MEDICINES AUSTRALIA

Submission to the Senate Community Affairs Committee

National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007

13 June 2007

MEDICINES Australia
Better Health through Research and Innovation

Executive Summary

The innovative medicines industry in Australia makes a vital contribution to our economy and national well-being. The industry is diverse and must stay competitive in a global marketplace. The Government's PBS reform policy will see individual companies face significant and in some cases, severe detrimental impacts. Through mandatory price reductions for the medicines it delivers to market, the industry will make an estimated collective contribution of at least $1.2 billion, or two-thirds of the anticipated $1.7 billion in total gross savings the Government is expecting from the proposed reforms over the coming years.

Nevertheless, on balance Medicines Australia supports the intent of proposed PBS reforms contained in the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 ('Bill').* There are three major reasons for this. Sustaining the PBS will provide

- Patient access to cost-effective new medicines into the future
- Certainty for future pharmaceutical and biotech industry investment; and
- Savings or 'head room' for Government to re-invest into new medicines.

In short, responsible measures to sustain the PBS make good public policy.

However, the Bill requires improvements in several areas to improve the policy's effectiveness and protect patients. There are two key areas where Medicines Australia strongly recommends changes to the Bill to ensure delivery of policy intent. They relate to a) the treatment of fixed dose combination products in the proposed formulary lists, and b) the management of patient premiums.

Recommendations

1. The Senate support the Bill.

2. The Committee seek to amend the Bill for single brand combination products to be classified into the F1 formulary.

3. The Committee seek to amend the Bill so that the existing practice for managing patient premiums be maintained (i.e. proposed provisions for premiums ***not*** be introduced).

This submission will make the case to substantiate recommended changes to the Bill.

1. Introduction

The Government announced it would reform the Pharmaceutical Benefits Scheme (PBS) on 16 November 2006. The legislative amendments required to

implement these reforms are contained in the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007*. The reforms put in place structural changes to the pricing of medicines on the PBS to achieve good value for listed medicines, while delivering long term savings to support the continued listing of cost-effective medicines into the future.

The reform package includes:

- a new structure to the PBS Schedule with new pricing arrangements for listed medicines, including statutory price reductions and greater transparency through price disclosure requirements;
- a pharmacy support package to help community pharmacists to adjust to the new arrangements;
- streamlined authority approvals for a large number of medicines, which will give doctors more time to spend with their patients;
- establishing a working group to consider issues of continued access to innovative medicines through the PBS; and
- a public awareness campaign to increase knowledge and usage of generic medicines.

The Bill contains amendments to the *National Health Act 1953* that will change the pricing arrangements for medicines to make sure that the Government pays lower prices for multiple brand medicines, without increasing the costs for patients and taxpayers.

2. Overall, the Bill should be supported

Medicines Australia supports reform of Australia's Pharmaceutical Benefits Scheme (PBS) and supports the Government's PBS reform policy. While the pharmaceuticals sector is diverse, and the impacts of the reform proposal will affect different companies in different ways, on balance Medicines Australia believes that, overall, the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007* should be supported.

The Government's reform policy contains measures that will benefit the community, Government and the industry. The policy will help to ensure patient access to innovative, new medicines in the future while capturing greater value for the Government and taxpayers from both generic and originator medicines in the off-patent market. This will help make the PBS sustainable in the long term.

Benefits for patients

Patients will benefit because the measures help to ensure that new medicines developed in the future will be subsidised by the PBS. They will enjoy cheaper medicines where the price of those falls below the co-payment level. Moreover, no patient will have to pay a cent more than today, and no more than the

standard co-payment to achieve these benefits from the reforms. Patients also indirectly benefit as taxpayers, due to savings to Government over several years.

Benefits for Government

The Government will benefit by having a financially sustainable PBS in the future that is able to meet the needs of Australians and the ageing population. The PBS will be able to afford to subsidise the latest new medicines. Government and taxpayers will also benefit by having more competitively priced generic medicines so they will not be subsidising overpriced, older generic medicines. Savings from the off-patent market will come from both generic and originator manufacturers. While the Government has provided estimates for savings from the proposal, Medicines Australia believes that the savings achieved from the overall package could be significantly more than suggested by Government estimates.

It is noted that the Government's reform package will also deliver greater transparency in pricing. The ex-manufacturer price will be listed and the trading terms negotiated by pharmacists as part of negotiations in the market place will, as part of the reform package, also be made public. This is a welcome initiative and is supported by Medicines Australia.

Net benefit for the pharmaceuticals industry despite short term detrimental impact

Although generally the industry supports PBS reform, the impact differs for companies depending on their product portfolios and their position in the market. Many off-patent manufacturers, both those originator companies that are members of Medicines Australia and other generics off-patent manufacturers, face significant losses in revenue as a result of the mandated price cuts and price disclosure system to be introduced.

Given that Medicines Australia members account for around two-thirds of the off-patent market by value in Australia, it will be Medicines Australia members that will bear the bulk of the impact of the savings initiatives in the policy. Based on the Government’s figures, Medicines Australia estimates that the its members will make at least $1.2 billion, or two-thirds, of the contribution to the total savings of the proposal.

PBS reform also results in significant losses for some patented brands, particularly those in Therapeutic Group Premium (TGP) groups. Some single brand combination products are also affected. As with price reductions for off-patent products, price reductions for these patented products will have major impact on companies, particularly in the short term; the on-patent status of these products and lack of competition for them means the price reductions are a difficult issue for many companies.

While the industry is diverse and different companies will face different impacts of the policy, on balance Medicines Australia supports the Government's reform policy as it will provide greater certainty for future industry decisions and investment. Companies will be able to develop and list new, innovative medicines in Australia with greater certainty about whether these products will be listed on the PBS and how they will be priced once listed. Ensuring the PBS will be able to list new medicines in the future, and greater predictability about their price once listed, will provide companies with greater confidence in bringing such new treatments to Australian patients.

The reforms will also provide a more competitive generics market in Australia which provides both opportunities and challenges for Australia's pharmaceuticals industry – both originator and generic pharmaceutical companies. The initiatives to drive competition in the Australian generics market will provide the Government with the financial 'headroom' to fund new medicines. The PBS supply chain will become more transparent as a result of price disclosure, leading to a more competitively priced market. The Government reimbursement price for off-patent medicines will be more reflective of the true market price and also more aligned with the lower global price. Moreover, the competitive market provides opportunities for generics manufacturers, including those that are members of Medicines Australia, to compete in the generics market. Some Medicines Australia member companies believe these reforms create a new opportunity to compete in the generics market.

Recommendation 1

The Senate support the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007.

3. Recommended improvements to the Bill

In order to fully deliver on the intent of the Government's PBS reform policy, Medicines Australia has identified two key areas in which the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007* should be improved. The key areas related to the treatment of fixed dose combination products and the management of premiums. Amendment on these fronts will provide greater certainty in patients' access to medicines, improve the quality use of medicines, provide greater choice for patients, and encourage competition in the off-patent market. The reforms will help ensure the PBS reforms achieve their intended objectives.

The Government has since made several amendments to refine the define the interaction of 'bioequivalence' and 'biosimilar'. The amendments are a technical drafting change that clarifies the scientific fact that because a medicine may be a

biosimilar does not necessarily mean it is 'bioequivalent', as was implied by the original Bill. Medicines Australia supports these amendments.

a) Treatment of fixed dose combination products

Combination products

A combination product is a product that is made up of more than one chemical. The pricing of combination products is usually based on the sum of the individual components in accordance with PBAC guidelines. The development of combination products has been driven in large part by patient need, particularly in disease areas where combination therapy is common like HIV and asthma. In areas where patients have to take multiple medicines, combination products meet clinical needs by helping to reduce 'pill burden' and improve patient compliance with recommended treatment. Combination products are an important treatment innovation that is providing new options for patients and doctors. They are improving the quality use of medicines and driving costs out of the health care system.

Proposal in the Bill

The Bill as currently drafted creates a separate list for single brand fixed dose combination products (FDCs) and states that the price of these products will be linked to the price of their component parts. For example, if a combination product has two components on the PBS and one of them is in F1 and the other in F2T, it will take a proportionate price cut on 1 August 2008 when its F2T component product takes its 25% price cut. Changes relating to the creation of a separate list of single brand combination products relate to s.85AB(5) in the Bill and the system of price treatment of these products relate to s.99ACC and s.99ACE in the Bill.

Problems with the proposal

The current treatment of combination products in the Bill is a substantial, problematic issue for a number of reasons. At the very least, if the Bill is not amended, the risk is that patients will have fewer options for medicines, they will pay more for the medicines they need and there will be less incentive for industry to bring such innovative medicines to market in the future. Further elaboration as to why the Bill as it stands on this matter is problematic follow.

1. Patients will be disadvantaged – they will have less choice and pay more

Patients will be disadvantaged in at least two ways by the proposed treatment of combination products. Firstly, the result would be less likelihood that combination products will be made available to patients in the future. Secondly, and as a consequence of the likelihood that less combination products are available in the future, patients are likely to have to pay multiple co-payments for treatment instead of one co-payment for a combination product. Patients on combination products only have one prescription and, therefore, only pay one co-payment. By contrast, where a patient has to take two or more separate individual medicines, they have multiple prescriptions and therefore pay multiple co-payments. The potential lack of combination products may mean that some groups of patients will have to pay two or more co-payments where they may have only had to pay one if an appropriate combination product was available.

2. The value to patients of combination products is not given due consideration

The blanket approach to combination products does not permit adequate consideration of patient impact and the potential that combination products do contribute a benefit for patients over and above the impact of their individual components. Patient impact is one of the most critical determinants of therapeutic success; patient acceptability will ensure that clinical trial effectiveness is duplicated in community practice. The patient impact of combination products sets them apart from their individual components and the proposed Bill does not allow consideration of this factor.

3. The current proposal is inconsistent with other aspects of the policy

Medicines Australia contends that the proposed classification of combination products is not consistent with other parts of the reform policy.

Most single brand 'fixed dose combinations' of medicines are neither interchangeable with multiple brand medicines nor available as multiple brands. Combination products are innovative in their own right and should be treated in a manner consistent with the policy; namely that single brand combination products should be in F1 and multiple brand combination products in F2.

Other inconsistencies include:

- Patented combination products are not able to have price reductions staged over time, unlike patented medicines in F2T
- Combination products are the only single brand medicines that are subject to flow-on price reductions from price disclosure, and
- Single brand combination products cannot apply patient premiums because there is only one brand of that product, unlike their individual components molecules and other products facing price reductions

The policy inconsistencies are evident in the creation of a separate formulary status for combination products; this underscores the differential treatment of these medicines.

4. Disincentive to industry innovation

The management of combination products proposed in the Bill does not recognise the level of research and innovation that goes into the development of such products. Such products involve significant resources in R&D and clinical trials. Moreover, the current situation provides a disincentive for companies to list combination products on the PBS in the future. Under such a regime, there is little incentive for a company to spend the time, resources and money to develop a combination product when it will be reimbursed at the same price as its component parts.

5. Inconsistency with current PBAC guidelines

The proposed treatment of combination products is also inconsistent with the PBAC guidelines for the listing of combination products. These guidelines recognise that there may be a clinical rationale for use of the combination product rather than the individual components or that the appropriate comparator for a combination product may not the individual components. While the Government's own PBAC guidelines recognise the potential clinical benefit of combination products, the pricing treatment of such products proposed in the Bill does not.

6. Substantial negative impact on a number of companies

The current proposal for combination products in the Bill will also have a substantial negative impact on a number of Medicines Australia member companies. The sudden shift in the pricing of combination products proposed in the Bill will have substantial impacts on these companies and their operations. Because companies will not have built the new regime into their forward planning, the adverse impact of the proposed approach on those companies affected is likely to be significant.

Recommended solution

To ensure consistency with the Government's intended policy, Medicines Australia requests that single brand combination products be classified into the F1 formulary, and that movement of these combinations into the F2 formulary should only occur when there is a listing of a generic combination product. This would avoid a disincentive for companies to develop and list combination products in Australia. Consistent with the rest of the policy, when a second brand of that combination product is listed on the PBS, that product should then move into F2 and be subject to the normal price reduction mechanisms.

Recommendation 2

The Committee seek to amend the Bill for single brand combination products to be classified into the F1 formulary

b) Provisions relating to the application of patient premiums

Patient premiums

The PBS subsidises many medicines which are molecules or chemicals that have a therapeutic effect on patients. When a particular medicine goes off-patent, other suppliers may enter the market and supply additional brands of that same medicine to the PBS. The Government subsidises each brand of a medicine up to the cost of the lowest-priced brand of that medicine. Under the Government's policy, if the patient chooses a brand with a higher price, the patient pays the difference between the subsidised price and the higher-priced brand. This is called a 'brand premium' and is payable in addition to the patient co-payment. The existing policy ensures that patients will always have access to a brand of a medicine that is 'premium free'; that is, where the patient is only required to pay the standard co-payment. Thus patients always have the option of only paying their standard co-payment and no more.

The existing policy, which has successfully operated for years, allows companies to apply to the Minister for premium increases at any time. There are no legislative restrictions either on the size or timing of those premium changes. This is consistent with the general principle that while the Government may control the size of its own reimbursement price, there is no Government price setting controls in the private market.

Trends in brand premiums since 2000 are presented in Table 1 below. As at 30 June 2006 there were 345 products with a brand premium out of a total of approximately 2800 products[1]. The average brand premium is $2.76 with the weighted average brand premium being $1.76.

Since 2000, the proportion of prescriptions dispensed at the benchmark price, and therefore without a premium, has steadily increased from 44% to 63% by 2006. Moreover, the number of brands on the PBS at the premium-free benchmark price has more than doubled since 2000. This suggests that patients are increasingly preferring to use premium-free medicines, and this is encouraged by various Government policy initiatives.

[1] Pharmaceutical Benefits Pricing Authority 2006 *Annual Report*, p. 10.

Table 1: Brand premiums on the PBS

	2000	2001	2002	2003	2004	2005	2006
Number of products with a premium	253	297	293	315	323	335	345
Average brand premium	$2.12	$2.20	$2.83	$2.79	$2.85	$2.78	$2.76
Weighted average brand premium	$1.45	$1.68	$1.57	$1.73	$1.89	$1.77	$1.76
Brand premium range	$0.23 to $43.28	$0.01 to $45.33	$0.01 to $79.48	$0.01 to $79.48	$0.06 to $79.48	$0.06 to $79.48	$0.06 to $79.48
Prescriptions dispensed with a brand premium in the previous 12 months (million)	33.4	33.4	33.3	30.1	28.5	30.0	30.1
Prescriptions dispensed at the benchmark level in the previous 12 months (million)	26.3	29.4	32.6	39.7	43.1	50.5	51.9
Percentage at benchmark level	44	47	49	57	60	63	63
Brands at the benchmark price	434	766	854	953	979	996	1014

Source: Pharmaceutical Benefits Pricing Authority annual reports, 2002-03 to 2005-06.

When there are two or more different medicines within a therapeutic group on the PBS that have similar therapeutic effects, the Government provides a subsidy up to the cost of the least expensive medicine. If the patient is prescribed a higher-priced medicine within a therapeutic group, the patient pays the difference between the subsidised price and the higher priced medicine. This is called a 'therapeutic premium'.

Therapeutic group premiums (TGPs) range from $1.35 to $7.01 (Table 2). Since 2003, the number of items with a TGP has increased slightly from 60 to 75. A doctor can always seek a TGP exemption for a patient by obtaining a waiver from Medicare Australia.

Table 2: Therapeutic group premiums on the PBS

	2003	2004	2005	2006
Number of items with TGP	60	70	72	75
Average TGP	$4.09			
Premium range	$1.60 to $7.01	$0.64 to $7.01	$1.35 to $7.01	$1.35 to $7.01
Brands at benchmark price	176	172	139	n/a
Brands with brand premium	33	37	37	n/a
Items with therapeutic premium	14	11	9	9

Source: Pharmaceutical Benefits Pricing Authority annual reports, 2002-03 to 2005-06.

Special Patient Contributions (SPCs) are applied where there is a disagreement between the manufacturer and the Government over the dispensed price for a medicine. SPCs are normally paid by the consumer in addition to the relevant

patient co-payments. To date, there are only six medicines that have SPCs. A doctor can obtain an exemption from Medicare Australia for a patient to pay this contribution where there is no suitable alternative for the patient.

Proposal in the Bill

The Bill contains several provisions pertaining to mandatory reduction of premiums, and the prohibition of the introduction of, or changes to, premiums at the same time as mandatory price reductions are implemented. The Bill requires that patient premiums, namely brand premiums, therapeutic group premiums and other special patient contributions, be reduced by the same percentage as mandatory reductions in the Government's reimbursement price and other reductions arising from the price disclosure provisions. The Bill also prohibits companies changing their premiums on the day a mandatory price reduction occurs. The provisions dealing with the treatment of premiums relate to s.99ACE, s.99ACF and s.99ADH in the Bill.

Problems with the proposal

The proposed provisions to control patient premiums are a substantial, problematic issue for a number of reasons. The proposed changes to premium policy will be an impediment to achieving one of the key PBS reform objectives, namely more price competition in the off-patent market.

If the Bill is not amended, the resulting effects will be less incentive for patients to choose the lowest priced brand, reduced competition in the off-patent market, less incentive for companies to provide multiple brands of medicines, and a reduction in the commercial feasibility of having multiple suppliers in the market. This is inconsistent with the policy intent of the PBS reform proposal. This Bill also effectively moves the Government's role from controlling and determining its own reimbursed price to a new paradigm of controlling and determining the market price.

1. Government role in pricing

Medicines Australia considers it a significant issue that price control is being levied on medicines to an extent that has never before been part of Government policy and law under the PBS. While Government has sought to effectively control and manage its own reimbursed price, this Bill also effectively seeks to control the market price of a medicine. This carries concerns from a microeconomic perspective and creates legal issues which may themselves make these provisions subject to challenge. The measure essentially introduces government price-setting in the private market for medicines at a time when government measures to control prices in other private markets are being wound

back or abolished. This is a significant policy change and represents a shift towards Government price control in the private sector.

2. Impediment to competition in the off-patent market

Medicines Australia asserts that the proposed limitations on changes to premiums compromise one of the major foundations of the PBS reform package, namely the use of competition in the off-patent market to achieve lower prices.

One aspect of the Government brand price policy, which will continue unchanged in the future, is the choice patients have to avoid premiums. In situations where some brands of a medicine have a patient premium, the patient will always have the choice to buy a 'premium-free' medicine and thereby only pay the standard patient co-payment.

Patient premiums have been demonstrated to affect the uptake of 'premium-free' brands of a medicine, in that the higher the premium, the greater incentive the patient has for choosing premium-free brands. Medicines Australia does not consider restrictions on the application of premiums to be consistent with providing an incentive for premium-free brands to be used. Patients always have the freedom to decide whether they are prepared to pay more for a brand of a medicine with a premium or choose a brand with no premium. So, when companies charge or increase a premium for their brand of a medicine, they do so acknowledging the likely negative impact on volume. This is not a theoretical concept; current practice under the existing policy demonstrates that the shift to the benchmark product is accelerated by the application of a premium. Mandatory reductions in the size of premiums, as proposed in the Bill, will actually reduce the incentive for patients to switch to 'premium free' medicines.

Commercial viability and competition between a number of brands is also important for patients. Premiums provide incentives for companies to bring new brands of medicines to the PBS which in turn helps ensure that a medicine has a range of suppliers.

3. Increased regulatory complexity and burden for business and the Government

The provisions in the Bill represent an increase in regulatory burden on business and on the Government. The provisions exert a measure of control on the application of patient premiums that is not currently in place. Current policy is that companies can change premiums on the day of any reduction in the government reimbursement price and that premiums are not required to match reductions in the government reimbursement price. The proposed change therefore represents an increase in regulatory burden on companies. The Government will also have to cope with the burden of a much more complicated system of premiums, whereby premiums may reduce on one day when the mandatory reduction applies, followed by further changes in subsequent months.

The proposal to reduce premiums at the time of mandatory reductions is unilateral and compulsorily requires a reduction in premiums without reference to companies.

In addition, Medicines Australia is concerned about the prohibition of introduction of premiums at the same time as a new brand enters the market and triggers a statutory price reduction, often a 12.5% reduction. To date companies have been able to request the application of a patient premium, and Medicines Australia would not want the existing arrangements to be ruled out by the legislation.

4. No additional benefit for patients

The proposed arrangements for controlling changes in premiums will do little to help patients. Under the Government's brand premium policy, no patient is required to pay a brand premium if they so choose because there will always be a premium-free medicine where the patient only has to pay a co-payment. This policy will not change with the Bill.

This means that patients already have the freedom to decide for themselves whether to pay a premium for a particular brand of a medicine or have a brand dispensed with no premium. No patient, either under the current system or under the new policy, will need to pay more for their medicines than the standard co-payment if they so choose.

Two initiatives in the PBS reform policy will help ensure that patients are aware that they do not need to pay any more than the standard co-payment for a medicine if they so choose. As part of the PBS reform policy, the Government has announced that it will be spending $20 million on a generic awareness campaign designed to increase consumer awareness about the option they have to have a premium-free medicine. The policy also contains a $1.50 incentive paid to pharmacists for every prescription they fill with a product that is a premium-free product at the benchmark price. Both of these initiatives will accelerate patients' shift to premium-free benchmark priced products that has already been occurring since 2000.

5. Patients will save money from PBS reform

One outcome of the PBS reform policy is that the price of many medicines will fall, and in many cases this price will fall below the general co-payment level. This will mean that patients, particularly general patients, will save significant amounts of money because they will pay less than the co-payment for their medicines. For example, the Pharmacy Guild of Australia has estimated that patients will save money as a result of price reductions in around 430 medicines, equating to approximately 1500 brands, initiated by the PBS reform policy.

As the price of medicines falls below the co-payment level, patients will see increased savings and lower spending on medicines. Medicines Australia,

utilising modelling developed in collaboration with the National Centre for Social and Economic Modelling (NATSEM), estimates that concessional patients, those PBS patients with concession cards, will be no worse off under the Government's PBS reform proposal and will not have to pay any additional costs for their PBS medicines. The same estimates indicate that general patients, those patients without a concession card, will save between 10% to 11% per year in the spending on medicines as a result of the PBS reform proposal by 2012-13. This translates to a saving for working families with general patients (ie. families where no family member has a concession card) of around $50 a year.

6. Questionable constitutional validity

The proposal for statutory price reductions in relation to premiums will introduce a statutory obligation to sell brands of pharmaceutical items to which a premium applies under an arbitrary system of price control without reference to just terms. In effect, sponsors (responsible persons) will be required to sell brands of pharmaceutical items to which a premium applies at reduced prices by reference to random percentage reductions to be imposed on set dates as specified in the legislation.

The existing premiums policy means that pharmaceutical items for which there are bioequivalent substitutes can be priced according to the competitive constraints imposed by the market. The so-called "premium" is nothing more than the price that the competitive market will bear from time to time.

For example, when a statutory price reduction will apply to the determined price, it would impose an artificial (and unfair) burden on the sponsor, and distortion in the market, applied arbitrarily to premiums in a competitive market environment.

Recommended solution

To ensure consistency with the Government's intentions for PBS reform, Medicines Australia seeks the removal of the legislative provisions related to premiums.

Medicines Australia does <u>not</u> support measures to regulate the operation of premiums. It requests that the current policy which operates today with regard to patient premiums continue.

Patient safeguards, namely that there will always be a premium-free medicine available and doctors' ability to seek a premium waiver from Medicare Australia, will still be in place. It means that companies would continue to have the freedom to change their premiums on the day of price reductions and premiums would not be reduced by virtue of there being a mandatory cut.

Allowing the existing arrangements to continue will complement the shift to a more competitive generics market, preserve patient choice, and avoid a more complex and burdensome regulatory environment.

Recommendation 3

The Committee seek to amend the Bill so that the existing practice for managing patient premiums be maintained (i.e. proposed provisions for premiums not be introduced).

4. Biologicals

Biopharmaceutical products (biologics) have unique characteristics because of their high molecular weights, their complex three-dimensional structures, the complexity of their manufacturing processes by living organisms and the dependence of biological activity on reproducibility of the production process, thereby ensuring patient safety. Due to the complexities inherent in the manufacture of biotechnology products, the relatively simple processes governing approval of generic small molecule drugs are inadequate for the approval of biosimilars. The TGA has adopted European (EMEA) Guidelines for the evaluation of similar biological medicinal products.

There is no agreed definition of the term "biosimilar" and it has not been explicitly defined with the proposed PBS reforms. When the TGA registers a biosimilar product, although this is unlikely to be "interchangeable" with the innovator, registration implies that the product is similarly safe and effective compared to the innovator biological product.

Medicines Australia accepts that such registration may be used as a trigger for the cost savings identified in the PBS reform legislation. However, such cost savings must only be applied to the biosimilar and the reference innovator product. It is critical that the goals and outcomes of the PBS reform align with those of the TGA. This can be achieved, with subsequent cost savings, by ensuring that the appropriate regulatory body, the TGA, decides when sufficient evidence has been presented to achieve the above. Care must be taken when introducing any legislation for reimbursement to ensure that the rules and outcomes intended for the reimbursement legislation align with those of the regulatory process.

While the Government has already proposed sensible amendments to the legislation with regard to biosimilars, Medicines Australia believes there is need for further dialogue between the industry and Government to ensure the legislation implements the intent of the Government's reforms with respect to biosimilars and ensure consistency with TGA regulatory processes, by the

inclusion of a deeming provision in the regulations that would make the above clear.

Appendix : Medicines Australia and the Australian pharmaceuticals industry

Medicines Australia currently represents 46 research based pharmaceutical companies that discover, develop and manufacture prescription medicines in Australia. Our members are largely originator pharmaceutical companies that supply, create, develop, manufacture and export both innovative, patented medicines as well as originator brands of off-patent medicines.

Medicines save lives, reduce and cure disease and save Federal and State government expenditure on more expensive treatments such as surgery, hospitalisation and the need for increased aged or institutional care.

They also reduce workplace absenteeism, increase workplace participation and productivity – all of which are essential stimulants to the economy.

The latest independent research shows that it now costs more than $1.2 billion to bring a new medicine on the 12–15 year journey from discovery to market. Only five of every 10,000 medicines investigated are tested in clinical trials. Of those five, only one is ever approved for patient use.

Our companies directly employ 15 000 people in Australia[2]. They indirectly employ 36,000 people across at least 300 firms and institutions, including manufacturing, research and wholesaling.

Our companies have a collective turnover of approximately $7.8 billion.

The Australian pharmaceutical industry represents 1% of the global pharmaceutical market.[3]

Yet we are one of the biggest exporters of elaborately transformed manufactured goods from Australia. In 2006, Australian medicinal and pharmaceutical manufacturing exports totalled $3.5 billion[4], more than the wine industry. Our industry is a key contributor to Australia's manufacturing export performance and there is potential to grow Australia's global contribution.

The pharmaceutical industry is one of Australia's major knowledge-intensive industries and is a key investor in biomedical R&D. In 2006, the pharmaceutical industry invested $456 million in R&D in Australia. This represents 5.4% of total

[2] Australian Bureau of Statistics, 2006. Catalogue number 8221.0, *Manufacturing Industry*.
[3] IMS Health, 2007.
[4] Australian Bureau of Statistics, 2007. Unpublished data.

Australian business expenditure on R&D.[5] Our industry is the largest employer of science graduates outside the government funded sector.

A survey of Medicines Australia members in 2005 found that

- 80 per cent of Medicines Australia members conduct R&D in Australia
- 30 per cent of member companies' own R&D was contracted out to or in collaboration with hospitals, public research agencies, universities and other private research companies
- 54 per cent of R&D conducted on behalf of others (almost all of whom were foreign affiliates of member companies) was contracted to or in collaboration with academia or medical research institutes.

Pharmaceutical companies are constantly working on bringing new effective medicines to patients. Globally there are over 1,000 new medicines in clinical trials for Alzheimer's disease, stroke, cystic fibrosis, arthritis and many other diseases. For cancer alone, there are almost 400 medicines under development.

Over the last decade, over 300 medicines have been made available globally to treat various diseases.

On average, only three out of ten medicines will recoup their R&D cost of development, clinical trials, registration and marketing. With such high R&D costs, patent and intellectual property protection has become a major issue for the pharmaceutical industry.

Member companies of Medicines Australia are committed to the four elements of the National Medicines policy:

- Timely access to medicines
- Safe and efficacious medicines
- Quality use of medicines, and
- A viable and responsible industry.

Whilst the Australian public sector has seen an increase in its expenditure on pharmaceuticals, this level is not high relative to other OECD countries and is below the OECD average. In fact, Australia's level of spending as a share of the economy is only now equivalent to the OECD average of ten years earlier.

Innovative/patented medicines accounted for around 39 per cent of the total $6.8 billion budget of the PBS in 2004-05. Off-patent originator brands represented 24% of total PBS expenditure in 2004-05.

[5] Australian Bureau of Statistics, 2006. Catalogue number 8104.0, *Research and Experimental Development, Businesses.*

Our industry views the PBS as an investment, not a cost. Our industry supports evolution and reform of the PBS to ensure its transparency and long-term sustainability.

Medicines Australia believes the Government's PBS reform package will:

- Ensure access to best medicines for Australians
- Sustain the PBS, and
- Secure Australian jobs and investment.

Medicines Australia is committed to working in partnership with government to ensure sustainable health and a sustainable industry for the benefit of all Australians.