MEDICINES Australia

Submission

to the

Review of Pharmacy Remuneration and Regulation's

Interim Report

Introduction

Medicines Australia welcomes the Interim Report from the *Review of Pharmacy Remuneration and Regulation*.

Medicines Australia is the peak industry body representing the research-based innovative pharmaceutical industry in Australia. Our members research and develop, manufacture and supply medicines and vaccines to the Australian community. Our members represent over 80 per cent of the Australian prescription medicines market by value.

Pharmacists play a crucial role in the delivery of health and health care outcomes in Australia; like innovative medicines manufacturers, they are part of the broader pharmaceutical supply chain. Currently, remuneration of the pharmaceutical supply chain makes up a significant share of Australian Government, and consumer/patient, pharmaceutical costs. Reforms that are likely to impact on the operations of the supply chain, including manufacturers, will require further consultation with the sector to avoid unnecessary or unintended consequences.

Central to Australia's world-leading health care system is universal medicines access underpinned by the National Medicines Policy (NMP) and the Pharmaceutical Benefits Scheme (PBS). It is imperative that any reforms to pharmacy regulation and remuneration must align with the objectives of the NMP; and be consistent with tenets of the Pharmaceutical Benefits Scheme (PBS).

Medicines Australia has not responded to all the options presented, because we are not convinced that a case for broad ranging and radical reform has been made.

Rather, Medicines Australia has considered the options and makes some general observations along a number of themes, and has responded to specific options only on an exceptions basis.

The themes are:

- Policy objectives should focus on patient access and outcomes as an overarching goal;
- Policy in this important area should be evidence based, including regulation on retailing particular products such as homeopathic products;
- All policies should be assessed for cost-effectiveness;
- Policies should be as transparent as possible; and
- Policies should be harmonised as much as possible, consistent with reducing the burden of red tape.

Where this submission makes some detailed comments about specific options, it aims to indicate:

- support for some options presented where relevant, including reasons;

- does not support some of the options presented where relevant, and outlines why this option should not be supported; and
- requests for further information where Medicines Australia considers the options would benefit from further discussion.

This submission is designed to provide a broad representation of the views of our members. In addition, Medicines Australia anticipates that individual members may make separate submissions to the Panel to draw further upon the themes and highlight areas where they identify specific impact at company-level.

We acknowledge that the release of the Report follows extensive consultation and deliberation. We look forward to continuing our engagement with the Panel, the Australian Government, the Department of Health and key stakeholders, as the Review continues and the final report is developed.

OVERVIEW

The National Medicines Policy and sector agreements

Australia's NMP is a cooperative endeavour to deliver better health outcomes for all Australians. It relies upon the sustainable existence of the broader pharmaceutical supply chain (including the medicines industry, wholesalers, and pharmacists).

Community Pharmacy Agreements (CPAs) have been in place in Australia for many years. Successive CPAs have provided predictability and stability for Government, community pharmacy and consumers. Similarly, the 2017 Strategic Agreement recently signed with the innovator medicines industry builds on the landmark 2010 Memorandum of Understanding (MOU).

These agreements generate savings to the Australian Government and are intended to provide a period of predictability and stability for the medicines industry, Government and consumers. Medicines Australia supports agreements where such agreements are transparent, consistent with NMP objectives, ensure consultation between relevant or affected parties, and promote predictability and stability.

The Pharmaceutical Benefits Scheme (PBS)

Access to innovative pharmaceutical products, including vaccines, via the PBS has been a major contributor to Australian health outcomes for over 50 years.

The PBS is widely recognised as one of the best publicly-funded medicines systems in the world. It provides Australians with timely, reliable and affordable access to medicines, regardless of where they live and consistent with the objectives of the NMP. One of the major strengths of the PBS is that it is a national program, ensuring a consistent approach to evaluation, funding, and distribution of medicines.

The sustainability of the PBS is the result of successive reforms, many in collaboration with the innovative medicines industry. These measures include *price disclosure*, which enables market pricing for off-patent medicines. In addition, risk sharing and rebate agreements between medicines sponsors and the Government (particularly for high-cost medicines) work to deliver a financially sustainable PBS.

Although overall public health expenditure may have grown, PBS expenditure has seen below inflation growth over recent years, and has remained at around 0.6% of GDP.[1] This low level of growth is expected to continue, providing exceptional value for the Commonwealth, with increased overall health and reduced expenditure for more expensive levels of care and greater productivity[2].

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[1] Medicines Australia 2016. Submission to the 2016-17 Federal Budget. Available: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20160205-MA-2016-draft-budget-submission-Final.pdf

[2] Lichtenberg, F. 2015. The impact of pharmaceutical innovation on premature mortality, hospital separations and cancer survival in Australia. Columbia University. Available: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20151124-Lichtenberg-paper.pdf

KEY THEMES

Medicines Australia is not persuaded that a case for broad-ranging or radical reform has been made. Many of the options are quite radical, and would provide major disruption to a system that has served Australia well for many years. Rather than embarking on major reforms that would overturn many successful arrangements and lead to great unpredictability, Medicines Australia believes that incremental changes should be explored to make the existing systems work more efficiently.

Medicines Australia considers that, in addition to the specific comments, all options should be evaluated with respect to the following:

- Patient Access and Outcomes
- Evidence-based Policy
- Cost-Effective Policy
- Transparent and Predictable Policy
- Harmonised Policy

Patient Access and Outcomes

Medicines Australia supports improved patient access and outcomes and would support moves to put patient access and outcomes at the heart of the supply chain. Members of Medicines Australia are committed to delivering improved access and outcomes across the whole of the supply chain.

Medicines Australia members are subject to rigorous safety and efficacy standards in registering and listing their medicines. When patients receive PBS-listed medicines through a community pharmacy, the medicines are safe, efficacious and cost-effective. All options to improve the other areas of the medicines supply chain to improve patient access and outcomes would be of great benefit to Australian patients.

Further, technological advancements such as electronic databases and systems will improve regulatory processes, reducing the burden of red tape, and ensure that Australians get faster access to quality medicines.

Evidence-based Policy

Medicines Australia notes that the process of listing medicines on the PBS is subject to rigorous cost-effectiveness assessment, and considers this system appropriate to maintain the integrity of the PBS. Other elements of the supply chain should not be exempt from this assessment where taxpayer funds are concerned.

Although Medicines Australia supports community pharmacies supplying a range of treatments and services to Australians, it is important that the Government subsidises only products and treatments for which there is robust evidence for their efficacy.

Cost-effective Policy

Medicines Australia supports fit-for-purpose cost-effectiveness measures around the listing process and believes there is scope to improve cost-effectiveness measures in other areas of the supply chain.

As the interim report notes, pharmacy remuneration for dispensing, and remuneration for wholesaler distribution is a significant proportion of the Government-reported expenditure on the PBS.

In particular, in assessing appropriate levels of remuneration for dispensing, Medicines Australia considers that it would be appropriate for remuneration to include consideration of the cost-effectiveness of dispensing activities and services. It is important to be clear that Medicines Australia does not have a view on the particular fee or structure of the remuneration – rather that it should be cost-effective.

Transparent and Predictable Policy

Medicines Australia supports transparent and predictable policy across the sector, and particularly around some specific supply costs of medicines. It is not clear that all elements of the supply chain are subject to rigorous cost-effectiveness tests, or that they are transparent and predictable.

For example, PBS expenditure reported in the Commonwealth Budget Papers is often incorrectly viewed as all relating to manufacturers. It does not outline supply chain costs, which are trending towards 40% of total PBS expenditure. Medicines Australia considers that this is one area where a more detailed breakup of expenditure in public documents would assist in public debate.

Further, in a competitive international business environment, uncertainty of policy approaches brings additional cost. Given the lead times and risk involved with developing new medicines, transparent and predictable policy is important to ensure Australians continue to receive top quality medicines.

Harmonised Policy

Medicines Australia supports harmonised policy arrangements across the states and territories, wherever possible and appropriate, to ensure that patients do not experience barriers to access and improved health outcomes. Harmonised regulation provides a more certain business environment, leading to greater efficiency and more cost-effective medicines.

Specific Observations on Options Proposed

Medicines Australia makes the following specific observations on the options outlined below. Otherwise, Medicines Australia's views on the options relate to the themes outlined above.

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.*

Medicines Australia supports Option 2-3. The approach would improve data management and transparency, and continue the move towards more modern systems and processes through use of electronic systems and databases. This would improve patient access and likely health outcomes.

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.

Medicines Australia supports Option 2-4. Manufacturers of PBS-listed products comply with strict TGA requirements regarding packaging and labelling.

Medicines Australia has worked closely with the TGA on the TGA Labelling Orders reforms. Further, we have been invited to contribute to the work of the Australian Commission on Safety and Quality in Health Care which aims to standardise pharmacy dispensed labelling. In developing the standard, work will include dispensed label content, format and design, health literacy, and consumer testing.

Given the number of initiatives being progressed in relation to labelling and dispensing, the Australian Government must ensure that initiatives are complementary and the relevant parts are kept cohesive. We also note that any changes to current systems need lead time and should be consulted upon closely with manufacturers.

There is also an onus on the pharmacist to comply with other regulations regarding labelling on dispensing.

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.

Medicines Australia does not support Option 2-6.

CMI was intended only as a tool to assist health care consumers to know and understand their medicines and how to take them, consistent with the Quality Use of Medicines in the National Medicines Policy.

CMI should not be seen as a substitute for the conversation between the prescriber and the patient.

At the point of dispensing, it is pharmacists who play a critical role in reminding patients about how to comply and adhere to their medicines and who can refer patients to the CMI in which the medicines information is made available to them.

Rather than presenting a hardcopy leaflet, which is costly and time-consuming to maintain, this important information is now also available via the TGA's new, free MedSearch App. We also note that the Australian Digital Health Agency, has also established a Medicines Safety Programme Steering Group to improve the access and quality of medicines information through the use of digital health. Medicines Australia is a member of this group.

At a multi-level stakeholder forum on CMI hosted by Medicines Australia in August 2016, participants concluded that more can be done to support prescribers and pharmacists in relation to CMI, primarily through professional training and education, and that more needs to be done about health literacy in Australia. Raising literacy levels in the community is vital to achieving the Quality Use of Medicines. We believe that CMI assumes a level of health literacy in Australia that does not exist - a number of studies have demonstrated that overall, Australian health literacy levels are low.

We would like the Panel to note that there is an Australian Government Financial Literacy Foundation and we consider that it the time is right for the Australian Government to explore the concept of a Health Literacy Foundation, perhaps using CMI as an early area of focus.

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.

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.

Medicines Australia supports Options 2-7 and 2-8. The establishment of electronic prescriptions and a medications record will enable broader linkages of health records, and the real-world evidence data that this creates, which is so important in the development of more specialised cost-effective treatments for patients. Medicines Australia notes that such options should be considered in the context of the development of opt out electronic health records.

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.

Medicines Australia supports Option 2-10, as post-hospital patient adherence is important to ensure continued improved patient outcomes

There is evidence that this does not occur in all cases, which potentially means that the cost of the medicines and the health intervention is wasted. This may flow on to further hospitalisations, primary care visits, and further need for pharmaceuticals. Any improvements to adherence would improve this cost effectiveness, and lead to reduced patient and government cost, and improvements in quality of life and productiveness.

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.*

Medicines Australia does not support Option 3-2.

Complementary medicines are sold through a number of channels, including pharmacies and supermarkets. Arbitrary restrictions on pharmacies would be anti-competitive. To ensure a level playing field, it would be necessary to address complementary medicines sold in supermarkets, which would add an additional layer of complexity and regulation.

Medicines Australia considers that any issues with complementary medicines would be better considered through the scheduling policy framework.

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.

Medicines Australia supports Option 3-4. Homeopathy does not have a robust evidence base and for this reason should not be allowed for sale in a community pharmacy.

By allowing sale of homeopathic products in a community pharmacy, it lends credence to the idea that homeopathic products and PBS-listed medicines may be an equivalently effective treatment.

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.

Medicines Australia supports Option 4-6. Such an approach supports access for patients who may not otherwise receive the service, and therefore lead to improved health outcomes. One example of this would include vaccinations being provided by pharmacists in addition to general practitioners, with associated benefits to patients and the community through herd immunity.

Further, cost effectiveness principles indicate that the remuneration should be applied for the provision of the specific service.

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.

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.

Medicines Australia supports both Options 5-9 and 5-10, based on overarching themes regarding harmonisation and transparency.

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:*

e. an initial Panel of around five wholesalers would be approved. It is expected that these will include the existing CSO Distributors
f. 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
g. 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.*

Medicines Australia supports competition and efficiency in the wholesale supply arrangements, and supports the Panel exploring further efficiencies in the current system (i.e. Option 6-1 – alternative 3). However, it does not support or advocate for monopoly wholesale supply arrangements, nor does it support mandating the transfer of wholesale supply to manufacturers (Options 6-1, Alternatives 1 and 2).

Enforcing a “one-size-fits-all” supply chain arrangement would put considerable pressure on existing wholesalers with the risk that some of them would no longer continue operations Suppliers are free to take on direct arrangements where it is commercially suitable for them. However, for many smaller manufacturers, this is not a viable option due to scale limitations.

Indeed, because there are multiple wholesalers at the moment, and multiple possible arrangements, there is some robustness in the supply chain. Should the model reduce the number of wholesalers, mandating that manufacturers are responsible for wholesale supply may increase supply-chain vulnerability due to reduced numbers of wholesale channels.

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.

Medicines Australia seeks further clarify on this Option, including:

In placing such a cap on the cost of medicines, somewhere in the supply chain will bear additional risk. Where that risk would lie should be clarified before this proposal is further developed. In addition, if there is a "gap" between the cost of the medicine and the price, the option would benefit from further clarity around:

- the stakeholder responsible for claiming the gap (i.e. the wholesaler or the manufacturer from the Government);
- the process for claiming the gap;
- the timing of the gap (i.e. when the pharmacists receives the stock, or when the stock is dispensed);
- The payment terms of the gap; and
- Whether the cap would create a perverse incentive for pharmacies to overstock high-cost medicines at the expense of other medicines that could be in their inventory.

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.

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.

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.

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).

Medicines Australia supports broader stakeholder consultation as part of Community Pharmacy Agreement (CPA) negotiations. It is important for such negotiations to ensure that relevant stakeholder's perspectives are included where necessary, without making such negotiations so protracted as to become inefficient for stakeholders and government.

For Medicines Australia, it would be important to be included on negotiations that relate to wholesaling, PBS funding, and costs. The Government agreed to consult with the industry as part of the strategic agreement, which is an indication of how agreements of this nature ensure co-ordinated policy development and broad consultation and collaboration with interested stakeholders.

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.*

Medicines Australia would support greater cost-effectiveness analysis and transparency in remuneration, in line with the key themes outline above. Medicines Australia would seek further clarity regarding the funding mechanism referred to in paragraph e. of this option.

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.

. Medicines Australia would support measures that would provide greater support for Indigenous Australians in line with the National Medicines Policy of equitable access to medicines, as well as any efforts that improve patient access and outcomes for these Australians who could potentially benefit greatly from health interventions.

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.

Medicines Australia supports in-principle Option 10-1 on the basis that Government funded dispensing remuneration, agreed mark-ups, and distribution fees should be consistent regardless of whether they are prescribed as a S85, S94 or S100 benefit. This would be fair, equitable and in the best interests of patient access.

Medicines Australia understands that distribution for s100 medicines provided through community pharmacies is not covered under CSO arrangements, or an agreed supply framework. This leads to inequity of access in meeting patient demand. The distribution and pharmacy dispensing costs for s100 products is being covered by either wholesalers, pharmacists, manufactures or potentially patients. In addition some small volume s100 products are not stocked by all wholesalers at all, and manufacturers can only cover limited quantities in response to specific orders.

In enacting reform under such an option, distribution costs should be added to the current Dispensed Price for Maximum Quantity (DPMQ) for s100 products or through a flat payment as part of the Community Service Obligation to supply s100 medicines within the same timeframes as others.

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.

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.*

Medicines Australia supports in-principle Options 10-2 and 10-3 on the principles of cost-effectiveness and harmonisation.

The minimum quality standards should be consistent with the principles of Good Manufacturing Practice (though not necessarily the detail), and appropriate quality assurance processes should be put in place.

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

Medicines Australia does not support Option 10-5.

The decade-old reforms of Formulary 1/Formulary 2, with the savings from Formulary 2 delivered through competition, has provided significant savings to government over many years. There is no evidence provided that limiting the number of medicines arbitrarily on the PBS would provide additional sustainable savings whilst maintain patient access.

Such an approach would restrict supply of medicines, risking supply disruptions with associated negative impacts on health outcomes for patients, in conflict with the idea of improved access for patients.

Further, patient and prescriber choice should be retained in the provision of medicines. Specifying a fixed number of options would not preserve that important feature of the current system, and would be of questionable benefit. Indeed, in restricting supply for certain conditions, it may come at considerable cost to patients and the community.

There is no evidence to suggest that the overall cost of medicines is too high. Growth in PBS expenditure has generally been below inflation in recent times. Mechanisms around price disclosure and the current formulary structure have been very successful in ensuring that PBS expenditure has been and continues to be sustainable, and Medicines Australia supports this approach.

Conclusion

Medicines Australia commends the Review and its aim to provide recommendations to support future Government decisions on the remuneration and regulation of community pharmacy (including wholesalers) in subsequent Community Pharmacy Agreements.

Medicines Australia further supports achieving arrangements which are transparently cost-effective for Government and consumers, financially sustainable, considerate of current and future expectations for the community pharmacy sector, and effective in delivering quality health outcomes and promoting access and quality use of medicines.

Medicines Australia looks forward to further consultation with the Panel and thanks the Panel for considering this submission.