Interim Report for the Review of Pharmacy Remuneration and Regulation

Submission by

Dr Ken Harvey

Associate Professor

and

Dr Prasad Ranaweera

Sri Lankan Department of Health Fellow

School of Public Health and Preventative Medicine

Monash University

23 July 2017

Summary

Chapter 2: Consumer Access and Experience

Finding	Option
PRICING VARIATIONS The variation in pricing for medicines due to pharmacy pricing discretion creates consumer confusion.	**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. **COMMENT: We agree. It is inequitable that some pharmacies charge prices near the co-payment even though the general patient price can be much lower. In addition, many patients have no opportunity to shop around for a better price.**
THE $1 DISCOUNT The $1 discount has not led to appropriate outcomes for consumers.	**OPTION 2-2: $1 DISCOUNT** The government should abolish the $1 discount on the PBS patient co-payment. **COMMENT: The hope was that competition would mean that all consumers would be offered a discount and thus an incentive to choose a generic drug; in practice, this produced inequity as solo pharmacies, especially in rural (poorer) areas did not offer the discount whereas some others, in city areas with more competition did.** **We agree; abolish the $1 discount.**
PBS SAFETY NET The current PBS Safety Net system is not transparent and is difficult for consumers to document and understand. The lack of transparency and understanding also results in the Safety Net not being utilised to the extent possible, which disadvantages the more vulnerable consumers.	**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. **COMMENT: We agree with all the above suggestions.**

LABELLING The label is a vital part of the supply of PBS medicines. It is relied on by patients and health professionals for the proper identification, dosage, categorisations and monitoring of medicines.	**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.** **COMMENT: We agree. Appropriate monitoring on proper labeling to ensure quality use of medicine is crucial. Random checking should also be done.**
CONSUMER INFORMATION ON PHARMACY SERVICES Information about pharmacy services is inconsistent and inadequate to support sufficient consumer awareness and choice.	**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). **COMMENT: Agree**
CONSUMER MEDICINES INFORMATION While Consumer Medicines Information (CMI) leaflets are generally available, there are variances in how these are provided to consumers. Some consumers may be unaware of the availability of a CMI and there is a risk that these may not be provided, which could impact on quality of care.	**OPTION 2-6: CONSUMER MEDICINES INFORMATION** 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. **COMMENT: We agree. However, there are many problems with CMI; numerous versions for each brand which may differ; distribution is problematical (not all new script's dispensed currently get a CMI) and many consumers are unaware that CMIs are available on NPS & TGA web sites.**
THE BENEFITS OF AN ELECTRONIC HEALTH RECORD FOR CONSUMERS The current paper-based system of prescriptions used in Australia is outdated. It inhibits the creation of a universal medication record for Australians, creates excessive administration, is less convenient for consumers and presents significant challenges in meeting the standard required for quality use of medicines.	**OPTION 2-7: ELECTRONIC PRESCRIPTIONS** 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. **COMMENT: In principle, yes, but first numerous problems must be fixed; current My Health Records are usually not kept up-to-date by GP's; specialists rarely use them and hospital discharge summaries (including discharge medication) are not usually added and numerous commercial**

	prescribing and dispensing software appears lacks mandated communication standards.
ELECTRONIC RECORD KEEPING Australia lacks an integrated and effective universal health record system. This reduces consumer access to best-practice care and continuity of care between providers.	**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 vaccine register. **COMMENT: Agreed; but see problems listed above.**
MANAGING RISKS ASSOCIATED WITH 'CHANNELLING' PRESCRIPTIONS The introduction of a compulsory electronic prescription record could introduce risks of inappropriate behaviour, such as channelling of prescriptions, that will need to be managed appropriately.	**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. **COMMENT: Agreed.**
MANAGING MEDICINE RISKS ASSOCIATED WITH HOSPITAL DISCHARGE AND READMISSION The lack of a robust framework for the management of medicines between hospitals and community pharmacies creates risks for patients on discharge.	**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. **COMMENT: Agreed.**

Chapter 3: The Role of Community Pharmacy in Medicine Supply

Finding	Option
THE ROLE OF COMMUNITY PHARMACY	**OPTION 3-1: COMMUNITY PHARMACIES – MINIMUM SERVICES**

Finding	Option
There are certain minimum services that all community pharmacies should provide in order to meet consumer and government expectations about the level of consistency that is required from a national pharmacy network.	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. **COMMENT: Agreed**
COMPLEMENTARY MEDICINES Consumers value access to complementary medicines in the community pharmacy setting, where they can receive advice on their selection and use that is backed by an appropriate level of evidence.	**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. **COMMENT: Agreed. A prominent sign should be displayed above the complementary medicine area which states, "Complementary medicines are not evaluated by Australian Health Authorities to see if they work and they may interact with the conventional medicines you are taking. Please consult a pharmacist about these medicines".** **There should also be no companion sales pressure, see:** https://www.pharmacynews.com.au/news/latest-news/companion-sales-handout-to-be-destroyed **but:** http://www.pharmabuddy.com.au/
PHARMACY ONLY AND PHARMACIST ONLY MEDICINES (SCHEDULE 2 AND SCHEDULE 3 MEDICINES) Complementary medicines pose a risk to consumers when they are not clearly separated from Pharmacy Only and Pharmacist	**OPTION 3-3: PLACEMENT OF PHARMACY ONLY AND PHARMACIST ONLY (SCHEDULE 2 AND SCHEDULE 3) MEDICINES WITIHN 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:

Finding	Option
Only (Schedule 2 and Schedule 3) medicines.	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. **COMMENT: Agreed**
HOMEOPATHIC PRODUCTS There are unacceptable risks where community pharmacies are allowed to sell homeopathic products.	**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. **COMMENT: Agreed. See also:** https://theconversation.com/pharmacists-are-trusted-medical-professionals-so-they-shouldnt-sell-remedies-that-lack-evidence-65148 https://theconversation.com/new-complementary-medicine-health-claims-lack-evidence-so-why-are-they-even-on-the-table-80896

Chapter 4: Community Pharmacy Remuneration by Government

Finding	Option
SOURCES AND TRANSPARENCY OF PHARMACY REMUNERATION The extent and quality of data and information is currently not adequate to inform decisions and determinations about the costs related to an efficient dispensing service.	**OPTION 4-1: ACCOUNTING INFORMATION** 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

Finding	Option
	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. **COMMENT: Agreed**
BASIS OF EFFICIENT DISPENSING COST/REMUNERATION Remuneration should be based on the efficient costs of dispensing within a best-practice pharmacy.	**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. **COMMENT: Agreed.** **OPTION 4-3: BENCHMARK FOR AN EFFICIENT DISPENSE** 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. **COMMENT: Agreed.**
THE COSTS OF DISPENSING Remuneration for dispensing should be based on the incremental costs of dispensing	**OPTION 4-4: REMUNERATION FOR DISPENSING – FORMULA** 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.

Finding	Option
rather than fully distributed or stand-alone costs.	**COMMENT: Agreed.**
STRUCTURE OF REMUNERATION FOR DISPENSING The current formula for the remuneration for dispensing paid by the government to community pharmacy is overly complex and opaque. The formula should be simplified to improve the transparency and simplicity of government payments.	**OPTION 4-5: REMUNERATION LIMITS** 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. **COMMENT: Agreed.**
REMUNERATION – ALTERNATIVE SERVICE CHANNELS Government is currently paying different amounts through different mechanisms for the same service supplied by different primary health professionals.	**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. **COMMENT: Agreed.**

Chapter 5: The Regulation of Pharmacy for Medicine Supply

Given the Government's recent commitment in the 2017–18 Budget to continue the current pharmacy location rules, the Panel considers that options 5-1, 5-2 and 5-3 are no longer immediately relevant to this Review. They have been presented but will not be considered further by the Panel. However, the Panel will continue to consider options to modify the location rules that have been put forward on the assumption that the current location rules will be retained.

Finding	Option
REFORMS TO PHARMACY LOCATION RULES Certain aspects of the pharmacy location rules are limiting competition and are unnecessary in some areas.	**OPTION 5-1: LOCATION RULES – REMOVAL AND REPLACEMENT** The government should remove the location rules for community pharmacies. It should replace the location rules with one of the alternatives presented below. **OPTION 5-2: URBAN LOCATION RULES** **5-2. ALTERNATIVE 1:** The government should undertake an analysis (as per Option 4-2) to determine and implement efficient remuneration for the dispensing of PBS medicines. Following the implementation of efficient remuneration and a suitable transition period (no later than 31 December 2020), the government should remove any restrictions to limit the ability of any qualified pharmacist or pharmacists to establish a pharmacy to dispense PBS medicines at any location in urban areas.

Finding	Option
	5-2. ALTERNATIVE 2: The government should replace the location rules in urban areas in two stages: 1. For the first five years, the government should: a. establish an independent statutory authority (the Pharmacy Location Board (PLB)) of five members, at least two of whom are persons who have been, but are no longer, engaged either directly or indirectly in community pharmacy. No PLB member may be a current pharmacy owner. Any pharmacist wishing to establish a new pharmacy in an urban location would be required to apply to the PLB for a provider number. The PLB would assess all such applications and engage in relevant consultation as it sees fit. The PLB would issue a provider number if (and only if) in the opinion of the PLB, this would materially improve consumer access to PBS medicines b. undertake an analysis (as per Option 4-2 above) to determine and implement efficient remuneration for the dispensing of PBS medicines. 2. Prior to the end of the five-year period, the government should assess whether the PLB is required in urban areas or whether consumer access to PBS medicines would be appropriately served by removing any remaining restrictions that limit the ability of any qualified pharmacist or pharmacists to establish a pharmacy to dispense PBS medicines at any location in urban areas. **COMMENT: Preferred.** **5-2. ALTERNATIVE 3**: New pharmacy location rules should be introduced based on existing rules. This includes: a. retention of the prohibition within the location rules relating to the co-location of approved pharmacies in supermarkets b. the establishment by the Department of Health and the Guild of a joint working group with the aim of identifying and addressing any anomalies that have arisen over time, to ensure the location rules remain responsive to the evolving needs of the community.
	OPTION 5-3: NON-URBAN LOCATION RULES **5-3. ALTERNATIVE 1:** The government should replace the pharmacy location rules in non-urban areas by establishing an independent statutory authority (the Pharmacy Location Board (PLB)) of five members, at least two of whom are persons who have been, but are no longer, engaged either directly or indirectly in community pharmacy. No PLB member may be a current pharmacy owner. Any pharmacist wishing to establish a new pharmacy in a non-urban location would be required to apply to the PLB for a provider number. The PLB would assess all such applications and engage in relevant consultation as it sees fit. The PLB would issue a

Finding	Option
	provider number if (and only if), in the opinion of the PLB, this would materially improve consumer access to PBS medicines. The PLB would also work with the local Primary Health Network (PHN) in any relevant region to determine areas where there is a lack of appropriate pharmacy services and work with the PHN to initiate a tender to seek options by pharmacists to provide the identified services. The government would appropriately fund PHNs and the PLB to carry out these tenders and, where relevant, to provide any subsidy determined through the tender process. **5-3. ALTERNATIVE 2:** New pharmacy location rules should be introduced based on existing rules. This includes: a. retention of the prohibition within the location rules relating to the co-location of approved pharmacies in supermarkets b. the establishment by the Department of Health and the Guild of a joint working group with the aim of identifying and addressing any anomalies that have arisen over time, to ensure the location rules remain responsive to the evolving needs of the community.
REFORMS IF THE LOCATION RULES ARE RETAINED IN SOME PARTS OF AUSTRALIA The policy in respect of pharmacy location rules is unclear. This results in different interpretations of their purpose and intent and reduces the ability to monitor performance and the achievement of outcomes.	**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.
OVERLAPPING OWNERSHIP AND LOCATION OF PHARMACIES The pharmacy location rules have not established robust competition between independent pharmacies in some locations. Rather, in some locations, either individual pharmacists or small groups of pharmacists have been able to monopolise some or all pharmacies. This is inconsistent with the objective of Australia's competition laws.	**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.

Finding	Option
	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. **COMMENT: Agreed.**
PHARMACY ACCESS AND OPENING HOURS In urban Australia, there are pharmacies currently operating with extended hours (from around 7 am to 11 pm); however, consumers often lack information about these pharmacies and they are not evenly spread through urban areas.	**OPTION 5-6: INFORMATION ON PHARMACY OPENING HOURS** The Pharmacy Atlas (Option 2-5) should include information on pharmacy opening hours. **COMMENT: Agreed.** **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. **COMMENT: Agreed.**
THE RURAL PHARMACY MAINTENANCE ALLOWANCE There are a number of anomalies in the administration of RPMA payments that serve to reduce the effectiveness of the program.	**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. **COMMENT: Agreed.**
VARIATIONS AMONG STATE AND TERRITORY REGULATORY ARRANGEMENTS RELATING TO COMMUNITY PHARMACY The community pharmacy sector is subject to a complex array of regulations made by state and territory governments as well as the Australian Government.	**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. **COMMENT: Agreed.**

Finding	Option
TRANSPARENCY IN GOVERNMENT PROGRAMS Community pharmacy expenditure and funding is insufficiently transparent to demonstrate value and performance in meeting the objectives of the National Medicines Policy.	**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. **COMMENT: Agreed.**
EVALUATING, MONITORING AND REPORTING ON REGULATION There is a lack of coordination and consistency in the current monitoring, evaluation and reporting systems relating to the regulations around community pharmacy. This has a potential to undermine community faith in the community pharmacy network in Australia.	**OPTION 5-11: EVALUATION MECHANISMS** The government should require the establishment of appropriate evaluation mechanisms to measure compliance and performance. **COMMENT: Agreed.**

Chapter 6: The Distribution of Medicines to Community Pharmacy

Finding	Option
ENSURING TIMELY MEDICINE ACCESS Current supply chain arrangements (terms of trade and supply conditions) involve unnecessary regulation, as well as Community Service Obligation (CSO) payments that appear unconnected with relevant distribution costs, and may be leading to wholesale margins that are higher than necessary for an effective and efficient supply chain.	**OPTION 6-1: COMMUNITY SERVICE OBLIGATION REMOVAL, RETENTION OR REPLACEMENT** **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.

Finding	Option
	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. **COMMENT: ALTERNATIVE 3 preferred.**
PROCEDURES AND REMUNERATION FOR THE SUPPLY OF HIGH-COST MEDICINES The supply of complex and high-cost medicines does not sit well within existing supply chain and pharmacy remuneration arrangements. Supplying these medicines is of significant concern for a number of pharmacies.	**OPTION 6-2: SUPPLY OF HIGH-COST MEDICINES** 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. **COMMENT: Agreed.**

Chapter 7: Future Community Pharmacy Agreements

Finding	Option
THE COMMUNITY PHARMACY AGREEMENT PROCESS The Sixth Community Pharmacy Agreement (6CPA) process was not adequate, as reflected in the submissions to this review. The Australian National Audit Office (ANAO) was also critical of some of the processes in the Fifth Community Pharmacy Agreement (5CPA), which have been partially addressed in 6CPA.	**OPTION 7-1: SCOPE OF COMMUNITY PHARMACY AGREEMENTS – DISPENSING** 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. **COMMENT: Agreed.** **OPTION 7-2: SCOPE OF COMMUNITY PHARMACY AGREEMENTS – WHOLESALING** The government should ensure that the regulation and remuneration of wholesaling of PBS-listed medicines should not form part of future Community Pharmacy Agreements. **COMMENT: Agreed.** **OPTION 7-3: SCOPE OF COMMUNITY PHARMACY AGREEMENTS – PROGRAMS AND SERVICES**

Finding	Option
	The regulation and remuneration of professional programs offered by community pharmacies should not form part of future Community Pharmacy Agreements. **COMMENT: Agreed.** **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). **COMMENT: Agreed; especially consumer representation.**

Chapter 8: Health Programs Offered by Community Pharmacy

Finding	Option
LEVERAGING PHARMACY AND PHARMACIST CAPABILITY Significant opportunities exist for the better use of community pharmacy and pharmacist programs and services in improving the health of Australians.	**OPTION 8-1: DOSE ADMINISTRATION AIDS – STANDARDS** 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). **COMMENT: Agreed.** **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

Finding	Option
	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. **COMMENT: Agreed.**

Chapter 9: Access to PBS Medicines and Community Pharmacy Services for Aboriginal and Torres Strait Islander People

Finding	Option
SECTION 100 REMOTE AREA ABORIGINAL HEALTH SERVICES PROGRAM Access to medicines for Indigenous Australians under the section 100 RAAHS Program and the CTG PBS Co-Payment Measure has created a number of challenges in ensuring a consistent level of care to the intended patient group.	**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. **COMMENT: Agreed.**
PHARMACY OWNERSHIP AND OPERATIONS BY ABORIGINAL HEALTH SERVICES The current inability of an AHS to operate a community pharmacy poses a significant risk to patient health in some rural and remote areas of Australia.	**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. **COMMENT: Agreed.**

Chapter 10: Further Issues

Finding	Option
SECTION 100 HIGHLY SPECIALISED MEDICINES The distinction between highly specialised and other PBS medicines is causing administrative inefficiencies and unnecessary risks to patient health.	**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. **COMMENT: Agreed.**
CHEMOTHERAPY COMPOUNDING – PAYMENTS	**OPTION 10-2: CHEMOTHERAPY COMPOUNDING – PAYMENTS**

Finding	Option
The rationale for differential payments for compounding of chemotherapy preparations is not substantiated on the basis of patient risks or health outcomes for medicines that must meet an appropriate level of quality, whether prepared at a TGA licensed or non-TGA-licensed facility.	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. **COMMENT: Agreed.**
CHEMOTHERAPY COMPOUNDING STANDARDS The current standards for the compounding of chemotherapy medicines in community pharmacy and other facilities appear to be overly complex. The oversight currently includes legislation, codes and guidelines. The overlap and inconsistency of these across Australia do not provide clear rules or guidance for compounders.	**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. **COMMENT: Agreed.**
CHEMOTHERAPY COMPOUNDING PRACTICE MODELS There are a number of good practice chemotherapy compounding models that can be leveraged to improve access to existing compounding arrangements.	**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. **COMMENT: Agreed.**
TIGHTENING THE LISTING OF GENERIC MEDICINE A more targeted approach to listing PBS medicines can improve supply chain efficiency and reduce costs to the Australian community	**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. **COMMENT:** Agreed.
MACHINE DISPENSING Overseas experience has demonstrated advantages in the use of remote dispensing machines.	**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. **COMMENT:** **Trial yes**