; currently absent from many health system initiatives. Despite this, pharmacists have a key role in contributing to patients’ My Health Record, to both assist in the creation of robust data on health outcomes and to improve individual patient outcomes through the facilitation of integrated and collaborative care.

As the health system’s medication experts, pharmacists will need to play a prominent and consistent role in the Government’s eHealth initiatives in order to maximise the anticipated benefits, such as improvements in medication safety. Early data indicate that community pharmacies are eager to participate in this initiative.

If this data collection and analysis is desirable, would funding be needed from Government or from another source? If so, what would be the avenue for such funding?

Critical facilitators of pharmacist involvement are appropriate information, training and incentives. However, at present, only GPs are incentivised to upload information onto My Health Record.

PSA believes that the Government needs to establish a similar incentive scheme to maximise the opportunity for pharmacists to assist in providing information to consumers and facilitate their registration process as well as uploading relevant data. The network of community pharmacies in Australia and the accessibility of pharmacists to consumers are vital resources that should be both utilised and supported appropriately.

Evidence on effective implementation shows that Government will need to invest in the implementation and evaluation of this initiative.
If they are not receiving the relevant service, do consumers know the avenues for feedback or complaint? Are these feedback mechanisms adequate or should they be improved? If so, are there ways of using technology to provide better feedback?

PSA believes that consumers are aware of the avenues available to them to make a complaint if they are dissatisfied with their experience with any health practitioner or health service, however, PSA also recognises that more could be done to raise consumer awareness of this process.

At present consumers are able to make a notification to the Australian Health Practitioner Regulation Agency (AHPRA) and/or make a complaint to the relevant State or Territory body – a process which AHPRA can guide the consumer through. This process could be improved through the use of technology, however, as it is currently paper based.

What services should a consumer expect to receive from a community pharmacist who dispenses their medicines? Why should the consumer expect these services?

The previously cited PricewaterhouseCoopers research also assessed consumer needs and expectations in the context of community pharmacy in Australia. In terms of consumer expectations as they relate to community pharmacy, it was found that consumers expect:

- the pharmacist to provide advice on medicines;
- to be offered a generic version of a medicine if it is available;
- to be informed when updated information becomes available on medicines;
- for the pharmacist to provide health advice on minor conditions;
- for the pharmacist to collaborate with their GP if necessary;
- to be able to speak privately with the pharmacist; and
- to be treated with respect and consideration.

PSA believes that all of the consumer expectations detailed above are appropriate expectations for consumers of community pharmacy services in Australia. They also accord with PSA’s Code of Ethics and Professional Practice Standards. Furthermore, PSA believes that consumers should also receive accurate and timely supply of prescription medicines, in accordance with Domain 4 of the National Competency Standards Framework for Pharmacists in Australia – which details the pharmacists’ obligation to assess the prescription, consider the appropriateness of the prescription and dispense the prescribed medicines in a safe and professional manner.
What are the minimum services that consumers expect (and should receive) at the time of dispensing? Do these differ between initial and repeat prescriptions? Are these services being provided by all pharmacies?

The consumer expectations detailed in response to Question 99, are also the minimum services that consumers should expect from their community pharmacist at the time of dispensing.

PSA believes that pharmacists should use their professional judgement when assessing the level of information required to be provided during the dispensing of both initial and repeat prescriptions – a one size fits all approach is inappropriate. For example, initial dispensing is often thought of as more complex or time-consuming due to the need for counselling on a new therapy, or a device demonstration etc. However, dispensing repeat prescriptions provides an opportunity for the pharmacist to discuss and follow up on issues such as side effects and medication adherence.

PSA is not aware of any data to allow the question of whether all pharmacies are providing these services to be answered. The Pharmacy Guild, through their Quality Care Pharmacy Program, may have data to inform this question. The 5CPA required all pharmacies to display a Consumer Services Charter but adherence to this charter did not form part of the publicly available evaluation.

What does ‘transparently cost effective’ mean for consumers in the context of remunerated pharmacy services?

As the Australian National Audit Office (ANAO) report on the 5CPA reiterated that transparency in the expenditure of any Government funds is critical.

PSA believes that information relating to the expenditure of public funds on remunerated pharmacy services – and the outcomes of these investments - should be available in an accessible and transparent way for consumers and the broader public.

Whilst the Government has committed to review existing remunerated pharmacy services for their value and cost-effectiveness as part of the 6CPA, using a robust health technology assessment process, it remains to be seen how transparent the process and outcomes of these reviews will be to consumers.

In your experience, are community pharmacies generally delivering these services?

Community pharmacies in Australia have provided, and will continue to provide a vital network for primary and preventative community-based health care.

PSA has previously flagged, and shares concerns raised in the ANAO SCPA report regarding the transparency of information relating to service delivery, including geographic spread, and reach to consumers who stand to benefit the most. This lack of transparency makes it difficult to evaluate whether or not valuable and cost-effective pharmacy services are being delivered to all consumers—despite repeated calls by PSA over successive Agreements for more robust evaluation and transparency.
Are there currently some programs that are viewed as additional to dispensing which should be included as part of the service provided by a pharmacist when a prescription medicine is dispensed (for example, a medicines check or review)? If so, how should pharmacists be remunerated for providing these services? Should such services be included each time a prescription is filled or should ‘initial’ and ‘repeat’ prescription dispensing involve different services?

PSA has previously proposed that remuneration for pharmacists should recognise the professional input of pharmacists along a professional services continuum from dispensing through to medication management and chronic disease monitoring based on the individual consumer. As indicated earlier in this document, there is no one-size-fits-all approach to either initial or repeat prescriptions. For further information on the proposed medication management continuum, please see Appendix 1.

Is there a variation in service standards between different pharmacy models?

Whilst there may be anecdotal evidence that suggests there are variations in service standards between different pharmacy models, PSA is not aware of any robust data to demonstrate this.

Feedback from PSA members suggests that the financial pressure on the current business model of community pharmacy due to PBS reforms and the increasing “discount” environment is having an impact on the ability of pharmacies to deliver non-remunerated services.

As part of the National Health Determination made in 2007 by the Minister for Health all pharmacists are required to comply with both PSA’s Code of Ethics and Professional Practice Standards, in order to receive payment for the dispensing and supply of PBS medicines. However, PSA understands that there is currently no audit process to assess adherence to these standards. PSA would urge Government to consider investing in the development of robust quality indicators and metrics to objectively assess adherence to these standards across all community pharmacies in Australia. Doing so would provide the data to answer many of the previous questions.

Do community pharmacies that offer discount medicines provide lower levels of service? If so, what evidence is there available to support this?

Data provided to the Senate Community Affairs Committee as part of an answer to estimates questions on notice showed that as of February 2016, 79% of community pharmacies were offering some form of discounting through the implementation of the $1 discount. Whilst there is no evidence to support the statement that discounting results in lower levels of service, PSA is aware that the financial impact of offering these discounts has led some pharmacies to make changes that include a reduction in staff levels and a reduction of the non-remunerated services they may have previously offered. This may have an impact on service provision, but this has not been assessed as part of the Government’s implementation of this policy measure.

How do we measure the quality of services provided by the pharmacy?

The first step necessary is the development of robust quality indicators and metrics to objectively assess adherence to practice standards across all community pharmacies in Australia. As indicated earlier in this document, all pharmacists are required to comply with both PSA’s Code of Ethics and Professional Practice Standards, in order to receive payment for the provision of PBS medicines and 6CPA services. Yet there is currently no audit process to assess adherence to these standards in the delivery of these services. PSA recognises that the exact mechanism for evaluation is outside the scope of this review, and believes it should be considered further.
What do consumers expect from community pharmacy in relation to their medicines?

As per the consumer expectations detailed in PSA’s response to Question 99, the PricewaterhouseCoopers report indicated that consumers expect the pharmacist to provide advice on medicines, to be offered a generic version of a medicine if it is available and to be able to speak privately with the pharmacist about their medicines if required.50

How informed are consumers of the scope of medicines and related services that can be provided by pharmacists without referral to a General Practitioner?

The PwC research highlighted the need to increase consumer awareness around what health services, other than the dispensing of medicines, can be accessed by community pharmacy.51 This will be integral in ensuring consumers recognise the full capabilities of community pharmacists and the contribution that pharmacists can make as part of the primary care team.

In your experience, do community pharmacists provide appropriate advice for schedule 2 and 3 medicines?

PSA believes that pharmacists do provide appropriate advice for schedule 2 (S2) and schedule 3 (S3) medicines. Evidence from research conducted from 2002 - 2005 suggested that 66% of assessed pharmacies provided either satisfactory or excellent advice and service in relation to S2 and S3 medicines, with significant improvements observed over time.52 To PSA’s knowledge, this is the last publicly available evaluation of these services.

PSA continues to support the profession to provide timely, safe and high quality advice on S2 and S3 medicines through the development of robust guidelines, education and practice support tools, including; the Professional Practice Standards, Schedule 3 guidance documents and the Standards for the Provision of Pharmacy Medicines and Pharmacist Only Medicines in Community Pharmacy.

Pharmacists play an important role in assisting consumers to appropriately manage minor and self-limiting conditions through the provision of over the counter (OTC) medicines in accordance with Quality Use of Medicines (QUM) principles. PSA advocates strongly for a partnership approach to promote QUM and responsible self-medication.

Does the ‘retail environment’ within which community pharmacy operates detract from health care objectives?

As indicated in earlier responses, there are many different models of community pharmacy operating within Australia. PSA’s Health Destination program is focused on positioning the pharmacy as a central point of health care within a community. The image of the pharmacy does play a role in that, but there is no one-size-fits-all approach and health care objectives are met by pharmacists in a range of different settings. Additionally, some research indicates that the retail positioning of pharmacies may enhance their visibility and access for consumers.

PSA believes that if pharmacies create an environment which highlights price and convenience over advice and healthcare, consumers will also approach or initiate their health care interaction with a high priority on the former factors. This may impede the pharmacist-consumer interactions and potentially impact the quality use of medicines (QUM). Research has also shown that collaboration with other health care professionals is enhanced by pharmacies promoting a healthcare rather than price-focused image to the community.53
Viable Medicines Industry

Key Themes for Consideration

PSA has identified a number of the questions posed in the Review’s discussion paper as relating to the fourth objective of the National Medicines Policy; maintaining a responsible and viable medicines industry.

PSA is strongly committed to the existing community pharmacy network which serves the needs of Australians well. PSA believes the ongoing viability and infrastructure of the existing community pharmacy network should not be compromised as it is fundamental to providing all Australians with equitable access to cost effective medicines made available through the PBS.

Priority must be afforded to ensuring that the community pharmacy sector in Australia remains efficient, effective and viable to ensure that all consumers continue to have timely access to safe and affordable medicines.

Relevant Discussion Paper Questions

04 Should Government funding take into account the business model of the pharmacy when determining remuneration, recognising that some businesses receive significant revenue from retail activities?

PSA does not believe the Government should take into account the business model of pharmacies when determining remuneration.

09 Should the Government move away from a partnership arrangement? If so, what would take its place? For example, should the Government move to a more standard contracting or licensing approach with individual pharmacies or groups of pharmacies? How would such alternative arrangements be implemented?

Whilst there is certainly room for improvement in the negotiation, development and administration of the Community Pharmacy Agreement, these improvements should be made within the existing partnership framework. PSA strongly supports the retention of the current partnership arrangement with both the pharmacy sector and the broader medicines industry, and would urge the review to consider the improvements and amendments to the current arrangement which have been suggested as part of PSA’s response.
Is the ‘swings and roundabouts’ approach to remunerating pharmacists for dispensing appropriate? Does it lead to undesirable incentives?

Currently, remuneration for pharmacists is largely through the volume of dispensing and generic substitution. Historically, the remuneration derived from this has cross-subsidised pharmacies offering non-remunerated QUM services. Feedback from PSA members indicates however, that as a result of PBS reform, and the introduction of PBS saving measures including the $1 discount, many pharmacies are under increased financial pressure and are no longer able to offer non-remunerated QUM services to consumers.

A remuneration structure which allows pharmacists to better utilise their clinical knowledge and ensures that clinical activities associated with medication supply are strengthened, removes the incentives to operate in an environment which rewards volume – in many cases, at the expense of high quality clinical services which focus on consumer need.

Additionally, PSA would like to reiterate that the current remuneration structure for the supply of high cost PBS drugs through community pharmacy should be considered carefully by both the Review Panel and the Government, as feedback from members and the broader profession indicate that it is inadequate and could lead to unintended outcomes such as compromised consumer access.

Should dispensing fee remuneration more closely reflect the level of effort in each individual encounter through having tiered rates according to the complexity of the encounter? For example, should dispensing fees paid to pharmacists differ between initial and repeat scripts?

Dispensing and supply of medicines is wrongly perceived as an administrative task, when instead it represents a key consumer entry point into community pharmacy services. The provision of medicines is a core activity of pharmacists, and is not simply a supply function – it is performed in the context of having the highest regard for patient safety and promoting the judicious use of medicines.

To acknowledge the complexity of dispensing beyond “supply” and recognises the contribution of the pharmacist to consumers’ health care, pharmacists could be remunerated based on the complexity of the presenting consumer’s situation and/or the service provided – bringing pharmacists into line with other health professionals.

As detailed in an earlier part of this submission, PSA’s view is that remuneration for pharmacists should recognise their professional input along a professional services continuum from dispensing through to medication management and chronic disease monitoring based on the individual consumer. For further information on the proposed medication management continuum, please see Appendix 1.

The suggestion in this question regarding different dispensing fees for initial and repeat scripts is both inappropriate and simplistic, as the complexity of a prescription cannot be defined by whether it is an original or a repeat script. As indicated earlier in this document, there is no one-size-fits-all approach to either initial or repeat prescriptions.
Are the current fees and charges associated with the dispensing of medicine appropriate? In particular, do they provide appropriate remuneration for community pharmacists? Do they provide appropriate incentives for community pharmacists to provide the professional services, such as the provision of medicine advice, associated with dispensing?

The dispensing and supply of medicines encompass multiple components of professional activities and should be recognised and remunerated as a health service, not a retail transaction.

As noted in PSA’s response to Question 15, a remuneration structure which allows pharmacists to better utilise their clinical knowledge and ensures that clinical activities associated with medication supply are strengthened, removes incentives to operate in an environment which largely rewards volume – in many cases at the expense of high quality clinical service, focused on consumer need.

PSA has previously proposed a remuneration model for dispensing and consultations in the context of the medication management continuum. This model is outlined in Appendix 1.

Furthermore, as PSA has stated throughout this submission, we urge the Review Panel and Government to consider the remuneration pharmacists receive for the dispensing of high cost medicines such as the Hepatitis C treatments recently listed on the PBS. At present, pharmacists receive $70 to supply a medicine which may cost over $20,000.

Feedback from our members and the broader profession indicate that this fee is inadequate remuneration for the risk associated with the supply of such a high cost medicine, and has made the supply of these medicines unviable for many pharmacies – having a significant impact on patient access to these medicines.

As such, PSA believes that the Government should take steps to mitigate the risk associated with the stocking and supply of these high cost drugs.

PSA calls on both the Review Panel and the Government to urgently consider amending the remuneration structure for the supply of high cost drugs through community pharmacy to ensure that community pharmacies are able to continue to provide access to these potentially life saving medicines.

Is the Electronic Prescription Fee achieving its intended purpose of increasing the uptake of electronic prescribing and dispensing?

PSA understands that the impact of the Electronic Prescription Fee provided under the 6CPA has yet to be evaluated.

Data indicate that over $8 million was spent on the Electronic Prescription Fee in the 2014-15 financial year. However, PSA is unable to provide comment on whether or not this indicates an increase in the uptake of electronic prescribing and dispensing, as data prior to this period is unavailable, because as detailed in the ANAO’s audit report, the EPF budget was reallocated by the Department of Health.
More generally, is there a need for new business models in pharmacy? If so, what would such a model look like and how would it lead to better health outcomes?

PSA continually advocates for, and supports innovation in the pharmacy sector and believes that there is a need for, and an opportunity to, create new business models in community pharmacy.

PSA believes that there is a need for a stronger focus on meeting local health and consumer needs, and that a one size fits all approach to new models of pharmacy is inappropriate. This is the approach that PSA’s internationally-recognised Health Destination Pharmacy model has progressed.57

The Health Destination program supports a sustainable business platform with greater pharmacist-consumer engagement, allowing for opportunistic interventions and better targeting of services to local needs. The outcomes of pharmacist-delivered services on consumer health outcomes in a range of areas have been well documented.58

Is the current approach to CPA negotiations, as adopted in the 6CPA, an appropriate way to meet wholesalers’ needs? If so, why? If not, why not?

Again, PSA believes it is important to recognise that the 6CPA only commenced on 1 July 2015, and that thus far there has been no evaluation of whether it is meeting wholesaler’s needs, nor has there been any indication of how this will be objectively measured or evaluated.

Is a percentage mark-up paid by the pharmacist an appropriate way to compensate wholesalers? Would an alternative compensation arrangement be preferred? If so, please provide details of preferred arrangements.

PSA has not received any feedback which indicates that the arrangement is inappropriate.

Should the onus to negotiate the delivery of PBS medicines from manufacturers be placed on community pharmacies, either individually or as collectives? Would this be desirable or undesirable?

The onus to negotiate the delivery of PBS medicines from manufacturers should not be placed on community pharmacies. This would be undesirable as it could lead to inequitable arrangements and thus compromise one of the core objectives of the NMP, access to medicines.

Is the sale of schedule 2 and 3 medicines an important contributor to the income of community pharmacies?

The provision of schedule 2 and 3 medicines is a key activity for pharmacists, as they play an important role in assisting consumers to appropriately manage minor and self-limiting conditions through the provision of over the counter (OTC) medicines in accordance with Quality Use of Medicines (QUM) principles.

As these medicines, by law, are available only through pharmacies and by pharmacist consultation only, it would be fair to assume that schedule 2 and schedule 3 medicines are a significant contributor to the income of community pharmacies, but the proportion of this contribution to the overall turnover of the pharmacy would vary according to the business model of individual pharmacies.
Access to Medicines and Quality Use of Medicines

Relevant Discussion Paper Questions

12
Do current arrangements under the 6CPA lead to the appropriate creation and distribution of information relating to the use of medicines? If so, how and why? If not, why not and how could the distribution of this information be improved?

PSA believes it is important to recognise that the 6CPA only commenced on 1 July 2015, and that thus far there has been no evaluation of its impact on the distribution of information relating to the use of medicines, nor has there been any indication of how the impact will be measured or evaluated.

The provision of Consumer Medicines Information by pharmacists was evaluated as part of the 4CPA, and it is PSA’s understanding that many of the recommendations from that research were not implemented in subsequent Agreements.

Furthermore, PSA does believe that the business rules for professional programs relating to the provision of medicines information, for example, through Home Medicines Reviews, need to be more flexible and not setting dependent - to allow for the provision of the right care, in the right place at the right time.

PSA believes that HMRs and other QUM services should be able to be conducted at the location of the patient’s choice to ensure that pharmacist care is provided in a timely, accessible and culturally appropriate manner.

13
Is this requirement a significant impediment to online ordering and remote dispensing? If so, should this impediment be removed? In this scenario, what compensating arrangements would need to be implemented to ensure that there is appropriate oversight and control over dispensing and patient choice of pharmacy?

PSA does not believe the requirement creates a significant impediment to online ordering and remote dispensing.

33
Are pharmacy services accessible for all consumers under the current community pharmacy model? If not, how could pharmacy services be made more accessible?

PSA wishes to reiterate our belief that pharmacist services remunerated through the 6CPA, for example HMRs should not be setting dependent, and services designed to improve QUM should be flexible to meet patient need, delivered wherever the service is required.
Are there non-medicine-related services that pharmacists can or should provide to consumers due to their expertise as pharmacists or for other reasons (e.g. consumer ease of access to community pharmacies)? If so, why are these services best provided by community pharmacy?

The existing network of community pharmacies are uniquely placed within Australian communities, and are increasingly being recognised as a hub for preventative health activities. However, the full potential of pharmacists in this area has not been realised, nor has the existing network and infrastructure provided by these community pharmacies been leveraged to develop the scope of services that are available to consumers to both manage and prevent chronic and complex conditions.

More recently, Australia has caught up to many countries including; the United Kingdom, the United States, Canada, Portugal and New Zealand by enabling the necessary legislative amendments which allow pharmacists to deliver vaccinations in the community setting. This presents a major opportunity for the Government to leverage this ability to further improve herd immunity not only for influenza, but for all communicable diseases prevented by vaccination.

Furthermore, as detailed in the PwC report on consumer needs and expectations, consumers expect pharmacists to provide health advice on minor ailments. 51% of all consumers surveyed said that for advice on minor ailments and chronic conditions they would go their pharmacist in the first instance. Indeed, as the Review Panel and Government would be aware, most community pharmacies already provide these services, which are not currently remunerated through the 6CPA, nor any other arrangement.

Outside of community pharmacy, pharmacists provide a range of non-medicine-related services, such as in a general practice. This has been well documented in PSA’s Federal Budget Submission.

Is cost a barrier to accessing worthwhile health services offered by pharmacy?

PSA notes that there is an assumption in this question that some health services offered by pharmacy are not “worthwhile”. PSA notes that many community pharmacies offer valuable health services, which consumers may pay out of pocket for. PSA also recognises that the Review Panel would be aware of this after extensive consultation with pharmacists across Australia.

PSA wishes to reiterate that cost should not be a barrier for consumers to access health services provided by pharmacists, and believes that evidence-based, cost-effective pharmacist services which meet consumer needs represent a sound investment by Government.
If particular health services were deemed to be of clinical value and delivered good patient outcomes, what other mechanisms could allow these programs to be disseminated around the country to relevant communities and groups on an affordable basis?

As indicated in our response to earlier questions, PSA believes that a MBS payment is the most appropriate remuneration mechanism for the provision of evidence-based services provided by pharmacists, in the same way that GPs and other health professionals’ clinical services are recognised.

Pharmacists are currently the only AHPRA registered allied health practitioners not eligible to provide services through the MBS. Considering the evidence for pharmacists’ interventions on certain chronic disease markers, compared to a number of practitioners and items that are remunerated on the MBS, the exclusion of pharmacists should be viewed as an oversight and rectified by Government. This would accord with recommendations from both the MBS Review and the Primary Health Care Advisory Group (PHCAG), and would provide the flexibility for pharmacists to deliver this care in settings most appropriate for the consumer.

If the states and territories were to amend the ownership rules so that any party could own a pharmacy, subject to requirements for dispensing only by a qualified pharmacist, how would your response to the full or partial removal of pharmacy location rules change?

PSA supports retention of the current provisions relating to ownership of pharmacies. The main regulatory rationale and justification for these restrictions is that limiting the controlling interest in the ownership of pharmacy businesses to pharmacists promotes patient safety and competent provision of high quality pharmacy services and helps maintain public confidence in those services by ensuring pharmacists are in control of the policy making processes and are able to set the model of practice in that pharmacy. PSA would not support any changes to regulations that would result in a concentration of pharmacy ownership to a small number of groups which would dictate fewer models of practice. Further, limiting the number of pharmacy businesses that may be owned by a person or entity helps protect the public from market dominance or inappropriate market conduct.

Professional autonomy, objectivity and independence are critical to the practice of pharmacy and as such, PSA strongly believes it is not desirable that pharmacists practice in an environment (e.g. supermarkets) where they could be expected to meet certain operational policies or requirements which may not be in the best interests of professional pharmacy practice even if they may be regarded as accepted commercial business practices.

Should an approved pharmacy operating in an area for which the pharmacy location rules preclude the operation of a second pharmacy be required to provide a minimum level of services in addition to the dispensing of PBS medicines? Should such pharmacies also be required to maintain minimum opening hours in addition to those typically offered by community pharmacy?

All community pharmacies should aim to meet the health care needs of their local community through the provision of quality services and advice. PSA does not believe there is a "one size fits all" approach to determining appropriate service provision or pharmacy trading hours.

PSA believes that there are opportunities through the establishment of the PHNs and regionally focused health care delivery, to support pharmacies to maintain opening hours, in the same way that general practices are supported through After Hours incentive programs.
Could hospital pharmacies complement medicine dispensing and related services currently provided through community pharmacy or other public and private hospital pharmacies?

PSA is unaware of any need for hospital pharmacies to expand their services, as consumer access to community pharmacy is almost 100%, as previously stated.

How might broadening the services provided by hospital pharmacies improve consumer access in rural and regional Australia?

PSA strongly believes that the broadening of services provided by hospital pharmacies should only occur if consumer needs are not being adequately met by community pharmacy, and that decisions for this should be on a case by case basis. Supporting community pharmacies and/or individual pharmacists to deliver services in underserved areas may represent a more cost-effective solution than engaging hospital pharmacies – this needs to be explored in more detail.

Should hospital pharmacies be able to establish limited dispensing arrangements, either in-pharmacy or through a delivery or mail order service, to enable post-discharge services and continuity of care to patients in the community setting?

PSA reiterates that hospital pharmacy dispensing arrangements should only be expanded if there is community need. However, as indicated by the PwC report, consumer access to community pharmacies is extremely high.

Although s100 AHSs are able to fund the employment of a pharmacist from their primary health care budget, there are no specific funds to employ a pharmacist to conduct Quality Use of Medicines activities and manage the s100 program within the AHS. Do these arrangements impact on health outcomes?

The underlying assumption in this question is that there are sufficient primary care funds for Aboriginal Health Services to employ a pharmacist, an assumption which PSA believes to be incorrect. Feedback from members and the broader pharmacy sector indicate that whilst s100 allowances may support the employment of a pharmacist – the funding level is extremely inadequate.

PSA believes that careful consideration should be given to separating the supply function of pharmacists in AHSs with the provision of QUM services. Furthermore, PSA would suggest that funding provided for pharmacist delivered QUM services in AHSs would be more than offset by improvements in Aboriginal and Torres Strait Islander peoples health outcomes.

Could general improvements in remote dispensing improve the delivery of medicines in Aboriginal and Torres Strait Islander communities?

PSA believes that pharmacists should be remunerated for the provision of original labelled packs from s100 wholesale.
Should the s100 RAAHS program be extended to include non-remote AHSs? Similarly should the CTG Co-Payment measure and QUMAX programs be extended to include AHSs in remote areas?

As noted in response to Question 68, PSA believes that allowing remote s100 AHSs to write CTG scripts would be desirable. Currently, only AHSs in urban and rural areas, or Practice Incentive Program accredited General Practices are able to provide CTG prescriptions. Allowing remote s100 AHSs to provide CTG scripts would only improve access to medicines for Aboriginal and Torres Strait Islander peoples, providing continuity of access to medicines, especially for people who travel frequently between urban, rural and remote settings.

As stated previously, PSA believes that eligibility for medication access programs and services should be based on consumer need, not their location.

PSA reiterates the need for consideration of an overarching universal medicines access scheme for Aboriginal and Torres Strait Islander peoples which is not dependent on location or setting.

How could appropriate QUM activities be provided in all remote areas at a comparable level of quality to those provided in non-remote services?

People in rural, regional and remote Australia have worse health than people living in cities. They have higher rates of many diseases, more health risks and higher death rates in every age group. The level of Medicare expenditure per capita is less in rural and remote Australia than in metropolitan areas. The annual primary care deficit in rural and remote Australia is estimated to be $2.1 million. This underspend on primary care results to an extra $830 million being needed for hospitalisation costs.

In rural and remote communities where there is limited access to GPs, pharmacists often play important roles as primary healthcare professionals e.g. wound care, minor ailment diagnosis and treatment, chronic disease management.

Addressing the challenges of rural health provision will undoubtedly require some amendments to the current funding arrangements, so that the contribution of pharmacists in these settings can be optimised. Furthermore, PSA believes that pharmacists need to be remunerated for the provision of advice delivered by electronic media e.g. Telehealth as GPs and specialists are.

Should access to electronic patient health records be required for all health professionals treating Indigenous patients across all locations?

PSA strongly supports the use of electronic patient health records, and believes that they facilitate accurate and coordinated care across all patient groups.

Currently not all areas are covered by the 24-hours CSO obligations (such as Christmas Island, Derby (WA) and Mission River (QLD)). Are these exceptions leading to detrimental outcomes for patients? If so, why? If not, why not? If so, should they be included in the 24-hour rule? If so, how is this logistically possible? If not, are there other areas of Australia that could be excluded from the 24-hour rule without adverse patient impact?

Feedback from PSA members and the broader pharmacy sector indicates that these exceptions may indeed be contributing to poorer consumer outcomes. Excluding some locations from the 24-hour CSO obligations fundamentally challenges the first objective of the NMP relating to consumers having timely access to medicines.

As such, PSA believes that all areas should be covered by the 24-hour CSO obligations and that these provisions should be in place as soon as possible.
What data is already available in pharmacy and other parts of the health system that could be used to inform the monitoring and assessment of standards of delivery and health outcomes? How might a patient’s existing My Health Record be used to support this?

Previous Agreements have had some parameters in relation to service delivery evaluated but much of this is not publicly available – the Panel may be able to access it, however. As indicated in earlier parts of this submission, PSA is not aware of data pertaining to standards of delivery, and would recommend the development of robust quality indicators and metrics to objectively assess adherence to practice standards across all community pharmacies in Australia.

The Pharmacy Guild, through their Quality Care Pharmacy Program, may have data to inform this question, as well as the extensive data collected through the GuildCare software platform used by many pharmacies.

The collection of data throughout the SCPA for each of the professional programs would indicate there is data available, but it has not been made public, as highlighted in the ANAO’s report.69

PSA would urge the panel to seek this information.

Are consumers aware of what programs and general pharmacy services they are entitled to? Is there enough information available regarding the services for which they are eligible?

As PSA has previously stated, the available research in this area indicates that more could be done to increase consumer awareness of community pharmacy programs and services they may be entitled to.

Is the ability for the consumer to choose their pharmacist, and change pharmacists if they are dissatisfied, the appropriate or best mechanism to provide feedback?

As it stands, there are no restrictions on consumers being able to choose and change between pharmacists and community pharmacies. Additionally, as detailed in PSA’s response to Question 96, consumers are able to make a notification to the Australian Health Practitioner Regulation Agency (AHPRA) and/or make a complaint to the relevant State or Territory body – a process which AHPRA can guide the consumer through.
Are there appropriate standards for the dispensing of medicines and delivery of services by community pharmacy? If so, are these standards being upheld? If not, how could the current standards be improved?

There are appropriate standards for the dispensing of medicines and the delivery of services by pharmacists. The National Competency Standards Framework for Pharmacists in Australia, PSA's Professional Practice Standards and PSA’s Code of Ethics underpin all aspects of pharmacy practice, including dispensing and professional services in Australia. Furthermore, in order to be remunerated for the dispensing and supply of PBS medicines, the National Health Determination made in 2007 by the Minister for Health states that all pharmacists must comply with these guidelines and standards.

Additionally, the Pharmacy Board of Australia’s Guidelines for dispensing of medicines reinforce the obligations of pharmacists during the dispensing of medicines within the broad legal and professional framework that pharmacists practise within.

However, as PSA has stated previously there is currently no evaluation of whether these standards and guidelines are being complied with, and as such would urge the Government to invest in objective quality indicators and an audit process to assess this.

To what degree do current advertising restrictions limit the ability of pharmacies to promote medicines and related services available to consumers?

Advertising can be a complex activity when it involves therapeutic goods or health-related items or services. Advertisements for therapeutic goods need to be objective, be consistent with its scientific basis, and not compromise public health or patient safety. Furthermore, irrespective of how well or how poorly a therapeutic product is advertised, the benefits that may be realised are dependent not only on the correct use of the product but also on the characteristics and health factors of the consumer.

We firmly believe that, on balance, advertising Schedule 4 medicines carries a high risk that judicious and appropriate use of these potent medicines may be compromised and may have a negative or sub-optimal impact on the health of Australians. PSA remains committed to the current prohibition in Australia of direct-to-consumer advertising of Schedule 4 medicines. We do not support any relaxation of this restriction as we do not believe it is in the interests of public protection to do so.

Currently PSA supports the advertising of Schedule 3 medicines on a case-by-case basis. We do not believe that all Schedule 3 medicines are suitable for advertising and we are opposed to price promotion of these products. Clearly all Schedule 3 substances have been judged to meet the scheduling factors for this category of medicines and therefore may be regarded to carry comparable risk-benefit profiles. However, the approved indications and therapeutic profiles of Schedule 3 substances are variable and therefore PSA is of the view that suitability for a Schedule 3 product to be advertised may be influenced by these factors and characteristics.
Are the current restrictions on the sale of schedule 2 and 3 medicines an appropriate balance between access and health and safety for consumers? If not, how could this balance be improved?

Pharmacists play an important role in assisting consumers to appropriately manage minor ailments and self-limiting conditions through the provision of OTC medicines in accordance with Quality Use of Medicines principles.

PSA supports consumers continuing to have reasonable access to all current Schedule 2 and Schedule 3 medicines.

Pharmacists use their professional judgement to prevent the supply of products likely to constitute an unacceptable hazard to health or the supply of unnecessary and/or excessive quantities of medicines or products, particularly those which have a potential for abuse or dependency.72

As such PSA believes that the current restrictions on the sale of S2 and S3 medicines appropriately balance access to medicines with the safety of consumers.

What do consumers expect for the value of the PBS co-payment, noting it is intended to contribute to the price of the medicine, supply to pharmacy, a pharmacy handling fee and a professional dispensing fee?

As highlighted throughout this submission, the available research indicates that consumer awareness is low when it comes to community pharmacy services and expectations are consistent with this.

Not only could the transparency of pharmacy remuneration arrangements be improved, as stated previously, but more could be done to increase consumer awareness of services to which they are entitled.

Should pharmacists be able to discount the co-payment by more than one dollar if they choose to do so? Would such competition benefit or harm consumers? If competitive discounting is expanded for the co-payment, should any limits be placed on the potential discounts?

PSA firmly believes that pharmacists should not be able to discount the PBS co-payment by more than one dollar.

As stated earlier in this submission, PSA believes that discounting PBS prescriptions not only undermines the principles of universal access and equality which underpin the PBS, it also results in the commodification of medicines. PSA believes that this is undesirable as it may contribute to medicines being viewed as ordinary items of commerce, undermining the rigour underpinning the extensive regulatory processes that therapeutic goods are subjected to for the safety and benefit of consumers.

What services do consumers expect and value from pharmacists outside of standard business hours? Are there other settings or mechanisms that could deliver these services after hours?

As highlighted throughout this submission, the available research indicates that consumer awareness is low when it comes to community pharmacy services and expectations are consistent with this. This applies to both normal business hours and non-standard hours.

One of the roles of PHNs in their regional health service planning is to identify the services required and make best use of the available workforce and service providers to deliver those to consumers. PHNs have only just commenced (July 2016) their commissioning of health services to meet local needs. An evaluation of this will provide information to answer the question of whether services traditionally provided by pharmacies can be delivered in other settings. Similarly, whether pharmacists can provide services currently delivered by other providers.
Does more need to be done to encourage greater access to medicines and professional services through the expansion of existing rural and remote programs?

PSA has previously recommended that the 6CPA include a comprehensive evaluation of rural and remote pharmacy services. In addition, that Government consider investment in the following activities, with the objective of increasing consumer access to medicines and pharmacist services in rural and remote Australia:

• Investigate provisions for pharmacist dispensing at rural outposts;
• Reimbursement of rural pharmacists for a range of clinical services and telehealth, as per other health professionals; and
• Aligning pharmacy with other workforce programs, using the GISCA rural classification system.

Is it reasonable for consumers to expect that all community pharmacies provide these specialist services? If so, why? If not, why not?

Consumers should not expect all community pharmacies to provide all potential “specialist” services. PSA maintains that services provided through community pharmacy should be based on, and meet consumer health needs. A one size fits all approach for determining services offerings in community pharmacy is inappropriate.

Would it be desirable to align the delivery of specialist services to population need in local communities? If so, what is the best way of coordinating appropriate and relevant services for populations of need?

As stated previously, PSA is of the view that it is highly desirable to align the delivery of all health services to consumer health needs.

PHNs have been tasked by Government to take on the role of coordinating appropriate and relevant services for populations of need and PSA and pharmacists are already working with many of them around Australia.

How might access and service barriers identified above be resolved and consumer needs be better met? Is additional training and support within community pharmacy sites needed?

A thorough understanding - through better access to data and more transparent reporting - of the access and service barriers is needed in order to provide an informed response to how this might best be resolved. As indicated earlier, consumer access to pharmacies in Australia is extremely high.

At a system level, PSA has previously stated that Government does indeed need to invest in support for community pharmacies to ensure that funded services reach consumers most in need. Training, incentives and guidelines alone will not change practice. Evidence on effective implementation shows that investments are required in the following areas:

• Start-up costs (e.g. equipment, infrastructure);
• Purveyor support (e.g. forums, assessments, support for change);
• Funding for the services themselves; and
• Ongoing support of infrastructure for sustainability.

Evidence from the Australian Primary Care Collaboratives, used to effect change in General Practice, has shown that practices can be assisted to achieve incremental, rapid and locally relevant improvements across a broad range of clinical and practice business issues, and to sustain these changes.
Are there other inequities in terms of access to and quality use of medicines? If so, how should those be addressed and what population groups could be targeted?

Aboriginal and Torres Strait Islander people have two-to-three times higher levels of illness than non-Indigenous Australians. PSA acknowledges that this is a key area of policy focus for the Government, who have indicated their commitment to achieving health equality between Indigenous and non-Indigenous Australians within a generation. Together with changes to lifestyle factors, long term medicine treatment is usually needed to prevent or reduce disease progression and thereby minimise or delay negative outcomes of ill health. Despite the high burden of chronic disease, under-use of medicines amongst Aboriginal and Torres Strait Islander people persists, due to a range of factors – of which access is one.

Without improved medicine information and increased medicine adherence, it is likely that chronic disease for Aboriginal and Torres Strait Islander people will remain poorly controlled and morbidity and mortality rates will remain high. As suggested earlier in this document, to help address existing and significant inequalities in health status, Government should consider developing an overarching universal medicines access program for Aboriginal and Torres Strait Islander people.

Other population groups that need to be targeted include those living in rural and remote Australia, those with multiple chronic and complex diseases, and those transitioning between care settings, all of whom have been identified as at greater risk of medication misadventure.

What can be done to increase public awareness of available pharmacy programs and services, particularly specialist services?

As noted in the ANAO report, the transparency of pharmacy remuneration arrangements could be improved so that consumers are aware of what to expect from community pharmacies. More could be done to increase consumer awareness of services to which they are entitled, or from which they could benefit, based on their needs.

A multi-pronged approach – involving lay media as well as utilising existing networks such as PHNs and other stakeholders such as private health insurers, could be valuable in achieving this increased awareness.

How can we encourage and support consumers to engage more with their local pharmacy and what specific patient groups require more general awareness about available pharmacy services?

As stated above, patient groups that would benefit from targeted promotion about relevant services include those living in rural and remote Australia, those with multiple chronic and complex diseases, and those transitioning between care settings, all of whom have been identified as at greater risk of medication misadventure.
Access to Medicines and Viable Medicines Industry

Relevant Discussion Paper Questions

02

If it is desirable for the ratio of community pharmacies to population to increase or decrease in some areas, what in your opinion is the best way to encourage this?

PSA does not believe that the ratio of community pharmacies to population is an appropriate metric with which to measure access to medicines and pharmacy services. Many consumers in rural and remote settings still lack timely access to both medicines and pharmacist services, which are available to consumers in metropolitan areas. Furthermore, an individual’s health or social circumstances may inhibit their access to pharmacies, which is not addressed by ratio requirements.

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Is the Rural Pharmacy Maintenance Allowance (RPMA) the best way to encourage pharmacies to operate in locations where they would not otherwise be viable? Is community need a more appropriate measure than geographical location?

Feedback provided to PSA by members indicates that many rural and remote communities cannot sustain a viable community pharmacy, despite CPA incentives such as the Rural Pharmacy Maintenance Allowance (RPMA). Rural pharmacies can have higher cost to income ratio than urban pharmacies, due in part to the higher wages needed to attract pharmacists, higher stock levels (fewer deliveries), greater transport costs and sometimes more expensive rent and accommodation (e.g. mining towns). The lower socio-economic status of rural populations is also a contributing factor to pharmacy income.

It also appears that current rural pharmacy workforce programs do not fully take into account the shortage of pharmacists in rural areas and regional towns, classified as PhARIA 1. Health Workforce Australia (HWA) statistics show that not only is there is a shortage of pharmacists in these regional areas, but pharmacists, interns and students located there have high travel costs whilst being ineligible for current allowances. Furthermore, pharmacists are often unable to access/afford CPD events due to costs associated with travel, time and locums.

Thirty per cent of respondents to the Rural Pharmacy Survey conducted in June 2014, indicated that changes to rural program rules and the pharmacy rural classification system (PhARIA) under 5CPA had negatively affected them. The main concerns were the lack of ability to claim CPD and intern allowances. The capped HMR travel allowance also resulted in about 50% of HMR providers stating that they were doing fewer HMRs following the changes.
Is the Premium Free Dispensing Incentive achieving its intended purpose of increasing the uptake of generic medicines? Are there better ways to achieve this?

PSA is not aware of any publicly available data to allow us to form an answer to this question.

Should the timeframes for payment settlements for very high cost medicines be lengthened throughout the supply chain and mandated by Government?

Increasing the timeframes for payment is one way in which the financial burden of stocking very high cost medicines may be ameliorated. As indicated earlier in this submission, feedback from pharmacists indicates that the remuneration received for dispensing these high-cost medicines does not cover the inherent financial risks, nor the impact that stocking them can have on the cash flow of a community pharmacy. Perhaps of most concern is that a recent poll indicated that up to one third of community pharmacies would elect not to stock these items.

Together, these issues could have potentially serious repercussions for consumer access, continuity of treatment and outcomes, particularly for those in rural and remote settings. If not resolved, these issues are likely to worsen as more high-cost therapies move onto the PBS.

Are there better ways of achieving patient access to very high cost medicines through community pharmacy that reduce the financial risks to the supply chain and facilitate consumer choice?

In addition to the response to question 22 above, Government needs to consider and implement a long term, sustainable approach to the supply chain for very high cost medicines. This needs to involve consultation with all stakeholders – manufacturers, wholesalers, pharmacy owners and consumers.

Would any of these remuneration models be generalizable to other medicine services offered by pharmacies? Why or why not?

It is not clear what is intended here by the term “medicine services”, but PSA has stated clearly elsewhere in this document our position on the remuneration of pharmacist services according to complexity and consumer need (see also Appendix 1).

Would the removal of the location rules with the retention of the current state ownership rules for pharmacies increase or decrease access and affordability for pharmaceuticals to the public? Why and for what reasons?

As PSA understands, after review of Australian and international literature, there are insufficient data available to answer these questions. Current international experience suggests that the removal of all regulatory arrangements (including both location and ownership provisions) favours urban populations.78

PSA would urge the Review Panel to carefully consider the international evidence available on the unintended effects of removing community pharmacy regulations, particularly from jurisdictions where re-regulation has been required after a period of time to address the consequences of such changes.
Is the short distance relocation rule appropriate? Please provide examples to explain your reasoning.

PSA is not in a position to comment on the appropriateness of this rule due to the lack of publicly available data, but would reiterate the considerations outlined above in considering any changes to the rules.

A similar requirement exists with the same rule for relocation of pharmacies from within medical centres. Is this requirement for medical centres desirable or undesirable?

As above, PSA is not in a position to comment on desirability of this requirement, but would reiterate the considerations outlined above in considering any changes.

It has been suggested to the Review that pharmacies should be allowed to enter new locations subject to the payment of an appropriate approval fee to Government to prevent excessive entry to the pharmacy market. Any pharmacy then having been competitively impacted by a new entrant, or who would prefer to exit the market, would be able to receive compensation for surrender of its own approval number. Would such an approach be desirable or undesirable?

This suggestion and approach are both highly inappropriate and undesirable. Again, PSA would like to reiterate that medicines are not ordinary items of commerce, thus business rules which might work in other industries are inappropriate for community pharmacy and the health sector.

It has also been put to the Review that by limiting competition for existing pharmacies, the pharmacy location rules raise the profitability of some or all community pharmacies. Is this a reasonable expectation of the effect of pharmacy location rules? Please provide examples to explain your reasoning.

As previously stated, the objectives of the location rules are to ensure; all Australians have access to PBS medicines, a commercially viable and sustainable network of community pharmacies dispensing PBS medicines exists, and that consumers in rural and remote regions of Australia have increased local access to community pharmacies. The location provisions facilitate access to pharmacies by all segments of the population. This is of inestimable value in terms of delivering safe and reliable health care services. Moreover, as Australia’s population ages, a broad geographic spread of pharmacies proves invaluable in meeting the needs of older consumers. As such, PSA supports the retention of pharmacy location rules.

If pharmacies operating out of private hospitals were required to operate 24-hours a day, would this be beneficial for consumer access? Would it be viable or economical for private hospitals to provide this service?

As stated frequently throughout this document, there is nothing to indicate that consumers are experiencing difficulty in accessing medicines. It is reasonable for consumers to expect access to medicines outside of standard business hours to some degree.

As to whether private hospitals should be engaged to operate 24 hour services, more information is required to assess the viability of this and the appropriateness of it in preference to, or alongside community pharmacy. The Victorian Government’s pilot of 24-hour pharmacies will provide an important insight into the viability and utilisation of services and medicines access outside of standard business hours.
Should hospitals be able to open dispensing pharmacies in the community? Should hospitals be able to contract with specific community pharmacies? Under these arrangements, should community pharmacies be able to access medicines through hospital supply arrangements?

Again, if these arrangements are being proposed to fill access gaps, it is important to firstly understand if there are in fact such gaps. All available data suggest otherwise, and the opening of such arrangements may impact negatively on the viability of local community pharmacies.

What other opportunities are there for public and private hospital pharmacies in securing supply options for greater access to PBS subsidised medicines?

See response to Q58 above.

Should AHSs in all states and territories be able to operate a pharmacy business?

PSA is aware that in the Northern Territory, Aboriginal Health Services are able to own and operate a pharmacy business at Ministerial discretion. Whilst PSA recognises that benefit might be derived through both timely access to medicines in remote communities, and the provision of culturally appropriate pharmacy services, evidence suggests that currently it is difficult for community pharmacies in some rural and remote locations to remain viable – as such, PSA believes it is unlikely that many AHSs would have capacity to absorb the risk and liability associated with operating a pharmacy business.

Could there be more scope for tendering for the supply of medicines through AHSs?

PSA would strongly recommend that a pharmacist was employed through the AHS to ensure quality use of medicines, in keeping with PSA’s Federal Budget Submission.

Are there alternatives to the current CSO rules that would enable wholesalers to improve the efficiencies of their services without detracting from the consumer experience and access?

The efficiencies of wholesaling services is not something that PSA is able to provide comment on.

Pfizer supply direct and do not provide their medicines for supply through the CSO. Should all PBS medicines be available through the CSO, or is it appropriate for a manufacturer to only supply direct to the pharmacy?

PSA firmly believes that all PBS medicines should be available through the CSO, and further believes that it is not appropriate for a manufacturer to only supply direct to pharmacies, as it creates significant potential for fragmentation of access.

Should CSO wholesalers have such discretion, or should they as part of the CSO arrangements be required to provide minimum terms and conditions for PBS items?

Following on from PSA’s assertion in Question 78 that that all areas should be covered by the 24-hour CSO obligations, PSA firmly believes that as part of the CSO arrangements, wholesalers should have to provide minimum terms and conditions.
CSO wholesalers can require minimum ordering amounts for specific medicines. This is likely to reduce the cost to the wholesaler while increasing inventory costs and wastage for the pharmacy. Is this desirable or undesirable? Are there other parts of the wholesaling arrangements that create or encourage cost shifting that are undesirable for community pharmacy or consumers?

Increasing inventory costs and wastage for pharmacies is obviously undesirable. Wholesalers minimum ordering requirements may place undue burden on pharmacies, particularly smaller independent pharmacies. These requirements may have unintended consequences on consumers ability to access medicines.

Does the current CSO arrangement lead to strategic variation in trading terms by wholesalers that is detrimental to some community pharmacies and patients. If so, how? How could the current system be modified to remove such undesirable strategic behaviours?

Other than anecdotal evidence, there are limited data available to provide informed comment on this issue. In order to fully assess the potential consequences of changes to the arrangement, both positive and unintended, further investigation and modelling must be undertaken.

Could the Government provide either improved wholesale medicine delivery or equivalent wholesale medicine delivery at a lower cost to consumers and taxpayers by moving from a broad CSO system to an alternative system?

As stated above, PSA believes that there are limited data available to provide informed comment on this issue. In order to fully assess the potential consequences of changes to the current system, both positive and unintended, further investigation and modelling must be undertaken.

Should the onus for the delivery of medicines to community pharmacy around Australia in a timely fashion (e.g. 24-hours) be imposed on the manufactures as part of their listing requirements on the PBS?

As per PSA’s response to Question 75, PSA does not believe that it is appropriate for manufacturers to supply directly to pharmacies. As such, it would be inappropriate to place the onus on timely supply of medicines to community pharmacies on the manufacturer.

Would an improved approach to wholesale medicine delivery involve the Government tendering delivery on a nation-wide basis to one or two wholesalers (with appropriate redundancies)? Should it be done on a national, state or local basis? Should tendering be limited to only Pharmacy Accessibility Remoteness Index of Australia (PhARIA) 2, 3 and 4 locations, with open competition in PhARIA 1 areas?

As stated above, PSA believes that there are limited data available to provide informed comment on this issue. In order to fully assess the potential consequences of changes to the current system, both positive and unintended, further investigation and modelling must be undertaken.
The Review Panel notes that state and territory governments already tender for the supply of medicines to public hospitals, should the Commonwealth and state and territory governments work together for a single tendering model for relevant public hospitals and community pharmacy in the relevant state? If so, should it be for all medicines or specific medicines (e.g. biosimilar or generic medicines)?

PSA believes that the proposed model is undesirable as it may lead to differences in medicines access between State & Territories – fundamentally undermining the universality of the PBS and the objective of the NMP relating to consumer access to medicines.
Access to Medicines, Quality Use of Medicines, and Viable Medicines Industry

Relevant Discussion Paper Questions

07

Should the CPA be limited to dispensing and professional programs provided by community pharmacy only? If so, how can contestability and effectiveness be ensured in professional programs? If not, why not?

Whilst PSA recognises that the central element of the legislation underpinning the CPAs is to remunerate pharmacies for the supply of pharmaceutical benefits to the community, over time the Agreements have had an increasing focus on professional pharmacy services. As PSA outlined in our 6CPA Discussion Paper, arrangements for the professional programs appear largely to be viewed as “add-ons” to the dispensing aspects rather than having been developed as an integral element of a strategic approach to improving the health of the community and changing pharmacists’ practice. This issue was articulated in a review of arrangements for 4CPA which found that “there was no overarching plan for rollout of programs and consideration of how projects and programs interrelate and how this might be better managed from the perspective of pharmacists participating in the programs.”

PSA is concerned that continuing to frame Agreements without such a plan has the potential to diminish the impact of both parts of the Agreement. Whilst it is acknowledged that a number of the 6CPA professional programs are important contributors to maintaining and improving the health of the community, concerns have been expressed that some of the structural and governance arrangements – including those which tie the services to the community pharmacy setting – may be inhibiting the effectiveness of these programs for consumers.

The Pharmacy Guild of Australia are signatories to the Agreement, but the Agreement states that “the Department intends to ascertain through a formal process whether there are any persons interested in, and capable of, providing administration support in respect of the Community Pharmacy Programmes after the end of the first Financial Year of the Term. Any such process and subsequent engagement of one or more persons will be conducted in accordance with all standards of accountability required of the Department and relevant officials under the PGPA Act, including as set out in the Public Governance, Performance and Accountability Rule 2014, the Commonwealth Procurement Rules and the Commonwealth Grant Rules and Guidelines.”

Apart from a Request for Information in relation to the administration and management of the programs in February 2016, PSA is unaware of any further public process to allow a transparent or contestable process for determining the contracts for the administration of programs, which the Guild is listed as holding for the first year of the Agreement only, when it will then be invited to reapply alongside other parties. The total funding available is up to $44 million over the course of the Agreement (up from the $32.1 million received by the Guild in 5CPA) for program administration.

Greater transparency and consultation in the early phases of program design and planning, especially where collaborative services are proposed, should also be considered. Facilitating the engagement of consumers and other primary health care professionals (particularly general practitioners) in this process is a role that PSA could readily oversee, given our strong stakeholder relationships.
Is it appropriate that the Government continues to negotiate formal remuneration agreements with the Guild on behalf of, or to the exclusion of, other parties involved in the production, distribution and dispensing of medicines? If so, why? If not, why not, and which other parties should be involved? Is there currently an appropriate partnership with these other parties, including consumers?

Realising the objectives for 6CPA undoubtedly requires pharmacy’s relevant professional bodies to work together. This will assist in ensuring an evidence-informed approach and reduce unnecessary duplication of resources. Most importantly, this approach will provide the profession with the best chance of successfully implementing existing and new professional practice programs, thereby delivering high quality health services to the Australian public.

Despite PSA’s role as the peak pharmacists’ body, with a significant cohort of members who are owners of community pharmacies, since 3CPA, PSA’s role has been acknowledged only as “an active participant in those areas...related to professional practice”

An enhanced role for PSA in shaping the Agreements is supported by the profession. Without PSA, there is no voice for the many pharmacists employed within the community pharmacy sector, who in fact make up the largest proportion of the workforce.

PSA believes that if its advice and input are actively being sought to design the professional programs within the CPAs, then it is only fair and reasonable that PSA be considered as a joint signatory to the parts of the Agreement dealing with professional programs and services. Signatory status would of course need to be contingent on PSA being involved as an equal partner/participant in all discussions that relate to proposed professional programs and services in CPAs.

Would a community pharmacy that solely focused on dispensing provide an appropriate or better health environment for consumers than current community pharmacies? Would such a pharmacy be attractive to the public? Would such a pharmacy be viable?

It is unclear from the question how the Panel is defining “dispensing” and so if it includes the provision of pharmacist and pharmacy only medicines as well as prescription medicines and associated advice, there are pharmacies that arguably already operate on largely this basis. As indicated elsewhere in this submission, there are many different pharmacy models operating in Australia, and the ratio of non-scheduled products to the dispensary/S2-S3 varies significantly. Industry aggregate data indicate that the average ratio of income from the dispensary and pharmacy services to retail is 65:35, with some pharmacies already operating at a ratio upwards of 80:20.

In terms of the appropriateness of the environment, PSA has already articulated throughout this document the need for pharmacies to operate an environment which is conducive to health care interactions and the disadvantages of highly price-focused models.
What does innovation look like in community pharmacy? Is there sufficient scope and reward for innovation embedded in the current remuneration model? How could this be achieved?

PSA is aware that there are many individuals who are already delivering innovation in practice in the community pharmacy sector.

PSA, as the peak pharmacist body in Australia, aims to lead the profession in innovation in pharmacy practice. PSA continually advocates for the exploration of, and investment in innovative models of practice. Health Destination pharmacy is one such approach.

PSA believes that innovation in community pharmacy is being held back by incentives to operate in an environment which largely rewards volume – in many cases at the expense of high quality clinical service, focused on consumer need.

The full integration of pharmacists into a more collaborative, consumer-centred model of care, is necessarily a long term (>10 year) objective, likely requiring multiple funding streams and significant changes within the health system as a whole. This doesn’t mean, however, that incremental steps towards this objective cannot be made within the context of the 6CPA. A sound appraisal of what is achievable within the five-year CPA timeframe, from the perspective of all stakeholders, should be used to guide a pragmatic approach to improving current arrangements.

A remuneration structure is needed which allows pharmacists to better utilise their clinical knowledge and ensures that clinical activities associated with medication supply are strengthened and based on consumer need.

If hospital pharmacies were able to complement the services provided by community pharmacy, should all pharmacies be able to access similar purchasing arrangements?

As stated previously, PSA is unaware of any current need for hospital pharmacies to expand their service offering in the community to fill access gaps.

Could dispensing arrangements by hospital pharmacies to patients be extended to the broader community to complement access to medicines through community pharmacy?

PSA believes that if local community needs were not being met by community pharmacy, an argument could be made for dispensing arrangements by hospital pharmacies to be extended to the broader community. Equally, support could be provided to community pharmacies to assist them to address access gaps.

However, PSA is unaware of any evidence which would support this argument, as consumer access to community pharmacy, as previously stated is almost at 100%.
The s100 Support Program supports increased involvement of pharmacists in the supply of PBS medicines to AHSs. Is there further scope for pharmacists to be more involved without impacting on access to medicines? Should pharmacists be able to directly claim an MBS type payment for QUM activities conducted in AHSs? Could this be a trial program under the 6CPA?

PSA has, and will continue to, strongly advocate for an effective and sustainable model to support pharmacists working in Aboriginal Health Services.

A clinical pharmacist employed within an AHS can deliver medication advice and education to consumers and staff, and work with both consumers and other health professionals to improve medication adherence and reduce medication misadventure through tailoring medication regimens and overseeing medication management processes. Other activities that pharmacists are well-equipped to deliver within an AHS include; health promotion, disease prevention initiatives, and assistance with consumer self-management and judicious use of medicines.

The assumption in this question though, is that the s100 Pharmacy Support Allowance (the Allowance) adequately supports the involvement of a pharmacist in an AHS. PSA has received feedback from members practising in this area that there are significant issues with the allowance, and its ability to sustain the involvement of a pharmacist providing services outside of medicines supply.

PSA understands that the allowance is proportional to the volume of PBS items, and thus, when pharmacists decrease wastage in the system, the allowance decreases accordingly – leading almost, to a disincentive to decreases medicines wastage. Additionally, PSA notes that the allowance is also capped.

As called for in our Federal Budget Submission, PSA unequivocally supports the introduction of an MBS item for pharmacists providing QUM services in AHSs, bringing pharmacist remuneration in line with other health professionals practising in AHSs, for example, Aboriginal and Torres Strait Islander Health Workers, and General Practitioners.

In the 6CPA there was a change in the CSO requirements relating to 72-hour delivery for the 1000 highest volume medicines. Was this a desirable change? What impacts has this had and is there evidence available to demonstrate this?

As previously stated in response to Question 77, PSA believes it is important to recognise that the changes to the CSO as a part of the 6CPA only commenced on 1 July 2015, and that thus far there have been no evaluations of its impact on access to medicines, nor has there been any indication of how the impact will be measured or evaluated.

However, anecdotally, PSA is aware of instances in which the changes to the CSO have had a negative impact on consumer access to medicines due to delays in supply.
Access to Medicines, Quality Use of Medicines and Quality, Safety and Efficacy of Medicines

Ensuring the all Australians, regardless of location, have timely access to medicines and pharmacist advice which is safe, effective and of high quality is a key facilitator of PSA’s vision; improving the nation’s health through excellence in the practice of pharmacy.

Questions in the discussion paper, identified by PSA as being underpinned by the three NMP objectives of Access to Medicines, Quality Use of Medicines and the Quality, Safety and Efficacy of Medicines, focus mainly on complementary medicines in the context of consumer access and experience, and the appropriateness of the current two-tier remuneration structure for compounded medicines.

Relevant Discussion Paper Questions

Do consumers appreciate the convenience of having the availability of vitamins and complementary medicines in one location? Do consumers benefit from the advice (if any) provided by pharmacists when selling complementary medicines?

PSA believes that consumers do appreciate the convenience of having both vitamins and complementary medicines in one location.

A survey conducted by the National Prescribing Service (NPS) indicated that the three most common sources of information on complementary medicines, as reported by consumers were: family and friends, the internet and health food shop workers. It is concerning that pharmacists, as medicines experts, did not rank in the top three sources of consumer information on complementary medicines, however, PSA believes that consumers have the potential to benefit significantly from pharmacist advice on complementary medicines.

PSA is committed to supporting pharmacists to assist consumers in making informed decisions regarding complementary medicines and continues to advocate strongly for a partnership approach to promote QUM and responsible self-medication.

When discussing the use of complementary medicines with consumers, pharmacists must ensure that consumers are provided with the best available information about the current evidence for efficacy, as well as information on any potential side effects, drug interactions and risks of harm.

In the event that a consumer chooses to use a product with limited evidence, the pharmacist must advise the consumer on the risks of rejecting or delaying treatments for which there is good evidence for safety and effectiveness.
It is unclear to the Panel that there is any therapeutic difference between chemotherapy medicines provided by TGA licenced compounders and non-TGA licensed compounders. Is there any therapeutic difference, if so, what are they? If there are no therapeutic differences, should the payment of chemotherapy compounding be the same regardless of whether the provider is TGA licensed? If there are therapeutic differences, why should the Government continue to subsidise sub-optimal medicine?

PSA understands that the new fee structure recognises the additional costs associated with TGA licensing and the greater focus on the quality use of medicines that it provides.84

However, PSA also understands that there are no apparent therapeutic differences between chemotherapy provided by TGA licensed and non-TGA licensed compounders. Additionally, PSA understands from member feedback that the apparent difference in quality, responsible for the price differentiation, between chemotherapy provided by TGA licensed and non-TGA licensed compounders is difficult to quantify.
Access to Medicines, Quality, Safety and Efficacy of Medicines and Viable Medicines Industry

Relevant Discussion Paper Questions

Should there be requirements on wholesalers relating to minimum usage dates of stock? Would such requirements increase or decrease wastage in the system? Would this shift costs to community pharmacy and reduce the efficiency of the system?

Whilst PSA can appreciate that a requirement on wholesalers relating to minimum usage dates of stock could be beneficial, particularly for community pharmacies, PSA is concerned that practically, this could lead to wholesalers holding less stock on hand – potentially causing medicines supply and access issues across the community pharmacy sector.

Are the two compounding fees ($60 for TGA licensed, $40 for non-TGA licensed) reflecting a supply guarantee?

PSA does not believe that it has adequate information to provide an informed response to this question.

Should non-TGA licensed public hospitals be allowed to provide chemotherapy compounding services to other public and private hospitals?

PSA can appreciate that in some cases there may be potential benefit for non-TGA licensed public hospitals being allowed to provide chemotherapy compounding services to other hospitals. However, PSA has concerns that this opportunity could be perceived as a business opportunity, rather than an opportunity to ensure timely access to chemotherapy services to consumers.

Chemotherapy patients benefit from the ability of local chemotherapy manufacturing facilities to provide more timely medications to patients locally. These facilities generally do not hold a TGA licence. Is there a need for additional standards for non-TGA licensed compounders?

Feedback from PSA members indicates that consumers benefit significantly from local chemotherapy manufacturing – especially those in rural and remote regions of Australia.

Indeed many of the facilities do not hold TGA licenses. However, all facilities must still meet stringent guidelines. The Pharmacy Board of Australia has recently released a new set of Guidelines for the Compounding of Medicines – which include complex compounding, however the sterile compounding component of these is yet to be released.
Quality Use of Medicines and Quality, Safety and Efficacy of Medicines

Complementary medicines are a group of diverse products with varying levels of evidence to support their safety and efficacy. Key questions identified as pertaining to the NMP objectives of Quality Use of Medicines and Quality, Safety and Efficacy of Medicines cover the availability of complementary medicines in community pharmacy.

Pharmacists are committed to the principles of evidence-based medicine and play an important role in providing consumers with advice on complementary medicines in accordance with QUM principles.

Relevant Discussion Paper Questions

115

Does the availability and promotion of vitamins and complementary medicines in community pharmacies influence consumer buying habits?

Pharmacists, as medicines and medication management experts, have a fundamental role in ensuring consumers have access to safe and effective medicines. When discussing the use of complementary medicines with consumers, pharmacists must ensure that consumers are provided with the best available information about the current evidence for efficacy, as well as information on any potential side effects, drug interactions and risks of harm.

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Should complementary products be available at a community pharmacy, or does this create a conflict of interest for pharmacists and undermine health care?

In Australia, medicinal products containing herbs, vitamins, minerals, nutritional supplements, and homeopathic preparations may be referred to as complementary, natural or alternative medicines. Complementary medicines are a group of diverse products with varying levels of evidence to support their safety and efficacy.

PSA encourages pharmacists to consider the available evidence for the use of complementary medicines when deciding to stock them in their pharmacy, however, recognises that ultimately this decision lies with the pharmacy proprietor.

PSA is committed to supporting pharmacists to assist consumers in making informed decisions regarding complementary medicines and continues to advocate strongly for a partnership approach to promote QUM and responsible self-medication.

As previously stated, pharmacists have a key role in ensuring that consumers are provided with the best available information about the current evidence for efficacy, as well as information on any potential side effects, drug interactions and risks of harm.

Pharmacists should be guided by the PSA Code of Ethics, which states that the pharmacist must respect the autonomy and rights of the consumer to actively participate in decision making, and must balance this with the health and wellbeing of the consumer – the pharmacist’s first priority.

In the event that a consumer chooses to use a product with limited evidence, the pharmacist must advise the consumer on the risks of rejecting or delaying treatments for which there is good evidence for safety and effectiveness.

PSA does not support the sale of homeopathy products in pharmacy.
Quality, Safety and Efficacy of Medicines and Viable Medicines Industry

Relevant Discussion Paper Questions

**133**

It is the Panel’s understanding that the additional $20 payable for infusions compounded by TGA licensed compounders is remuneration for the cost of gaining and holding the TGA licence. Should the PBS provide additional remuneration for compounders that meet TGA licensing requirements?

PSA acknowledges that the new fee structure was implemented to reflect the additional costs associated with TGA licensing, however, it also recognises that the new funding model encourages the centralisation of chemotherapy compounding through TGA licensed facilities.

PSA does not believe that sufficient data exist to make an informed comment about whether the PBS should provide additional remuneration for compounders that meet TGA licensing requirements.

**136**

If it is appropriate to have differential payments for chemotherapy compounders, what is the best way for those payments to be made? What should form the basis of the difference of the payment?

PSA understands that the two-tiered remuneration structure for chemotherapy compounding was only introduced from 1 July 2015, as part of the 6CPA. As such, we believe that before further changes to payment systems are made, an evaluation of the impact of the changes implemented under the 6CPA on non-TGA licensed facilities should be undertaken to ensure that there have been no unintended consequences such as compromised patient access.
Access to Medicines, Quality Use of Medicines, Quality, Safety and Efficacy of Medicines and Viable Medicines Industry

Relevant Discussion Paper Questions

05

Is the CPA process consistent with the National Medicines Policy? Is it consistent with the long term sustainability and affordability of the PBS? Is it consistent with good government practice in terms of value for money (for both patients and taxpayers), clarity, transparency and sustainability?

There are a number of quite different elements to this question. Throughout this submission, PSA has made clear where we believe improvements could be made to the CPA process in terms of the governance, transparency and accountability. Some of the previous and existing processes are not consistent with good government practice, and the lack of transparency makes it very difficult to effectively assess whether the investments represent good value for money. This was highlighted in the ANAO report on 5CPA.90

Similarly, assessing the CPA against the NMP and PBS is not possible as there are no standard metrics by which to make such an assessment. PSA has expressed concern about the success measures that have been used in previous Agreements, which relate to uptake and total volume of services delivered, rather than the spread and reach of service delivery to consumers across Australia. Clinical outcomes and cost effectiveness do not seem to have been part of the evaluation parameters. Using indicators of uptake or participation alone leave us – collectively – with little insight on the impact of programs or how they might be improved for future Agreements.

Although changes have been made with the introduction of a health technology assessment process for 6CPA programs, there is little public information available on this, thus far.

06

What would be a preferable approach? Why would this be preferable? In particular why would this lead to better value for money and better meet the objectives of the NMP?

Relevant data should be collected on all pharmacy programs and be made publicly available to inform the development of pharmacy policy and health policy – including the NMP - more broadly. Given that all CPA services and programs are funded by the Australian Government and ultimately by taxpayers, all data collected and reported on these programs should be publicly available. This would allow these assessments to be made in relation to value for money and whether or not NMP objectives have been met.
Are there any other regulatory arrangements that should be introduced to promote high standards of delivery and accountability amongst pharmacies, wholesalers, manufacturers and other entities receiving funding under the PBS?

PSA has commented previously on the need for Government to consider investing in the development of robust quality indicators and metrics to objectively assess adherence to the professional practice standards across all community pharmacies in Australia. Despite the requirement under the National Health Determination made in 2007 by the Minister for Health for all pharmacists to comply with both PSA’s Code of Ethics and Professional Practice Standards, in order to receive payment for the dispensing and supply of PBS medicines, PSA understands that there is currently no audit process to assess adherence to these standards.

This is not a new regulatory arrangement but would enhance the existing regulatory framework from a quality perspective.

Are there any existing regulatory arrangements that are unnecessary or overly burdensome?

PSA has not received any feedback as part of its consultation to suggest this is the case.
Concluding Comments

As the peak organisation representing all pharmacists in Australia, PSA is committed to ensuring a viable and robust community pharmacy network which effectively meets the needs of Australian consumers.

PSA would like to reiterate that an underpinning principle in our consideration of, and response to, the issues raised in the Review is that altering regulation or practice in one area of the National Medicines Policy may have consequences – both intended and unintended - for other areas of practice.

Furthermore, all of the recommendations detailed in PSA's submission reflect the findings of the Combined Thematic Review of Access, Consumer Experience and Quality Use of Medicines which occurred under the Fifth Community Pharmacy Agreement. This review identified five areas for consideration in the design and development of any future community pharmacy agreements and programmes, including:

- A needs based, medication management continuum for consumers;
- Consistent QUM indicators for evaluating programmes;
- Continued and consistent measurement of the consumer experience;
- Integration of SCPA Aboriginal and Torres Strait Islander programmes with related programmes outside of SCPA; and
- Overarching evaluation through the life of the community pharmacy agreement.

PSA believes that the Review is an opportunity to positively shape the future practice of pharmacy in Australia, to improve our nation’s health through excellence in pharmacist care.

There is clearly much more that can be done to optimise the contribution of pharmacists to the Australian health system. Pharmacists are best placed to provide medication management, high quality medicines advice and education for consumers with chronic and complex conditions and contribute to preventive health activities. There is great potential to positively impact the health outcomes of all Australians, while reducing unnecessary health system expenditure. Pharmacists and the community pharmacy sector are critical to the Government's efforts to achieve sustainable, efficient and quality healthcare.
Appendix 1

PSA recognises that the potential model, detailed below, would require trial and evaluation.

Consultation model – the medication management continuum

The model outlined below separates the administrative tasks that are performed as part of the process of dispensing a prescription from those that contribute to quality use of medicines and require a pharmacist’s unique expertise. It also recognises the role of the pharmacist in applying clinical reasoning to a decision about the need for additional services, including, for example, a follow-up MedsCheck.

The ‘consultation model’ would comprise a reallocation of funding based on the following principles:

1. The administrative component of dispensing comprises data entry, picking of medication and claiming.

2. When a medication is supplied to a consumer a consultation should occur between the pharmacist and the consumer and this consultation should be recognised and remunerated as a professional consultation.

This model would see pharmacists paid based on the consultation between the pharmacist and the consumer and should include the clinical aspects of a pharmacist involvement in ensuring the medicine is safe and appropriate for the consumer. The remuneration for this activity should be based on the time spent with the consumer during the consultation as well as the time taken in preparing for the consultation.

This element would see pharmacists’ remuneration becoming consistent with that of GPs and allied health providers, who are reimbursed by the MBS in a manner which reflects the time and/or complexity involved in each consultation.93,94 It addresses the need to reflect the various services pharmacists can and do provide, across a continuum of care needs based on the individual consumer (see Figure). A robust documentation and audit system, with reporting linked to clear outcome measures, would need to be applied to such a model.

The consultation model represents a significant change in not only community pharmacy practice, but also in remuneration structure. The primary difference being, pharmacies would be remunerated for the number of professional consultations undertaken by each pharmacist, as opposed to solely the number prescriptions dispensed. The number of prescriptions dispensed each year (approximately 271 million) is therefore not an appropriate basis on which to base the consultation model, nor is the number of individual patient visits to pharmacy per year (approximately 300 million). Further modelling work, with access to relevant data, will need to be undertaken to ascertain the cost of this option. Fees applicable to GP professional consultations and Allied Health Provider consultations could be used for comparative purposes95,96.
Transitional model

The PSA recognises that the consultation model outlined above would take some time to implement, as pharmacists transition their professional practice to a consultation-style approach. There would also need to be significant changes made to dispensing/claiming software and the corresponding payment arrangements by Government. In that context, PSA envisages that an intermediate step towards the consultation model could incorporate the following components:

- Dispensing fee;
- Enhanced dispensing fee (e.g. complex patient/significant clinical issue identified); and
- Professional consultation fee (incorporating fees at various levels or tiers which could cover services such as a New Medicines Service and MedsCheck).

Rather than being based purely on the pharmacist’s time, this transitional model would be a first step towards this and would recognise and pay the pharmacist based on the complexity of the presenting consumer’s situation and/or service provided.
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