

Review of Pharmacy Remuneration and Regulation
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REVIEW OF PHARMACY
REMUNERATION
AND REGULATION:

PSA'S RESPONSE TO
THE INTERIM REPORT

2017



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Foreword

The Review of Pharmacy Remuneration and Regulation (the Review) provides us with an opportunity to consider fundamental change to the way that the pharmacy profession utilises its significant skills, training and expertise to improve the use of medicines in primary care. We must grasp this opportunity to do things better.

Unfortunately, the Review does not provide options that will see long-term, sustainable reform and development of the community pharmacy sector. What it does offer, however, is the opportunity for Government to take up the call for profession-led development of a spectrum of pharmacist activities that recognise and appropriately remunerate the clinical input of the pharmacist and the value they add to the health system.

A strategic approach to the role of pharmacist services in the community, how they are funded and how they are delivered, is urgently required. Health care is changing and we can no longer see pharmacist services delivered in primary care as being only available through a community pharmacy. This stifles innovation within our profession, and more importantly, consumer access and quality use of medicines. Similarly, limiting funding of pharmacist services in the community to only the PBS contributes to Australia's pharmacists being underutilised in roles across the broader health system.

PSA's vision has pharmacists delivering services tailored to consumer need, delivered at the right time, by the pharmacist with the right skill set in the right setting. Recognising the importance of this, we will likely end up with a very different Agreement for pharmacist services in the future. One in which services form a continuum from dispensing through to comprehensive medication review, delivered in an individualised manner based on patient need and focussed on the quality use of medicines.

The guiding principle in developing pharmacist services must be to utilise their skills, expertise and training to the full scope of practice to benefit our communities. A strategic approach to services delivered by pharmacists across primary care, and how these are funded, should encourage innovation, ensure viable services and a sustainable and prosperous community pharmacy network. We must build on what works well within our community pharmacy network and utilise this platform for the delivery of medication management services that improve outcomes for the patient.

Whilst PSA welcomes the recommendation that we should be involved within the next Agreement, this will only partially address the challenges of reform required. If we don't truly have a continuum of professional services for pharmacists to deliver in community pharmacy, if we don't have pharmacist services that can be integrated into the primary care landscape across settings, and if we don't truly value pharmacist services based on the outcomes that they deliver to the consumer rather than savings in the PBS budget, then the outcomes of future Agreements will be only more of the challenges that we have in the present day. The players must be different, the game must be played differently, and the results must be different.

In this submission, PSA has responded to the options presented by the Review Panel. Given that there is no strategic reform process for pharmacist services within the primary care setting as a component of this review, we believe it is incumbent on the peak professional organisation for Australian pharmacists to lead this agenda. To develop and future-proof the opportunities for pharmacists to deliver medication management services that improve the use of medicines in Australia, we intend to do just that.



Dr Shane Jackson FPS
PSA National President

About PSA

The Federal Government has granted 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 (HPAB) Program.

PSA proudly represents Australia's 29,000¹ pharmacists working in all sectors and locations.

PSA's core functions 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.



Key Messages

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. However, over time the Agreements have had an increasing focus on professional pharmacy services, yet arrangements for the professional programs have seen them implemented 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.

Continuing to frame Agreements with this piecemeal approach inhibits the effectiveness of these programs for consumers, and their broader impact on the health system. Involving PSA, as the peak national body for all pharmacists, in Agreement governance, planning and implementation will improve the ability of Government to utilise CPAs as an instrument to achieve the objectives of the National Medicines Policy.

In response to the options presented by the Review Panel in this Interim Report, PSA offers the following;

Community Pharmacy Agreements

Future Community Pharmacy Agreements must support a viable sector, and consider all aspects of the supply chain, including manufacturing, wholesaling, distribution, community pharmacy infrastructure and pricing, including to consumers. However, PSA is of the view that this should be considered independent of the investment in dispensing and other clinical services, as the supply infrastructure needs to be sustainable on its own, without reliance on cross-subsidisation through program/ service funding.

Professional programs offered by community pharmacies need to be considered in the context of consumer health needs and the evolving way in which people are accessing care. Pharmacist services remunerated by Government should allow for flexibility in terms of service setting to most appropriately meet consumers’ needs.

PSA is pleased to see the Panel make the significant recommendation to involve PSA, as the peak national body for all pharmacists, in future Community Pharmacy Agreement (CPA) negotiations. Including PSA at the table for these discussions is both timely and necessary. It will add considerable value to future Agreements by including PSA’s recognised expertise as well as giving a voice to all pharmacists working to deliver services to the community.

Dispensing and Remuneration

Discretionary discounting by pharmacies, whether done independently or through the Government’s \$1 discount measure, undermines the universality of the PBS and actively works against the objectives of the National Medicines Policy.

Dispensing and supply of medicines is wrongly being perceived as an administrative task, when instead it represents a key consumer entry point into pharmacist services. The provision of medicines with clinical input 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.

Any changes to the remuneration for dispensing should be modelled and considered extensively prior to adoption and implementation as they may have significant unintended consequences, potentially compromising the viability of the pharmacy sector.

PSA believes that the Panel's use of economic principles to support the reasoning for changes to the way pharmacists are remunerated for dispensing is flawed and inappropriate, as medicines and health services requiring the cognitive input of clinicians are not ordinary items of commerce and hence are not comparable to commodities such as gas or electricity.

PSA believes that 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.

PSA believes that remuneration for medicines supply, dispensing activities and clinical services 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.

PSA believes that an MBS payment is an appropriate remuneration mechanism for the provision of medication management services provided by pharmacists – including services provided by pharmacists working in general practice, in the same way that GPs and other health professionals' clinical services are recognised.

Standards of Practice & Quality Indicators

PSA believes that standards and guidelines including the development of quality indicators for pharmacist practice would address the challenge of setting the minimum requirements that a community pharmacy should meet in order to receive remuneration. It is vital that the standards and guidelines for pharmacist practice that are developed by PSA are supported in their implementation.

PSA believes that developing specific quality indicators for pharmacist practice is in the long term interest of meeting the objectives of the National Medicines Policy, and continuing to improve health outcomes for individuals and the population through evaluation and practice improvement processes. As the custodian of the Professional Practice Standards, PSA is ideally placed to lead the development of this work.

PSA's Response to the Interim Report

Context

PSA framed its response to the Review's earlier Discussion Paper in the broader health reform and National Medicines Policy context.

The statement that Australia needs a viable community pharmacy sector is often repeated, but what is now clearly needed in response to this Interim Report is a more explicit discussion of what sits behind this and how exactly we might achieve sustainability in the sector.

PSA acknowledges that the levers that are used at a national health policy and regulatory level directly impact business models in the pharmacy sector. For example, the historical reliance of the Community Pharmacy Agreements on the savings generated in the PBS budget to fund clinical services delivered by pharmacists has, not surprisingly, resulted in pharmacies using – as noted by the Panel in their Discussion Paper – the same cross-subsidy principles in their business models.

The community pharmacy sector in Australia is a complex system. Ensuring support for the infrastructure that facilitates the delivery of a drug from the manufacturer to the consumer in accordance with the National Medicines Policy, and all of the elements of the supply chain that this encompasses, requires completely different considerations to that of a healthcare encounter between a pharmacist and a consumer.

PSA's response to the Review's Interim Report is delivered with a deep understanding of the complexities of these issues.



Response to Individual Options

OPTION 2-1 PRICING VARIATIONS

The payment made by any particular consumer for a PBS-listed medicine should be the co-payment set by the government for that consumer or the dispensed price for that medicine, whichever is the lower. A community pharmacy should have no discretion to either raise or lower this price.

PSA supports the assertion that a community pharmacy should have no discretion to raise or lower the price of a PBS-listed medicine, with the exception of additional allowable fees.

Discretionary discounting by pharmacies, whether done independently or through the Government's \$1 discount measure, undermines the universality of the PBS and actively works against the objectives of the National Medicines Policy.

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.

Every conversation between a pharmacist and a consumer that is about price is a missed opportunity to have a conversation about the consumer's medicines use and the quality use of medicines. No other health professional in Australia spends their time with a patient in this way.

OPTION 2-2 \$1 DISCOUNT

The government should abolish the \$1 discount on the PBS patient co-payment.

PSA has staunchly opposed the \$1 discount, introduced as part of the Government's PBS Access and Sustainability Package. As such, PSA strongly supports the Review Panel's call for the abolition of the \$1 discount – however, PSA disagrees with the Panel's assertion that the \$1 discount is evidence that existing remuneration for dispensing is too high.

PSA believes that the \$1 discount 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.² 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.³

Data from the Community Pharmacy Agreement (CPA) Expenses Report 2015-16, indicates that of the 92.6 million eligible PBS prescriptions dispensed nationally between 1 January 2016 and 30 June 2016, only 27.3 million (29.5%) had a discount applied.⁴ These statistics further demonstrate that the impact of the measure is highly variable, further compromising equity of access.

PSA believes that both the concept and implementation of the \$1 discount represent a failure in health policy, which fundamentally undermines the National Medicines Policy.

OPTION 2-3 PBS SAFETY NET

In relation to the PBS Safety Net, the government should:

- a. require the PBS Safety Net to be managed electronically for consumers. This expectation should be automatic from the consumer's perspective
- b. investigate whether the PBS Safety Net scheme can be adjusted to spread consumer costs over a twelve-month period
- c. provide sufficient transparency in the way a patient's progress towards the PBS Safety Net is collated, including information on any gaps in how it is calculated
- d. investigate and implement an appropriate system which allows payments for opiate dependence treatments to count towards the PBS Safety Net.

PSA agrees in principle with the suggested changes to the way the PBS Safety Net is administered and monitored. In the above option there are a number of considerations to be taken into account which PSA has outlined below:

- a. PSA agrees that the PBS Safety Net should be managed electronically and automatically, analogous to the MBS Safety Net. PSA would expect that this recommendation could be implemented more rapidly than some of the other suggestions in this option, due to the existing framework provided by the MBS Safety Net.
- b. Feedback from PSA members indicate that there is support for potentially spreading consumer costs for the PBS Safety Net over 12 months – however, there are significant concerns regarding the feasibility and practicality of implementing this suggestion.
- c. PSA believes that providing sufficient transparency in the way a patient's progress towards the PBS Safety Net is collated is important. PSA believes that a key facilitator of this recommendation would be the implementation of Part A of this option, electronic management of the PBS Safety Net.
- d. PSA strongly supports the recommendation that payments for opiate dependence treatments should count towards the PBS Safety Net. Addiction is a health condition, hence Opioid Replacement Therapy should be treated as any other medicine.

OPTION 2-4 LABELLING

All PBS medicines provided to patients should be appropriately labelled and dispensed. Where there is a system in place that involves 'remote' dispensing or 'bulk supply' then this system will require appropriate monitoring to ensure the quality of medicine supply.

As per the Pharmacy Board of Australia's (PBA) *Guidelines for the dispensing of medicines*, the requirements for labelling dispensed medicines are specified in legislation in force in the jurisdiction in which a pharmacist is practising.

In addition to the PBA guidelines⁵, PSA's professional practice standards⁶ and dispensing guidelines⁷ address the labelling of dispensed medicines, with a view to:

- ensuring lawful possession by the patient
- maximising the benefits of the therapy
- improving the patient's understanding of the treatment
- enhancing adherence, and
- minimising adverse effects.

With regards to the issue of bulk supply, as per our original submission to the Review's Discussion Paper, PSA believes that pharmacists should be appropriately remunerated for the provision of original labelled packs from s100 wholesale.

OPTION 2-5 PHARMACY ATLAS

There should be an easily accessible and searchable 'atlas' of all community pharmacies in Australia that provides key patient information, including the services and programs offered by that pharmacy, the opening hours of the pharmacy and any specific accessibility services of the pharmacy (e.g. multilingual staff). The 'atlas' should be easily accessible to consumers (e.g. through mobile-friendly applications).

PSA agrees in principle with this option, however we question if this should be a priority, given that undertaking the creation and maintenance of the proposed standalone atlas of community pharmacies would be costly and labour intensive, when instead these resources could be put towards patient care activities.

Precursors to the proposed atlas already exist in a number of forms including; The Pharmacy Guild of Australia's *Find a Pharmacy* website, and the Australian Government's *healthdirect* website. Hence PSA instead proposes that specific accessibility information (ie. multilingual staff and services) should be made available through these existing channels.

OPTION 2-6 CONSUMER MEDICINES INFORMATION

2-6

A Consumer Medicines Information (CMI) leaflet should be offered and made available to consumers with all prescriptions dispensed in accordance with Pharmaceutical Society of Australia (PSA) guidelines. The PSA guidelines and the distribution of CMIs to consumers need to be audited and enforced to ensure compliance.

Pharmacists and the pharmacy industry should continue to work on the improvement of CMIs and the use of technology to make medicines information more available to consumers.

PSA would like to note that the PSA guidelines quoted in this option, *Consumer Medicine Information and the pharmacist*, actually state that “Pharmacists must use their professional judgement and discretion in each situation to ensure they are providing balanced information to the consumer”. The guidelines go on to state that “CMI leaflets *may* be offered to the consumer each time a product is dispensed. Whether this is appropriate is a matter for professional judgement.”

PSA strongly agrees that pharmacists should comply with PSA guidelines pertaining to the provision of CMIs. PSA would also note that the issue of the provision of medicines information is covered under Standard 6: Medicines Information in the recently released Professional Practice Standards - Version 5.⁸

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 medicines⁹, PSA understands that there is currently no audit process to assess adherence to these standards, as such PSA would strongly support the creation of indicators to facilitate audits and monitor compliance against the standards. It is of note that this would not be a new regulatory arrangement but would enhance the existing regulatory framework from a quality perspective.

PSA has commented previously, there is a 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.

OPTION 2-7 ELECTRONIC PRESCRIPTIONS

2-7

The government should initiate an appropriate system for integrated electronic prescriptions and medicine records as a matter of urgency. Under this system the electronic record should become the legal record. Participation in the system should be required for any prescriber of a PBS-listed medicine, any pharmacist wishing to dispense a PBS-listed medicine and any patient who is seeking to fill a PBS prescription.

PSA agrees with this option as presented by the Review Panel. If this option were to proceed, PSA would urge the Government to consider not only the necessary legislation and guidelines surrounding the use of such a system, but also the need for implementation support to ensure appropriate and timely uptake and use of the system – as this is long overdue and has been functional in Europe for decades.

OPTION 2-8 ELECTRONIC MEDICATIONS RECORD

The electronic personal medications record should cover all Australians and ensure appropriate access by, and links between, community pharmacy, hospitals and all doctors. This record should also include a vaccines register.

PSA has been a strong proponent of a functional and comprehensive digital health record. As such, PSA welcomes calls for an all-encompassing electronic medication record but firmly believes that this should form a part of *MyHealthRecord* – not a standalone record.

PSA believes that it is important to note that the value of utilising pharmacists in digital health initiatives comes not only from the provision of dispensing histories, but mainly from pharmacists using their unique skills and medicines expertise to meaningfully engage with the information contained in digital health records to optimise medication regimens and ensure the safe, effective and judicious use of medicines.

Devoting resources towards the effective and sustainable implementation of *MyHealthRecord* is preferable to diverting resources towards the creation of a universal electronic medicine record as a stop gap measure, as suggested by the Panel.

OPTION 2-9 ELECTRONIC PRESCRIPTIONS – CONSUMER CHOICE

The choice of where a consumer has an electronic prescription dispensed should remain a decision for that consumer. The consumer may request that the electronic prescription be directed to a particular community pharmacy for dispensing (including an online pharmacy if that is the consumer's choice). For avoidance of doubt, a prescriber may not direct an electronic prescription to a particular community pharmacy for dispensing. This will require appropriate oversight and enforcement by professional bodies.

As noted by PSA in our response to Option 2.7, consumer choice should be a fundamental principle underpinning the use of electronic prescriptions, therefore, we welcome the Review Panel's acknowledgement that the choice of where a consumer has an electronic prescription dispensed should remain a decision for that consumer. PSA agrees that robust legislation, guidelines and monitoring practices would be required to prevent "script channelling".

PSA wishes to reiterate that dispensing and supply of medicines is wrongly being perceived as an administrative task, when instead it represents a key consumer entry point into pharmacist services. The provision of medicines with clinical input 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.

As such, while PSA agrees with the need for consumer choice to be protected, care is required to ensure that the use of an electronic prescription and online pharmacies does not create unintended consequences such as fragmentation of care - minimising the opportunity for a pharmacist to meaningfully interact with a consumer.

OPTION 2-10 MANAGING MEDICINE RISKS FOR PATIENTS UPON DISCHARGE

Hospitals should work closely with community pharmacies to ensure patients have access to the medicines they require upon discharge. Consistent policies and procedures are required to ensure each patient has access to the medicines they require as well as appropriate education and information relating to their medications. This may involve the hospital providing a 'discharge pack' with an appropriate level of patient medication to allow the patient to safely access a community pharmacy and their community health practitioner without running short of medication.

PSA recognises the issue that this option is attempting to address – and agrees the lack of a robust framework for medicines management on discharge creates risk for patients – however we question the appropriateness of the proposed solution of “discharge packs”, which may not even be a viable option in some hospitals.

Significantly, medication-related admissions account for 20-30% of all hospital admissions for people over 65.¹⁰ Patients are most vulnerable at times of transition of care (such as post-hospital discharge), but 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.¹¹

PSA would instead recommend that the panel focus on discharge interventions for which evidence exists: those that involve a pharmacist. For example, medicines reconciliation, post-discharge HMRs and pharmacists in transitional care management/ liaison pharmacists.

Importantly, this approach puts the focus where it is needed for the person newly discharged into the community - the primary care setting. Focus should be applied to supporting pharmacists to enable the delivery of services to assist patients in their transition from hospital to community. There are significant cost savings to be gained from the implementation of medication management services that support patients in their transitions between healthcare settings.

OPTION 3-1 COMMUNITY PHARMACIES – MINIMUM SERVICES

3-1

The government should establish a process to determine the set of minimum requirements that a community pharmacy must meet in order to receive remuneration for dispensing. The government should initiate procedures to enforce these requirements and to have them updated at regular intervals. These requirements should be promoted by being incorporated within the Community Pharmacy Service Charter.

PSA agrees with this option, and believes that the development of quality indicators for pharmacist practice, which PSA has previously advocated for, would address the challenge of setting the minimum requirements that a community pharmacy should meet in order to receive remuneration. PSA believes that standards and guidelines including the development of quality indicators for pharmacist practice would address the challenge of setting the minimum requirements that a community pharmacy should meet in order to receive remuneration. It is vital that the standards and guidelines for pharmacist practice that are developed by PSA are supported in their implementation.

Indeed, the framework for the proposed quality indicators already exist; PSA's *Professional Practice Standards* and *Code of Ethics* as referenced in the National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007.¹²

PSA recognises that the Quality Care Pharmacy Program (QCPP) currently exists as a quality assurance program for community pharmacy, providing support and guidance on professional health services and pharmacy business operations. However, it does not focus on outputs or care delivered at an individual pharmacist level. Furthermore, QCPP does not measure health outcomes or how pharmacist practice, across all care sectors, contributes to, and supports the NMP objectives.

PSA believes that developing specific quality indicators for pharmacist practice is in the long term interest of meeting the objectives of the National Medicines Policy, and continuing to improve health outcomes for individuals and the population through evaluation and practice improvement processes.

The development of these quality indicators would be a discrete piece of work, to be led by PSA, and involve stakeholders from the pharmacy sector, the broader health sector, the Australian Commission on Safety and Quality in Health Care, and Government to ensure that they reflect contemporary pharmacist practice, including multidisciplinary care.

OPTION 3-2

COMPLEMENTARY MEDICINES – SUPPLY FROM PHARMACIES

Community pharmacists are encouraged to:

- a. display complementary medicines for sale in a separate area where customers can easily access a pharmacist for appropriate advice on their selection and use
- b. provide appropriate information to consumers on the extent of, or limitations to, the Therapeutic Goods Administration (TGA) role in the approval of complementary medicines. This could be achieved through the provision of appropriate signage (in the area in which these products are sold) that clearly references any limitations on the medical efficacy of these products noted by the TGA.

PSA agrees with Part A of the above option and recognises that pharmacists, as medicines and medication management experts, have a fundamental role in ensuring consumers have access to safe and effective medicines.

As per PSA's Complementary Medicines position statement, 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.¹³

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.¹⁴

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.¹⁵

With regards to Part B of the above option, PSA does not believe that it is the role of the pharmacist to provide information on the role of the TGA. PSA believes that signage denoting the difference between Registered and Listed medicines, explained in clear and simple language may be appropriate, but this would require further consultation with, and consideration by all stakeholders.

In the event that a consumer chooses to use a product with limited evidence, PSA believes that 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 encourages pharmacists to consider the available evidence for the use of complementary medicines when deciding to stock them in their pharmacy.

OPTION 3-3

PLACEMENT OF PHARMACY ONLY AND PHARMACIST ONLY (SCHEDULE 2 AND SCHEDULE 3) MEDICINES WITHIN A PHARMACY

Access to Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines should be clearly separated from complementary medicines within a pharmacy. Options to achieve this might include:

- a. ensuring that all Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines only be accessible from 'behind the counter' in a community pharmacy so that a consumer must always seek assistance or advice in obtaining these medicines
- b. requiring that complementary medicines are not displayed 'behind the counter' in a community pharmacy.

PSA agrees with the principle behind this option, however we disagree with, and question, the feasibility of the proposed solution – especially that which is outlined in Part A of this option. The placement and location of Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) is regulated by State and Territory poisons legislations.

Feedback from PSA members indicates that the solution proposed in Part B of this option would be contentious and challenging to implement in a nationally consistent approach. A number of members have indicated that some pharmacies might stock complementary medicines out of reach of the consumer / behind the counter to prompt intervention by the pharmacist – particularly in the case of complementary medicines with higher risk profiles and those that have demonstrated the efficacy and safety data required to meet TGA requirements for registered complementary medicines.

The development of a structured consultation framework for providing information and interventions related to S2, S3 and CAMs would facilitate the recording of these consultations. PSA has previously advocated for the development of a structured minor ailments service as part of supporting consumer-focused, collaborative models of primary care.¹⁶

OPTION 3-4

SALE OF HOMEOPATHIC PRODUCTS

Homeopathy and homeopathic products should not be sold in PBS-approved pharmacies. This requirement should be referenced and enforced through relevant policies, standards and guidelines issued by professional pharmacy bodies.

As clearly stated in both PSA's submission to the Review's Discussion Paper, and Complementary Medicines position statement, 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.¹⁷ As such, PSA strongly agrees with this option presented by the Panel.

OPTION ACCOUNTING INFORMATION

4-1

As soon as possible following the completion of this Review, the government, in consultation with the Pharmacy Guild of Australia and other stakeholders, should:

- a. determine a set of accounting principles that will apply for community pharmacies in order to provide the relevant information needed to determine the best-practice benchmark cost of a dispense (as these terms are defined in this report)
- b. require community pharmacy (as a condition of being approved to dispense PBS medicines) to provide the necessary accounting information to inform consideration in the development of each Community Pharmacy Agreement (including as a basis for the determination of a best-practice pharmacy). The relevant accounting information should be provided for each financial year and no later than 31 December of the following financial year (beginning with 31 December 2018)
- c. designate a body within the government (although potentially an existing independent statutory authority with the relevant expertise such as the Pharmaceutical Benefits Remuneration Tribunal or, more broadly, the Australian Competition and Consumer Commission) to provide a recommendation to the government on the best-practice benchmark cost of a dispense as required over time by the government. The first such advice is to be provided as soon as practical and certainly before the end of 2019. The timing of later determinations will depend on the process used in the future by the government to set the remuneration for dispensing PBS medicines
- d. the information and advice submitted to the government should form the basis for the average remuneration for a 'dispense' to community pharmacy in the future and certainly from the expiration of the Sixth Community Pharmacy Agreement. The provision of appropriate accounting information should be an ongoing requirement to support the development of each Community Pharmacy Agreement.

PSA believes that the issue of remuneration for dispensing is an issue which requires greater consideration than is possible within the remaining timeframe and capacity of the Review. As such, PSA would strongly recommend that this issue is explored as a discrete piece of work outside of the Review with appropriate stakeholders from the sector.

Any changes to the current system should be modelled and considered extensively prior to adoption and implementation as they may have significant unintended consequences, potentially compromising the viability of the pharmacy sector.

PSA believes that the Panel's use of economic principles to support the reasoning for changes to the way pharmacists are remunerated for dispensing is flawed and inappropriate, as medicines and health services requiring the cognitive input of clinicians are not ordinary items of commerce and hence are not comparable to commodities such as gas or electricity.

Even seemingly small interventions by pharmacists in their daily interactions with consumers can have significant impacts on both health outcomes and costs in the health system. Yet the Panel appear to ignore existing evidence which demonstrates this.^{18,19}

OPTION 4-2

REMUNERATION TO BE BASED ON EFFICIENT COSTS OF DISPENSING

The remuneration for dispensing paid by government and consumer co-payments to community pharmacy should be based on the costs of dispensing for an efficient pharmacy.

As per our initial submission to the Review, PSA believes that 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.

In our initial submission to the Review, PSA proposed a consultation model, outlined below, which recognises the medication management continuum and reflects both the time and complexity of consultations. PSA is surprised and disappointed that the panel chose to ignore this in commissioning modelling that used an economic frame only. By doing so, PSA believes the Panel has missed a significant opportunity to fully evaluate remuneration models which reflect the clinical nature of dispensing – such as the model below.

Consultation Model – The Medication Management Continuum

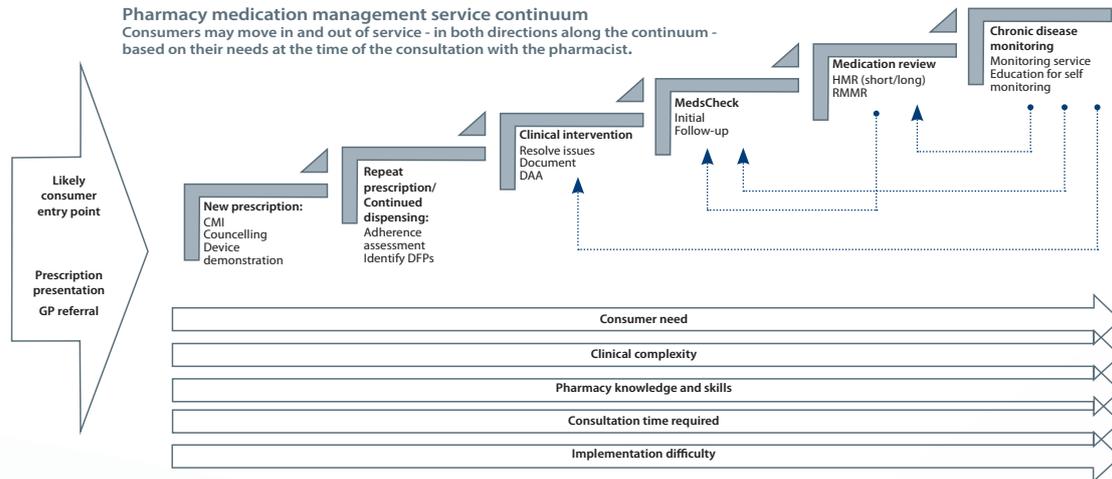
The model outlined below separates the administrative tasks that are performed as part of the process of dispensing a prescription from those that contribute to quality use of medicines and require a pharmacist's unique expertise. It also recognises the role of the pharmacist in applying clinical reasoning 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.^{20,21} 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 purposes.^{22,23}

Similarly, modelling a community pharmacy payment system on those used in other sectors and settings deserves further exploration. For example, the Diagnosis-Related Group (DRG) system used to assign value to clinicians services – including pharmacists – in the hospital setting could be considered.

Additionally, the Standardised Whole Patient Equivalent (SWPE) calculations for General Practices have historically been used to allocate incentive payments, could be used in calculating or assigning value to pharmacist services.

Both of the above systems reflect clinician input and community need, which is absent in the accounting frame currently being relied upon by the Panel.

Again, PSA believes that remuneration for dispensing is an issue which requires greater consideration than is now possible within the remaining timeframe and capacity of the Review. Given its significance, PSA strongly recommends that this modelling is undertaken as a discrete piece of work outside of the Review with involvement of appropriate stakeholders from the sector.

Any proposed remuneration model which is derived from this piece of work should ensure linkages to the quality indicators for pharmacist practice which PSA has previously touched on in this submission.

OPTION 4-3 BENCHMARK FOR AN EFFICIENT DISPENSE

4-3

On the basis of the information that has been made available to the Panel, and given the data limitations, the Panel considers that the current benchmark for a best-practice dispense be set within a range of \$9.00 to \$11.50. This should be reflected in the average remuneration paid to a pharmacy for a dispense.

As noted in our response to both Option 4-1 and Option 4-2, PSA believes that the reasoning underpinning the Panel's proposal for remuneration being based on efficient costs of dispensing is flawed.

However, PSA would like to take this opportunity to note that as per the information made available on the Review website and indeed in the Interim Report itself, there are significant limitations to the data that was used to model the "benchmark for an efficient dispense", as less than 1% of pharmacies in Australia completed the Review's *Pharmacy Financial Survey*. Given these obvious limitations – and the fact that fees have been over the upper limit of the proposed range, \$11.50, for many years now – PSA believes that the \$9.00 to \$11.50 quoted in the Interim Report is completely inappropriate, and questions why the figure was included at all.

OPTION 4-4 REMUNERATION FOR DISPENSING – FORMULA

4-4

The remuneration for dispensing should be a simple dispense fee based on the efficient, average, long-run incremental cost of a dispense in a community pharmacy.

PSA believes that it is inappropriate to suggest that remuneration for dispensing should be a simple dispense fee based on the efficient, average, long-run incremental cost of a dispense in a community pharmacy. The core clinical task of dispensing should be seen through the prism of improving health, not as a cost-driver in health.

More broadly, we believe that some of these options presented in the Interim Report are based not on viewing dispensing of medicines as a health-related activity, but rather as an economic activity. This 'economic lens' perpetuates the misperception that dispensing is not a clinical activity. Dispensing is the core focus of the majority of pharmacists in this country and this vital clinical activity should not be allowed to be treated as an administrative task associated with the supply of a medicine. Modelled appropriately, remuneration for dispensing could and should be linked to activity and outcomes.

OPTION 4-5 REMUNERATION LIMITS

4-5

If the government does not place an upper limit on the wholesale payment for a community pharmacist then the government should adopt a two-part tariff payment for the remuneration (i.e. a payment that involves a fixed payment per dispense, plus a payment that varies with the relevant cost of the medicine) to the pharmacist.

Under either a flat fee or two-part tariff, the average payment for a dispense should equal the required fee determined by the government, following the acceptance of Option 4-4.

PSA does not agree with the premise of Option 4-4, and therefore does not accept Option 4.5.

OPTION 4-6 REMUNERATION FOR OTHER SERVICES

Government should require that if the same service is offered through alternative primary health outlets then the same government payment should be applied to that service, regardless of the specific primary health professional involved.

PSA strongly agrees with this suggestion by the Review Panel and welcomes the acknowledgement that if the same service is offered through alternative primary health outlets then the same government payment should be applied to that service, regardless of the specific primary health professional involved. This option is particularly pertinent when it comes to pharmacists providing primary health services analogous to other health care providers, yet not being remunerated in either the same way, or indeed at all.

Two examples of this are pharmacist-delivered immunisation services and pharmacist-delivered chronic disease management services.

Since 2016, pharmacists in all States and Territories of Australia have been permitted to provide influenza vaccination to adults aged 18 years and over.

In evaluations of pharmacist delivered immunisation services in Queensland and Western Australia no major adverse effects have been reported and consumer experience evaluation demonstrated that the provision of vaccination services by pharmacists was extremely well received with over 95% of consumers surveyed completely satisfied that the vaccination was provided in a professional manner and that they were comfortable with the skills of the pharmacist providing the vaccination. Additionally, evidence has shown that when pharmacists are available to provide immunisations there is an increase in the overall vaccination rate in medically underserved areas.^{24,25}

However, when it comes to remuneration for providing immunisation services, pharmacists are unable to access the funding that General Practitioners, Aboriginal Health Workers and practice nurses (under the guidance of doctors) can access through the Medicare Benefits Schedule.

Furthermore, there is an opportunity to improve outcomes in the care of patients with chronic diseases and complex care needs by optimising the contribution of the pharmacist in multidisciplinary care teams and primary health care settings.²⁶ The Chronic Disease Management (CDM) Service is an example of a service funded through the MBS which represents high value care for patients with chronic disease and complex care needs; however, this service is currently under-utilised due to the exclusion of pharmacists as eligible allied health practitioners.

At present, under MBS Items 10950 – 10970 People with Chronic Conditions and Complex Care Needs, a GP can call on the specialist skills of an allied health practitioner through the Chronic Disease Management Service to help them meet the needs of consumers with chronic disease. Pharmacists are currently the only allied health practitioner who are not eligible to provide allied health services through the CDM service.²⁷ Given the central role of medicines in the care and treatment of consumers with chronic disease, this just doesn't make sense. Many consumers with chronic diseases are not achieving optimal health outcomes as a result.

OPTION LOCATION RULES

5-1
5-2
5-3

PSA acknowledges the Review Panel's note regarding the Federal Government's commitment in the 2017–18 Budget to continue the current pharmacy location rules, resulting in options 5-1, 5-2 and 5-3 not being considered further by the Panel.

PSA has noted that in the Interim Report the Panel has made a number of references to the co-location of pharmacies and supermarkets. As such PSA would like to reiterate that we unequivocally support 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 including alcohol and tobacco products.

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.

Furthermore, PSA notes that as per the research commissioned by the Review, consumer appetite for the co-location of pharmacies and supermarkets, and indeed pharmacy services through supermarkets is low – and hence questions the Panel's focus on this particular issue.

OPTION 5-4 LOCATION RULES – POLICY OBJECTIVE

If the government retains the pharmacy location rules (or some version of these rules) following the end of the Sixth Community Pharmacy Agreement then the policy objective of these rules should be clearly stated and the rules modified to ensure that the desired outcomes are achieved over the medium term.

The objective of the pharmacy location rules should be to assist the Australian consumer to ensure equitable and affordable access to medicines for all Australians, consistent with the National Medicines Policy, with evidence to demonstrate the achievement of this objective.

PSA believes that the objectives of the location rules are both clearly stated and consistent with the National Medicines Policy.

The objectives of the location rules, as outlined in the Fifth Community Pharmacy Agreement and unchanged in the Sixth Community Pharmacy Agreement, are to ensure²⁸:

- 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.

OPTION 5-5 LOCATION RULES – OWNERSHIP AND LOCATION

In areas where pharmacy location rules are maintained, any group of two or more pharmacies, each of which are located within 1.5 kilometres of another pharmacy in the group, that have an overlapping ownership should be considered to be a single pharmacy for the application of the location rules.

The nominal 'location' of this single pharmacy would be the location of the pharmacy within the group that had the smallest turnover (in terms of the number of Pharmaceutical Benefits Scheme scripts dispensed) in 2016.

For avoidance of doubt, a group of pharmacies would be considered to have an overlapping ownership if any individual or set of individuals have ownership of at least 20 per cent of the equity in each of the community pharmacies in that group.

It is also considered that this option should be implemented five years after this Review to allow an appropriate time frame for transition.

The oversight of this option should be undertaken by the Australian Competition and Consumer Commission.

As per PSA's submission to the Review's Discussion Paper, PSA is aware of proprietors owning two pharmacies that operate significantly different business models – providing consumer choice.

However, PSA also recognises that it is important that the arrangements in these cases are transparent and readily accessible to consumers.

PSA would have concerns about the implementation of any such changes, and believes that further consideration and consultation with the pharmacy sector is needed in order to avoid unintended consequences.

PSA would again urge the Review Panel to carefully consider the international evidence available on the unintended effects of altering community pharmacy regulations, particularly from jurisdictions where re-regulation has been required after a period of time to address the consequences of such changes.

OPTION 5-6 INFORMATION ON PHARMACY OPENING HOURS

The Pharmacy Atlas (Option 2-5) should include information on pharmacy opening hours.

As stated earlier in Option 2-5, PSA agrees in principle with the suggestion of the creation of a national, comprehensive database of pharmacy details and services – including information on pharmacy opening hours. Again, PSA notes that this information already exist in a number forms including; The Pharmacy Guild of Australia's Find a Pharmacy website, and the Australian Government's healthdirect website.

OPTION 5-7 24-HOUR PHARMACY INFORMATION AND RELATED SERVICES

The government should investigate the feasibility of a 24-hour telephone and or internet 'pharmacy hotline' to provide medicine information to consumers Australia-wide.

PSA agrees that a 24 hour medicines information service should exist – however, we do not believe that a new service needs to be developed. The infrastructure and expertise to provide this service already exists through the *NPS MedicineWise* Medicines Line (1300MEDICINE).

PSA believes that funding for this service should be increased to allow for pharmacists to operate the service 24 hours a day. At present Medicines Line only operates between 9AM and 5PM Monday to Friday – with only consumers in Queensland and Victoria having access to a pharmacist, and consumers from all other states and territories speaking with nurses.

OPTION 5-8 RURAL PHARMACY MAINTENANCE ALLOWANCE

In situations where there is more than one pharmacy within a 10-kilometre area that is receiving the Rural Pharmacy Maintenance Allowance (RPMA), the government should:

- a. only make payments to a single pharmacy in the area
- b. ensure that the pharmacy that receives the RPMA is based on the programs offered by that pharmacy, including services, opening hours and location (centrality and ease of access)
- c. ensure that the selection process is transparent.

PSA strongly disagrees with this option proposed by the Review Panel. PSA believes that the suggestion proposed by the panel is underdeveloped and may have significant unintended consequences – particularly a reduction in consumer choice and pharmacy accessibility.

Paying only one pharmacy in a rural area the RPMA, may have an effect on the viability of other pharmacies in the area – potentially leading to reduced opening hours or services and potential closure, hence the potential impact on consumer choice.

PSA would instead suggest that the RPMA could be strengthened by providing a core payment to *all* eligible pharmacies to ensure continued viability of the community pharmacy network in rural areas, with pharmacies being able to access additional payments on demonstration of provision of services.

OPTION 5-9 HARMONISING PHARMACY LEGISLATION

As early as practicable, the Australian Government, through the Australian Health Minister's Advisory Council, should seek to harmonise all state, territory and federal pharmacy regulations to simplify the monitoring of pharmacy regulation in Australia for the safety of the public.

In the long term, a single pharmacy regulator could be considered.

As an interim measure, state and territory registering bodies need to coordinate with the Australian Health Practitioner Regulation Agency to ensure that pharmacy regulations are being adequately monitored for best practice of pharmacy and the safety of the public.

PSA is aware and supportive conversations regarding the harmonisation of State and Territory Health Drugs and Poisons Regulations and regulations pertaining to the prescribing of S8 medicines, which invariably has flow on consequences regarding the dispensing of S8 medicines.

However, PSA is hesitant to agree, at this stage, with the option of harmonising State and Territory regulations regarding ownership and premises – as this is a complex issue and one which would require much further consideration outside the scope of this review.

If this option were to proceed, PSA, as the peak professional body for pharmacists in Australia should be consulted and engaged for the entire process, from initial discussion to implementation.

OPTION 5-10 TRANSPARENCY

It is important that, for each program that involves public funding, there is sufficient transparency as to the amount of funding provided by the government and the amount of funding provided by the recipient of the service.

PSA has consistently been a proponent for transparency regarding public funding for pharmacy services.

Historically there has been a complete lack of transparency around the development, negotiation and funding allocations of Community Pharmacy Agreements – this lack of transparency has a flow on effect on data collection and evaluation, as discussed below in Option 5-11.

PSA believes that remuneration for medicines supply, dispensing activities and clinical services 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 makers²⁹

OPTION 5-11 EVALUATION MECHANISMS

The government should require the establishment of appropriate evaluation mechanisms to measure compliance and performance.

PSA strongly supports the Panel's call for the establishment of appropriate evaluation mechanisms to measure compliance and performance.

As noted in PSA response to Option 5-10 there has historically been a complete lack of transparency around the development, negotiation and funding allocations of Community Pharmacy Agreements.

PSA has continually advocated for appropriate evaluation mechanisms and believes that 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, and that furthermore these data should be used to inform the development of pharmacy policy and health policy more broadly. Regrettably, this advice has not been taken up and has directly impacted the ability of Government to evaluate current programs.

A specific example which illustrates this is the Clinical Interventions program. The original research, funded by Government through the 3rd and 4th Agreements recommended categories for recording that would have allowed for cost-effective analyses to be undertaken. However, in implementing the Clinical Interventions program in the 5th Community Pharmacy Agreement, this recommendation was ignored and now the lack of data has been cited as a problem in establishing cost-effectiveness.

Encouragingly, under the new arrangements for some 6CPA programmes, pharmacists will be remunerated to collect data, however, PSA believes that there is still much to be done on appropriate evaluation mechanisms.



OPTION 6-1 COMMUNITY SERVICE OBLIGATION REMOVAL, RETENTION OR REPLACEMENT

6-1

6-1. ALTERNATIVE 1: The government should remove the Community Service Obligation (CSO), and suppliers of PBS-listed medicines should be placed under an obligation to ensure delivery to any community pharmacy in Australia within a specified period of time (generally 24 hours), with standard terms of trade offered to the pharmacy (such as four weeks for payment) using one or more of a specified panel of wholesalers as follows:

- a. an initial Panel of around five wholesalers would be approved. It is expected that these will include the existing CSO Distributors
- b. the relevant terms of trade and other supply conditions may vary between medicines. For example, for high-cost medicines or medicines that have cold-chain supply requirements, the supply conditions may differ from those for low-cost medicines to ensure that there is not an unreasonable risk or cost placed on either community pharmacy or consumers
- c. a cap should be placed on the amount that a community pharmacy contributes to the cost of a medicine. This cap should be in the range of \$700 to \$1000.

6-1. ALTERNATIVE 2: The government should retain the current CSO arrangements but ensure that all service standards, such as the 24-hour rule, are uniformly implemented.

6-1. ALTERNATIVE 3: The government should conduct a separate review of the CSO to ensure current arrangements demonstrate value for money. A review would also present an opportunity to potentially streamline existing or remove unnecessary regulation. Such a review would require the full cooperation of the CSO Distributors, which would provide financial data and other relevant information to government.

PSA urges the Review Panel to consider the effects of any potential change to the current arrangements which may result in unintended consequences to the supply chain or compromise access to medicines, and believes that any proposed changes to the current model would need to be comprehensively modelled and evaluated.

OPTION 6-2 SUPPLY OF HIGH-COST MEDICINES

6-2

In line with Option 6-1, patients should be able to receive high-cost medicines from the community pharmacy of their choice.

A cap should be placed on the amount that a community pharmacy contributes to the cost of a medicine. This cap should be in the range of \$700 to \$1000 so that all PBS-approved community pharmacies can supply all PBS medicines required by the public.

PSA, whilst recognising the issues pharmacies have experienced supplying high cost drugs, has been a strong advocate for consumers being able to receive high cost drugs from the community pharmacy of their choice.

PSA agrees in principle with the concept of a cap, however is unsure of where the suggested figure of \$700 to \$1000 has been modelled from, and hence questions the feasibility and appropriateness of the proposed amount.

As noted in the Interim Report, PSA has also 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.

The 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.

OPTION 7-1 SCOPE OF COMMUNITY PHARMACY AGREEMENTS – DISPENSING

7-1

The scope of discussions under future Community Pharmacy Agreements should be limited to the remuneration and associated regulations for community pharmacy for the dispensing of medicines under PBS subsidy and related services, including the pricing to consumers for such dispensing.

As highlighted earlier in this document and in PSA's submission to the Panel's Discussion Paper, it is critical that dispensing is not viewed as an administrative task, but a clinical service delivered by a health professional, and which is often the starting point on a continuum of increasing service complexity.

There is a genuine need for future Community Pharmacy Agreements to support a viable sector, and to consider all aspects of the supply chain, including manufacturing, wholesaling, distribution, community pharmacy infrastructure and pricing, including to consumers. However, PSA is of the view that this should be considered independent of the investment in dispensing and other clinical services, as the supply infrastructure needs to be sustainable on its own, without reliance on cross-subsidisation through program/service funding.

OPTION 7-2 SCOPE OF COMMUNITY PHARMACY AGREEMENTS – WHOLESALING

7-2

The government should ensure that the regulation and remuneration of wholesaling of PBS-listed medicines should not form part of future Community Pharmacy Agreements.

Further to the comments made above, in ensuring that the principles of the National Medicines Policy can be met in relation to equitable and timely access to medicines, it is imperative that future Agreements include regulation and remuneration of wholesaling - a key part of the PBS supply chain.

OPTION 7-3

SCOPE OF COMMUNITY PHARMACY AGREEMENTS – PROGRAMS AND SERVICES

The regulation and remuneration of professional programs offered by community pharmacies should not form part of future Community Pharmacy Agreements.

Research and evaluations conducted in successive Community Pharmacy Agreements over more than a decade have made evidence-informed recommendations regarding better targeting of services, 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*.

Professional programs offered by community pharmacies need to be considered in the context of consumer health needs and the evolving way in which people are accessing care. Pharmacist services remunerated by Government should allow for flexibility in terms of service setting to most appropriately meet consumers' needs.

If professional programs do not form of the Community Pharmacy Agreement, there remains a need for consumer access to pharmacist services and Government would need to ensure alternate mechanisms to allow for this. Whilst PSA has previously supported applications through an HTA assessment process such as MSAC, we have concerns about the timing of the availability appropriate data to allow these assessments, given the delays incurred in the 6CPA. Until such time as these data are available to allow robust assessment of services, there needs to remain in place a mechanism to ensure consumer access.

PSA is best placed, as the peak for pharmacists, to work directly with Government and other stakeholders to oversee and progress this.

OPTION 7-4

COMMUNITY PHARMACY AGREEMENT PARTICIPANTS

The parties invited to participate in future Community Pharmacy Agreements must include the Pharmacy Guild of Australia (as a representative of the majority of approved pharmacists), the Consumers Health Forum of Australia (as the peak representative consumer body in Australia on health-related matters) and the Pharmaceutical Society of Australia (as the peak representative body for pharmacists in Australia).

PSA is pleased to see the Panel make this significant recommendation to involve PSA, as the peak national body for all pharmacists, in future Community Pharmacy Agreement (CPA) negotiations.

Including PSA at the table for these discussions is both timely and necessary. It will add considerable value to future Agreements by including PSA's recognised expertise as well as giving a voice to all pharmacists working to deliver services to the community; this is something PSA, our members and consumers have advocated for more than a decade.

PSA should be a joint signatory to the parts of the Agreement dealing with clinical activities (including dispensing) and professional programs. Signatory status would of course need to be contingent on PSA being involved as an equal partner/participant in all discussions that relate to the proposed professional programs and services in 6CPA.

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 in this process is a role that PSA could readily oversee, given its strong stakeholder relationships.

OPTION DOSE ADMINISTRATION AIDS – STANDARDS

8-1

The government should establish clear, enforceable minimum standards for the supply of medicines by community pharmacies, including for dose administration aids (DAAs). There should also be appropriate compensation provided to community pharmacies for the dispensing of medicines using DAAs (in recognition that this tends to be a higher-cost activity than dispensing in manufacturer’s packaging).

PSA agrees with this option, however, we would suggest that minimum standards and service guidelines already exist for the provision of Dose Administration Aids (DAAs).

Standard 15 of the Professional Practice Standards covers the provision of DAA services, and PSA has also developed practice guidelines for the provision of DAAs. As such, PSA would suggest that these standards and guidelines should be enforced – rather than the development of a new set of standards by Government. If quality indicators for pharmacist practice were to be developed, as per PSA’s suggestion under Option 3-1, these documents would form the framework for the assessable indicator pertaining to the provision of DAAs.

Furthermore, PSA agrees with the Panel’s acknowledgement that pharmacists should be provided with appropriate compensation for the provision of DAAs. Encouragingly from July 2017 as part of the 6CPA, additional funding has been allocated for the DAA program, with pharmacies receiving \$6 per patient per week as a contribution towards the cost of providing the service to patients that meet the eligibility criteria.³⁰ PSA has also welcomed the announcement that from February 2018, pharmacists will also be remunerated for patient registration and data collection.³¹

However, even though PSA has welcomed the funding announcement for DAAs, we still have concerns regarding the proposed capping of DAA services per pharmacy, as this may lead to some patients who would benefit from DAAs missing out on the service.

OPTION 8-2

COMMUNITY PHARMACY PROGRAM – KEY PRINCIPLES

The range of programs offered by community pharmacy should be underpinned by the following principles:

- a. be based on evidence of effectiveness
- b. may or may not involve government paying for some or all of the cost of the service to some or all patients
- c. may in some cases be offered on the basis of each community pharmacy choosing whether or not to offer the program (with all community pharmacies being eligible to offer the program). In other cases, the program will only be available (with government payment) through pharmacies/pharmacists that are selected by the government (for example, through a tender process or as a result of negotiation between the government and the relevant pharmacies or pharmacists)
- d. for some programs, government remuneration for the program will be channelled through the users of the program (or their representatives) so that the users will decide which community pharmacies (or pharmacists) to use to deliver the program
- e. adequate funding for the above needs to be found outside PBS expenditure.

PSA broadly agrees with the suggestions detailed in this option. Specific comments on all parts of this option are detailed below;

- a. PSA has always believed that all services delivered by pharmacists should be underpinned by evidence. Additionally, we have strongly advocated for a stronger focus on research into the efficacy, effectiveness and implementation of evidence based pharmacy services.³²
- b. PSA accepts that the Government may or may not pay for some or all of the cost of the service to some or all patients. However, PSA would caution against using a patient co-payment as a price signal. Price signals work by encouraging consumers to think about whatever it is they are about to buy, and whether it's worth the cost. They also assume consumer knowledge of the product, and its value.³³ 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.³⁴
- c. As previously stated in our submission to the Review's Discussion Paper, PSA strongly believes that the provision of all health services should be based on patient need and that this principle should apply for pharmacist services offered in all settings, including community pharmacy.

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.

PSA is of the view that it is highly desirable to align the delivery of all health services to consumer health needs. We recognise that 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.

d. While PSA agrees with the need for consumer choice regarding which community pharmacies and pharmacists they will receive services from – PSA has received feedback from members with concerns regarding how this initiative would be implemented. As such, PSA would recommend close consultation with the profession as a whole, and clear and transparent communication with both pharmacists and consumers if this option proceeds.

e. PSA has also advocated for a sustainable and adequate funding source for pharmacist delivered services. The current system, by which pharmacist services delivered through the CPA are funded by savings generated in PBS drug expenditure is no longer appropriate nor sustainable. This is particularly the case when the impact of the pharmacists intervention generates cost savings elsewhere in the health system.

For example, PSA recognises that under current funding arrangements, accredited pharmacists are remunerated through the CPA for performing Home Medicines Reviews (HMRs) and Residential Medication Management Reviews (RMMRs). However, as CPAs – and the programs within them – have a finite budget; these services have always been subject to funding limitations, even before the latest round of arbitrary 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 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 believes that an MBS payment is an appropriate remuneration mechanism for the provision of medication management services provided by pharmacists – including services provided by pharmacists working in general practice, 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 in multiple settings, 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 markers³⁵, 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.³⁶

PSA continues to be a strong proponent 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.³⁷ Furthermore, it allows for services to be provided along a continuum, with the level of service being determined according to complexity and need.

OPTION 9-1 ACCESS TO MEDICINES PROGRAMS FOR INDIGENOUS AUSTRALIANS

The access to medicines programs for Indigenous Australians under the section 100 RAAHS Program and the Closing the Gap PBS Co-Payment Measure should be reformed so that the benefits to the individual follow that individual, regardless of where the prescription is written or dispensed.

In our submission to the Review's Discussion Paper, PSA noted that program specific rules can make navigation between CTG and s100 difficult for both Aboriginal and Torres Strait Islander people and health professionals.

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

As such, PSA welcomes this option presented by the Review Panel.

Allowing remote s100 AHSs to write CTG prescriptions and hospitals to provide CTG prescriptions to eligible out-patients would go some way to improving access 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.

Reforming 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.

OPTION 9-2 ABORIGINAL HEALTH SERVICE PHARMACY OWNERSHIP AND OPERATIONS

All levels of government should ensure that any existing rules that prevent an Aboriginal Health Service (AHS) from owning and operating a community pharmacy located at the AHS are removed. As a transition step, these changes should first be trialled in the Northern Territory, and governments should work together with any AHS that wishes to establish a community pharmacy.

PSA is aware that in the Northern Territory, Aboriginal Health Services are able to own and operate a pharmacy business at Ministerial discretion.³⁸

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.

Instead, PSA would strongly recommend that a pharmacist was employed through the AHS to ensure quality use of medicines.

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.

OPTION 10-1 SECTION 100 HIGHLY SPECIALISED DRUGS

The Highly Specialised Drugs (HSD) Program under section 100 of the National Health Act 1953 (Cth) should be reformed to remove the distinction between section 100 (Community Access) and other medicines listed within section 100 HSD arrangements. This should include, for example, harmonising access and fees regardless of where the medicine is dispensed.

PSA agrees in principle with this option. As stated in PSA's initial submission to the Review, 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.

In the event that this option were to proceed, PSA believes that the Government should take steps to mitigate the risk associated with the stocking and supply of these high cost drugs, to avoid problems similar to those experienced with the introduction of HIV and Hepatitis C treatments through community pharmacy.

OPTION 10-2 CHEMOTHERAPY COMPOUNDING – PAYMENTS

There should be no difference in the remuneration paid by the government for the compounding of chemotherapy medicines in any facility that meets the minimum quality and safety standards. In particular, there should be no additional payment for medicines that are prepared in a facility that exceeds the minimum standards.

PSA welcomes the Review Panel's suggestion that there should be no difference in the remuneration paid by the government for the compounding of chemotherapy medicines in any facility that meets the minimum quality and safety standards – this recommendation is in accord with PSA's initial submission to the Review.

OPTION 10-3 CHEMOTHERAPY COMPOUNDING – UNIFORM MINIMUM STANDARDS

There should be a clear, uniform set of minimum quality standards for all approved chemotherapy compounding facilities based in a hospital, a community pharmacy or elsewhere. These minimum standards should:

- a. not require that a compounding facility be Therapeutic Goods Administration (TGA) licensed to meet the minimum requirements
- b. mean that a TGA-licensed facility clearly satisfies the minimum standards
- c. reflect the variety of settings that are appropriate for the preparation of chemotherapy medicines, including 'urgent' preparation in a hospital setting or a community pharmacy setting.

PSA agrees that there should be uniform set of minimum quality standards for all approved chemotherapy compounding facilities based in a hospital, a community pharmacy or elsewhere.

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

PSA does note that although many facilities do not hold TGA licenses, 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.³⁹

OPTION 10-4 CHEMOTHERAPY COMPOUNDING – PRACTICE MODELS

Existing practice models in place in public hospitals for limited trade of medicines prepared onsite, such as radio pharmaceuticals, should be considered for providing greater access to chemotherapy arrangements.

PSA does support increased access to quality compounded chemotherapy products, however, as per other recommendations pertaining to medicine access – PSA would urge the panel to carefully consider all of the consequences that a change in supply arrangements may have to medicines access – both intended and unintended.

OPTION 10-5 OPTION 10-5: GENERAL MEDICINE – LISTING ARRANGEMENTS

When an ‘original’ (or ‘branded’) medicine comes off patent then the government should hold a tender for the listing of generic versions of the medicine. The government should limit the number of generic versions of a particular medicine to be listed to a relatively small number that is still sufficient to allow for patient choice (e.g. four generics and the original brand of the medicine). The chosen generics should be those best able to meet the distribution and other conditions required by the government at the least cost to the PBS.

PSA disagrees with this option, and questions the reasoning behind this proposal.

The Interim Report rightly acknowledges that the listing of medicines on the PBS is outside the scope of the Review. While PSA recognises that an efficient and effective pharmacy supply chain is critical, PSA has concerns that the above proposal could have a significant impact on the medicines industry in Australia, leading to medicines access issues.

Medicines shortages are becoming an increasing frequent problem, both in Australia and globally.⁴⁰ The issue is so common in Australia that the Therapeutic Goods Administration has set up a database, the Medicine Shortages Information Initiative, to provide information about prescription medicine shortages in Australia. A visit to the TGA database in early July showed 215 drugs listed on the site as current shortages with warnings of 11 more to come.⁴¹

Medicines shortages are a complex issue and they pose risks to patient health and burden the health system with additional costs. It is widely recognised that relying on a small number of sources for medicines is a risk factor for instability in medicines supply.⁴²

PSA reminds the Panel that medicines should not be considered as ordinary commodities of trade, and that any attempt to change the listing of medicines on the PBS for the purposes of efficiency should be considered carefully for potential unintended consequences, such as impact on medicines availability and accessibility.

OPTION 10-6 MACHINE DISPENSING

The government should trial the use of machine dispensing in a small number of relevant secure locations in communities that are not currently adequately served by community pharmacy. Such machine dispensing should be appropriately supervised and allow real-time interaction with a remote pharmacist. The range of PBS medicines available through machine dispensing also needs to be limited and should be based on an assessment of risk.

PSA supports the principle – increasing access to medicines in communities not currently adequately served by community pharmacy – of this option, and would be supportive of trial of the option, but only if the following conditions were met;

- access to real time interaction with, and advice from, a remote pharmacist (including through the use of telehealth models)
- appropriate supervision of machine dispensing (with the parameters of “appropriate supervision” being defined and informed by consultation with the pharmacy profession”)
- adequate and secure storage of medicines (including temperature considerations), and
- oversight and operation by a pharmacist who currently holds a PBS approval number to operate a pharmacy – with the location of remote machine dispensing being approved by the Australian Community Pharmacy Authority.

If a trial of such a model were to proceed, it would require robust evaluation.



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