Submission to the Senate Finance and Public Administration References Committee Inquiry into the Government's administration of the Pharmaceutical Benefits Scheme (PBS)

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Executive Summary

Australia's Pharmaceutical Benefits Scheme (PBS) facilitates access to prescription medicines by subsidising their costs, reflecting the premise that cost should not constitute a substantial access barrier to the medicines people need. The purpose of the listing process is to ensure value for money. It is not intended as a mechanism for cost containment.

Making all recommended medicines available to Australians on the PBS produces economy wide benefits, such as reduced mortality and incidence of disease, which eventually flows through to Government revenues and expenditure.

To meet the objective of providing equal and universal access to medicines that will achieve optimal health and economic outcomes, the Australian Government adopts a monopsony purchaser role. Not listing medicines that have been proven to meet the required criteria undermines the access objective while also creating a distorted, uncompetitive and inefficient 'market'.

The consequences of this market distortion impacts individual patients, the health system, the pharmaceutical industry and the economy as a whole. Treatment and prescribing decisions for patients should remain with clinicians, not Cabinet. To do otherwise undermines the fundamental objective of the PBS to achieve optimal health and economic outcomes.

The abandonment of the $10 million threshold at which Cabinet approval is required is inefficient, introducing further delay and expense to Government for medicines that are low cost in addition to being cost effective. It also politicises the listing process for medicines that are inexpensive and have not been subject to this level of political consideration previously.

In 2010 the pharmaceutical industry, through Medicines Australia, negotiated the first formal agreement with the Commonwealth in a Memorandum of Understanding (MoU), to provide a good framework for managing the PBS over the next three years. The unprecedented decision to defer PBS listing of recommended medicines has introduced uncertainty, delays, inefficiency and inequality to the listing process.

The uncertainty and unpredictability of when our medicines might be listed makes it very difficult for GSK to plan manufacturing production to meet stock requirements, recruitment and training of new staff and investments in other local activities such as post marketing clinical research or medical education. Increased uncertainty about the eventual use of a medicine in Australia will also make it increasingly difficult for us to secure local sites as part of global phase II and phase III clinical trials.

We recognise the Government faces difficult financial and budget decisions, especially during this current tight fiscal environment. However, we also firmly believe that Governments should avoid introducing practices that undermine a program's ability to deliver on its public policy objectives.

We respectfully submit that deferring the PBS listing of medicines recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) is not consistent with the objectives of the National Medicines Policy. Nor is it consistent with the stated intent of the MoU endorsed by Cabinet last year.

We believe that the current listing processes and conventions are already robust enough to produce the best value possible for taxpayers. Risk sharing in particular is another way that industry provides Government with budget certainty, by agreeing to provide rebates to the Government if a spending or patient cap is breached.

Indeed, it is difficult to name any other program across Government that can lay claim to equivalent rigour in assessing the economic value of government expenditure or where an equivalent level of program overspending risk is borne by the private sector.

For these reasons GSK firmly believes that Government should find any necessary budget savings from other less cost effective, less evidence based areas of Government spending.

The Government's 2010 Intergenerational Report demonstrates that the PBS is on a sustainable footing and should have the capacity to provide new medicines to Australians now and in the future.

A financially sustainable PBS is not just in the long term interests of Australian patients and taxpayers; it is in the long term interests of the pharmaceutical industry. GSK and the innovative pharmaceutical industry through Medicines Australia, take seriously our role, with Government, as co-stewards of the PBS.

The collaborative PBS data tracking and horizon scanning explicitly created by the MoU should continue and is far more likely to produce good social and economic policy outcomes than deferring listings. Deferrals are a blunt instrument in an already efficient program, and while they may deliver some short term savings, are likely to create more expense over the longer term.

GSK hopes that Government will reverse the short sighted decision to defer PBS listing of cost effective medicines as soon as possible. Continuing deviation from the past practice of listing all medicines meeting strict cost effectiveness criteria fundamentally changes the nature and purpose of the PBS. We strongly believe that it is unacceptable and unnecessary for Cabinet to unilaterally alter the PBS in this way.

Therefore we recommend that Government:

- overturn its previous decisions to defer the PBS listing of recommended medicines and move to facilitate the listing of medicines subject to deferral as soon as possible;
- ensure the PBS can properly fulfil its objective of providing access to cost effective medicines by observing long standing past practice of listing medicines recommended by the PBAC; and
- honour the intent of the MoU and continue to collaborate with industry to establish an agreed, factual basis for ongoing policy discussions concerning the sustainability of the PBS.

About GlaxoSmithKline Australia

GlaxoSmithKline (GSK) is a research-based pharmaceutical and healthcare company operating in more than 100 countries around the world. Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

Here in Australia we have a proud history dating back to 1886. Since then we have improved the wellbeing of Australians by delivering the highest quality medicines, vaccines and over-the-counter healthcare products. Our contribution to the Australian economy continues to grow in-line with our success and we know how important it is to have the right operating environment to thrive. Over the years we have built a strong and diverse business which now produces a quarter of the nation's $4.12 billion pharmaceutical and medicinal exports and provides around 1600 high skilled jobs.

Our medicines treat major disease areas such as asthma, virus control, infections, mental health, and diabetes, and we are pioneering new treatments for complex diseases like cancer. Our vaccines protect millions of Australians and we are the largest supplier of childhood vaccines to the National Immunisation Program (NIP). And yet, developing medicines has never been more challenging: it can take over 15 years and billions of dollars to bring just one successful product to market from thousands of potentials.

We are driven by a commitment to advance medicine. We invest around $56 million a year in local research and development, making us one of Australia's top 15 investors. Our scientists work with Australian researchers and doctors to discover new ways of treating and preventing disease. We currently have over 30 discovery projects underway and our Medicines Research Unit is the only Phase I facility supported by a pharmaceutical company in Australia.

The pharmaceutical sector in Australia and our relationship with Government is quite unique among Australian industries. The majority of our products – the medicines and vaccines Australians need to prevent and treat disease, stay healthy and productive – are not accessed by consumers in a free market. The majority of our medicines are purchased by the Government on behalf of the community, to be prescribed by health professionals, with patients making a modest contribution to the cost through the copayment.

Unlike other industries or businesses that set the price for their products by a traditional formula combining of cost of goods, market value and desired returns, GSK has our Australian prices determined by the value of the health outcomes our medicines produce.

This submission is being made on behalf of GSK Australia because the deferral of medicines recommended by the PBAC greatly concerns us. The PBS is a critically important component of Australia's healthcare system. Because it is the way the majority of our products are purchased, it is also a critical component of our ability to sustain a viable business in Australia.

On 25 February 2011, in her announcement of 52 new listings to the PBS, the Minister for Health and Ageing, the Hon Nicola Roxon MP also announced that Cabinet had deferred listings of seven new medicines and vaccines. This included GSK's combination therapy, *Duodart* (dutasteride/tamsulosin hydrochloride) for treatment of Benign Prostatic Hyperplasia (BPH).

While one component of *Duodart* is PBS listed, the other component is only available on the RPBS to veterans and their families. This made understanding how doctors would use *Duodart* and the impact across multiple Government programs more complex.

Following the February announcement GSK undertook discussions with Government to better establish how *Duodart* would be used by doctors and patients. It was agreed that there were immediate and long term benefits to patients and taxpayers by listing *Duodart* on the PBS. *Duodart* is expected to produce an overall saving to the budget.

On 21 June, Minister Roxon, announced the listing of 13 new therapies including three GSK products - *Duodart*, *Revolade* and *Fluarix*. However, the Minister also announced that the listing of GSK combination measles, mumps, rubella, varicella (MMRV) vaccine, *Priorix-Tetra* on the NIP has been deferred.

GSK has a strong and broad pipeline of potential new medicines with the potential to deliver more value to patients and taxpayers. We are very concerned that deferring the listing of new medicines on the PBS will lead to Australian patients being unfairly treated and not having access to the benefits of the latest treatments.

While troubled by the direct impact on our business, we are even more concerned about the potential for the very purpose and foundation of the PBS to be seriously undermined, to the detriment of patients, the health system and industry.

The Pharmaceutical Benefits Scheme and its objectives

Australia's PBS has evolved into a taxation-based, risk-pooled social welfare policy designed to provide universal access to medicines. The PBS operates under the umbrella of Australia's National Medicines Policy, which has as its overall aim "to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved."[1]

The PBS facilitates access to prescription medicines by subsidising their costs, reflecting the premise that cost should not constitute a substantial access barrier to the medicines people need. Today the PBS provides timely, reliable and affordable access to necessary medicines for Australians.

Recognising that subsidies are not costless to society, rather the costs are borne by the community as a whole, the National Medicines Policy also recognises that access should be supported by rational use of medicines.

Prescription medicines are assessed by an independent, expert committee called the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC evaluates the incremental cost effectiveness (including quality adjusted life years) of the medicine compared with other treatments it could replace. The PBAC must take into account the effectiveness and the cost of a medicine compared with other medicines or non-medical treatments such as surgery.

This means that to be approved or recommended by the PBAC, it has been demonstrated that the cost of funding the medicine is outweighed by the health and economic benefits its use will produce. Such benefits may include improvements in the extension of life, the quality of life, savings to other areas of the heath sector or other government programs such as hospital care.

In essence, the process can be thought of conceptually as one of 'purchasing outcomes' rather than products, because unless a new medicine offers an additional clinical benefit (an improved outcome) relative to current alternatives, it will not be listed at a higher price (i.e., receive a higher subsidy).

[1] Department of Health and Ageing, *National Medicines Policy, 2000* (Canberra: Commonwealth Department of Health and Ageing, 1999

The PBS has proven itself to be one of the best drug subsidy systems in the world and around 80 per cent of prescriptions dispensed in Australia are subsidised under the scheme.[2] The PBAC evaluation processes are evidence-based, scientifically rigorous, and methodologically current. Few other Government programs are subject to such rigorous assessment of return on investment and value for money.

Importantly, PBS processes are intended to ensure value for money whilst supporting affordable, equitable access to prescription medicines for all Australians. The PBS and its processes are **not** intended as a mechanism for cost containment.[3]

An investment in Australia's health and wealth

Making all recommended medicines available to Australians on the PBS produces economy wide benefits, such as reduced mortality and incidence of disease, that eventually flow through to Government revenues and expenditure in the form of lower treatment costs, increased labour force participation and productivity, personal income and tax levels, reduced welfare benefits and higher GDP.

The value of the health outcomes medicines produce has been significant. Australia has the second longest life expectancy in the world at 81.4 years. It has been estimated that roughly two thirds of the increase in life expectancy from 1995 to 2004 was due to new medicines introduced during this time.[4]

Advances in medicines and vaccines have contributed to the dramatic decline in deaths from infectious diseases. Vaccines, in which GSK is a world leader, are widely acknowledged as the most cost effective health intervention in history after clean drinking water. In Australia vaccines are responsible for low rates of many infectious diseases that were once common, including polio, measles, diphtheria, whooping cough, rubella, mumps, tetanus and haemophilus influenzae type b.[5]

HIV/AIDS, another disease area in which we pioneered treatment, is no longer an automatic death sentence but a chronic condition that can be managed through medication. Deaths due to AIDS have dropped dramatically and the number of AIDS notifications has declined despite the steady number of new HIV cases, reflecting the effectiveness of the antiviral medications to combat HIV.[6]

Major gains have also been made in the fight against cardiovascular disease (CVD). A 76 per cent fall in CVD deaths in just over 40 years (1968-2007) is partly due to improved medicines.[7]

Medicines also help increase our productivity. Over a million Australians use GSK asthma relief and prevention products. Since the late 1980s, the asthma mortality rate has fallen by about 70 per cent. In particular there has been a substantial decline in deaths attributed to asthma in 5–34 year olds, where the death rates have fallen by more than 85 per cent. In addition, the number of days asthma patients have spent in hospital have nearly halved.[8]

[2] Australian Institute of Health and Welfare 2010. *Australia's health 2010*. series12 Canberra: AIHW p393
[3] Department of Health and Ageing 2006, *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.1)*, Commonwealth of Australia, Canberra, December 2006
[4] Lichtenberg,F, Pharmaceutical innovation and the longevity of Australians: A first look, 2007
[5] Australian Institute of Health and Welfare 2010. *Australia's health 2010*. series12 Canberra: AIHW pp205-209
[6] Australian Institute of Health and Welfare 2010. *Australia's health 2010*. series12 Canberra: AIHW p214
[7] Australian Institute of Health and Welfare 2010. *Australia's health 2010*. series12 Canberra: AIHW p141
[8] Australian Institute of Health and Welfare 2010. *Australia's health 2010*. series12 Canberra: AIHW pp183-185

Sustainability through partnership between Government and Industry

In 2010 the Federal Government negotiated the first formal agreement with the pharmaceutical industry, through the Memorandum of Understanding (MoU) with Medicines Australia.

As the Minister for Health and Ageing said in her Second Reading speech in the Parliament when introducing the MoU last year on behalf of the Government:

> "The bill also embodies an historic level of cooperation and collaboration between the government and the pharmaceutical industry, represented by Medicines Australia. Through jointly negotiating these reforms, the government and the industry will help ensure the sustainability of the PBS in years to come.
>
> The bill sets out new PBS pricing arrangements aimed at reducing growth in PBS expenditure, ensuring access to quality medicines at a lower cost to the taxpayer, and providing certainty to the pharmaceutical industry in relation to PBS pricing policy".[9]

In addition to securing budget savings and ensuring the long term sustainability of the PBS, another objective of the MoU was to address the often lengthy delays in access to new medicines caused by the Cabinet review process. For example, prior to the MoU, patient access to important medicines such as *Sutent* for renal cell carcinoma (kidney cancer) was delayed by 10 months; *Avastin* for advanced bowel cancer, delayed by 12 months; and *Revlimid* for multiple myeloma delayed by 13 months, due to the requirement for Cabinet review and approval.

The intention of the MoU was to reduce the time to PBS listing for those medicines for which Cabinet approval is required. This is reflected in section 29 which commits the Commonwealth to use its best endeavours to implement a maximum timeframe of six months for consideration and decision by Cabinet.

The possibility of achieving a stable and predictable business and policy environment for the industry was central to Medicines Australia's decision to negotiate and sign such an agreement with the Australian Government. In return for delivering a minimum of $1.9 billion in savings to the PBS for the Australian Government, Medicines Australia believed in good faith that the Australian Government would abide by its explicit recognition of the need for such stability.

Over a quarter of GSK's business is in off-patent/generic medicines and we have a number of products coming off-patent in the coming years. This means the savings measures delivered through the MoU will reduce our revenue and create a more difficult operating environment. Despite this, GSK strongly supported the MoU and General Manager Deborah Waterhouse gave evidence in support of its enabling legislation to the Senate Community Affairs Legislation Committee Inquiry into the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*:

> "If this legislation goes through, for us that means going from being a growing business over the next two or three years to actually being a business whose revenue does not grow. We, like other MA members, will therefore be directly affected by the proposed price cuts and price disclosure rules.
>
> But the crucial factor for us and why we strongly support the legislation is that the certainty of the savings allows us to plan appropriately. We have already factored them into our budgets and business plans for the next two or three years.

[9] The Hon Nicola Roxon MP, Minister for Health and Ageing, Second Reading Speech *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*, House of Representatives, 29 September 2010

> Without the legislation that you are considering, the business environment becomes much more uncertain for us to manage. I will give you an example. We are currently putting a proposal to our organisation for significant investment in our Boronia site in the east of Melbourne.
>
> The proposed MOU and all that goes with it is a very, very strong reason why, given the certainty it would give us, Australia remains a very good place to invest. There will not be any ad hoc surprises or things that come up that we were not expecting which will knock the company off course. It is really helpful in building a stronger organisation within Australia to have that level of certainty".[10]

Just three months after providing this evidence on the importance of certainty to our business, the unprecedented decision to defer PBS listing of recommended medicines has introduced uncertainty, delays, inefficiency and inequality to the listing process.

Deferral of recommended listings undermines the purpose of the PBS

This Government is the first to defer PBS listing for medicines that have been thoroughly evaluated and recommended by the PBAC.

In response to a question on notice from the Hon Peter Dutton MP, the Minister for Health and Ageing stated that the decision to approve or defer the listing of medicines was based upon consideration of advice

> "provided by the PBAC in relation to the clinical need for each medicine or vaccine, including whether alternative treatment options exist, and whether there were comparable listings in the past three years".[11]

Using the existence of alternative treatment options as a basis to defer listing medicines on the PBS ignores the fact that each of the deferred medicines has been found by the PBAC to meet a demonstrated clinical need in the Australian community. Further, each was priced to reflect demonstrated value for money to the Australian taxpayer based on the health outcomes that would be purchased through public subsidy.

Like many areas of science and technology, advances in medicines occur at different stages and paces. While major breakthroughs do occur through major new scientific discoveries such as new molecules or gene regulation, many major improvements are achieved incrementally, where improvements in compounds build incrementally on previous compounds in the same therapeutic area.

Advances in cancer treatment are an example of how these incremental improvements lead to significant benefits over time. Individually many new cancer medicines have incrementally added benefit by extending a cancer patient's life by a matter of weeks or months. As each individual cancer medicine has been an incremental step forward in treatment, collectively the development in technology has significantly extended the life expectancy for cancer patients. Between 1988 and 2000, the average life expectancy for cancer patients increased by around four years, largely due to the availability of new treatments, with substantial social and productivity benefits.[12]

[10] Deborah Waterhouse, Tuesday, 9 November 2010 Community Affairs Legislation Committee Reference: *National Health Amendment (Pharmaceutical Benefits Scheme) Bill* 2010 Hansard p20

[11] Answer to Q 279 in writing, on 3 March 2011, House of Representatives Hansard 25 May 2011, p175

[12] Lakdawalla, D et al 2010. "An economic evaluation of the war on cancer", *Journal of Health Economics* (29) p333

The OECD has acknowledged:

> The value of incremental innovation depends on the extent to which it is evolutionary rather than duplicative. New products can offer significant advances in terms of improved efficacy, fewer adverse side effects, greater patient satisfaction (as tailoring to the individual as possible), better compliance and sometimes even increased cost-effectiveness.[13]

Different medicines, even those used to treat the same disease, work differently for different patients. Even medicines within the same therapeutic class can have differing effects at an individual patient level that can be as stark as the difference between treatment and no treatment. The first medicine in any therapeutic class to successfully enter the market and achieve listing on the PBS is not necessarily the best and it is essential that clinicians have access to a range of treatment choices where these exist and are proven to meet the cost effectiveness criteria for listing on the PBS.

To meet the objective of providing equal and universal access to medicines that will achieve optimal health and economic outcomes, the Australian Government adopts a monopsony purchaser role through the PBS. Not listing medicines that have been proven to meet the required criteria undermines the access objective while also creating a distorted, uncompetitive and inefficient 'market'.

The consequences of this market distortion impacts individual patients, the health system, the pharmaceutical industry and the economy as a whole.

While the PBS does not constitute a clinical guideline, by ensuring that the cost of medicines is not a substantial barrier it does play a role in facilitating optimal clinical practice. Therefore, the deferral of PBS listing for medicines is a barrier to healthcare and reduces the capacity of treating clinicians to make the best treatment choice for their patients. Instead of making a decision based on the clinical requirements of the patient, a doctor must also make a prescribing decision that takes into consideration the affordability of a medicine for that patient.

Continuing deferral of PBS listing for medicines transfers an increased proportion of the costs of important medicines from the Government to the patient. This will force some patients to make difficult choices about their medical care according to their capacity to pay. For some patients there is no alternative treatment or the alternative is not as clinically or cost effective and will compromise their health outcome.

Australians are entitled to believe that they already contribute through the tax system to a risk pooled scheme to cover the medicines they need, provided those medicines are cost effective. Patients denied PBS access to such cost effective medicines because they have been deferred, who choose to pay the full cost themselves, will in effect be paying twice for their medicine.

The facts demonstrate that Australian patients will be adversely affected by the decision to defer some medicines despite a belief by Government that alternative treatments are available. The practice of deferral also sets a dangerous precedent, with the Federal Cabinet now effectively involving itself in clinical decisions and deciding which medicines are required and which are not. As former health policy advisers to Prime Minister Julia Gillard, Lesley Russell, now a research associate at the Menzies Centre for Health and Silvana Anthony noted:

[13] Organisation for Economic Cooperation and Development. 2008. *Pharmaceutical Pricing Policies in a Global Market*. Paris, p56.

> "On what basis will Cabinet now decide which drugs are listed on the PBS – lobbying pressures, cost (as opposed to cost-effectiveness), or their own scientific and medical backgrounds?"[14]

Treatment and prescribing decisions for patients should remain with clinicians, not Cabinet. To do otherwise undermines the fundamental objective of the PBS to achieve optimal health and economic outcomes.

Delays in access to the best, most cost effective medicines will mean longer periods of debilitating illness for patients, time off work, increased use of other health services and, in some cases, could be life threatening. If they continue, the impacts will flow through to the wider economy through decreased workforce participation, increasing welfare payments, increasing health and hospital costs.

New practice for Cabinet consideration is inefficient

The abandonment of the $10 million threshold at which Cabinet approval is required is inefficient, introduces further delay and expense to Government for medicines that are low cost in addition to being cost effective.

In fact the Productivity Commission recommended the Government consider measures to ensure fewer medicines require Cabinet consideration in its *2008 Annual Review of Regulatory Burden on Business: Manufacturing and Distributive Trade:*

> The Government should consider the merits of increasing the threshold to account for price changes over the past six years and implementing an automatic annual indexation adjustment.[15]

The Productivity Commission advice was recently endorsed by the Senate Community Affairs References Committee who made unanimous recommendations to lift the $10 million threshold in the interest of providing more timely access to medicines.[16]

The new requirement for Cabinet to review and approve all PBS listings involving a financial impact, no matter how small, unnecessarily delays patient access to medicines. It also politicises the listing process for medicines that, at less than 1 per cent of overall PBS spend, are inexpensive and have not been subject to this level of political consideration previously. Patient groups will now need to take a more active role in lobbying their local politicians for the medicines they need.

The impact on the pharmaceutical industry

As we have noted elsewhere in our submission, the unprecedented decisions to defer PBS listing of recommended medicines and to require Cabinet review of even low cost medicines has introduced uncertainty, delays, inefficiency and inequality to the listing process.

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[14] *The Weekend Australian Financial Review*, 'Labor takes a wrong turn with PBS changes' 9-10 April 2011, p63

[15] Productivity Commission (2008) *Annual Review of Regulatory Burden: Manufacturing and Distributive Trades* p80

[16] After considering the relative costs and benefits of adjusting the threshold, the Committee unanimously recommended that, in the interest of Australian patients having timely access to necessary medicines:

- the threshold for Cabinet consideration of high cost medicines be adjusted, initially to the value the threshold would have had, had it been indexed annually since 2001;
- subsequently, the threshold should be indexed annually; and
- the Department of Health and Ageing examine the most appropriate indicator for indexing the threshold.

Senate Community Affairs References Committee, Inquiry into Consumer Access to Pharmaceutical Benefits Report, November 2010, p ix

This undermines the stability and predictability GSK and other companies need to be able to set our budgets and determine where and when to make the investments in stock, workforce and other activities that support a medicines' PBS listing.

For example, to meet the Government's own listing requirements, we need to purchase and warehouse sufficient stock to ensure the medicine is available to those who need it. On top of this we also need to invest in medical education programs, employ extra representatives and medical staff to support healthcare professionals to use a new medicine safely and effectively. Not having the confidence to make these investments in the lead up to an expected listing can lead to even further delays in medicine access for patients.

The uncertainty and unpredictability of when our medicines might be listed, even after achieving a positive PBAC recommendation, makes it very difficult to plan manufacturing production to meet stock requirements, recruitment and training of new staff and investments in other local activities such as post marketing clinical research or medical education.

Further, the effect of this uncertainty is not limited only to the introduction of new medicines. GSK Australia must compete with other GSK local operating companies for a share of the global investments in early phase clinical trials. Many emerging markets are increasing their capability for high quality clinical research and offering financial or market access incentives to attract investment. Increased uncertainty about the eventual use of a medicine in Australia will make it increasingly difficult for us to secure local sites as part of global phase II and phase III clinical trials.

Promoting best practice public policy as well as economic responsibility

As a business that must also ensure our budget adds up, making sometimes difficult financial decisions to achieve this, GSK appreciates the Government's prerogative to make spending decisions.

However, we also firmly believe that Governments should avoid introducing practices that serve to undermine a program's ability to deliver on its public policy objectives. We believe that deferring the PBS listing of medicines recommended by the PBAC is not consistent with the objectives of the National Medicines Policy - that access processes are made as simple and streamlined as possible, so that subsidisation of medicines is timely, mechanisms are understood, and unnecessary administrative barriers and expenses are avoided. Nor is it consistent with the stated intent of the MoU, signed by Minister Roxon and endorsed by the whole Cabinet last year.

Further, we believe that the current listing processes and conventions are already robust enough to produce the best value possible for taxpayers.

After a medicine is scrutinised by a health technology assessment process widely recognised as one of the most rigorous in the world (the PBAC) and found to be cost effective, there are still many other checks and balances to guard against inefficient spending and over utilisation or 'leakage'.

For example, a company must still negotiate a final price with the Pharmaceutical Benefits Pricing Authority (PBPA). The objective of the PBPA is to secure a reliable supply of drugs supplied under the PBS at the most reasonable cost to Australian taxpayers and consumers. The authority fulfils its objective by recommending prices for new medicines recommended for listing by the PBAC. While these prices do not exceed the cost effective price established by the PBAC, the final negotiated price is often below the cost effective price.

Commonly there can also be restrictions on prescribing a medicine, the particular patients it will be subsidised for, such as only those who show a treatment response, as well as risk sharing agreements between pharmaceutical companies and Government.

Risk sharing in particular is another way that industry provides Government with budget certainty by agreeing to provide rebates to the Government if a spending or patient cap is breached. In this way, the Government pays only the acceptable value for the health outcome and significantly shifts the risk of over utilisation to manufacturers.

Indeed, it is difficult to name any other program across Government that can lay claim to equivalent rigour in assessing the economic value of government expenditure or where an equivalent level of program overspending risk is borne by the private sector.

For these reasons GSK firmly believes that Government should find any necessary budget savings from other less cost effective, less evidence based areas of Government spending.

While it is not for GSK to identify savings outside the PBS, we respectfully submit that Parliament should facilitate efficient Government spending and appropriate budget savings where possible.

The PBS is sustainable

The PBS is sustainable and should have the capacity to provide new medicines to Australians now and in the future. Ensuring the sustainability of the PBS rightly has bi-partisan political support. Both major political parties have undertaken significant reform to the PBS at different times, and in both instances had the cooperation and support of industry through Medicines Australia.

These reforms are delivering savings to the federal budget. The $1.9 billion savings guaranteed by the MoU, an average saving of around $400 million a year, are the minimum which will be delivered.

The Government's 2010 Intergenerational Report demonstrates that the PBS is on a sustainable footing, revising down the projected increases in PBS spending from the 2007 Intergenerational Report. For example the 2007 Report projected real spending per person to reach $720 in 2019-20.[17]

The 2010 Report projects that real spending per person on the PBS will now only reach $500 in 2019-20, over $200 per person less than projected in 2007. It also projects PBS spending as a percentage of GDP will remain stable at 0.7 per cent until 2019-20.[18]

Collaboration should continue

A financially sustainable PBS is not just in the long term interests of Australian patients and taxpayers; it is in the long term interests of the pharmaceutical industry. GSK and the innovative pharmaceutical industry through Medicines Australia, take seriously our role, with Government, as co-stewards of the PBS.

[17] Appendix D IGR 2010 Table D.4: Projections of major components of Australian government spending in IGR 2007 (real spending per person 2009–10 dollars) p157

[18] Appendix A: IGR 2010 projections summary, Table A3: Projections of major components of Australian government spending in IGR 2010 (per cent of GDP) pg118 and Table A4: Projections of major components of Australian government spending in IGR 2010 (real spending per person, 2009–10 dollars) p119

The MoU explicitly provides for collaborative PBS data tracking and horizon scanning in clause 7 which states:

> Both parties undertake to jointly monitor trends in, and the drivers of, PBS expenditure through the Access to Medicines Working Group (AMWG), which will also develop a framework for this purpose. This will commence not later than 1 January 2011. The Commonwealth agrees to share with Medicines Australia, without cost, the information and analyses required to achieve this.

The intention of this clause was to establish an agreed, factual basis for ongoing policy discussions concerning the sustainability of the PBS. The first joint monitoring report on PBS expenditure is due to be considered at the August 2011 meeting of the Access to Medicines Working Group.

Once the measures contained in the MoU have been given a chance to deliver their guaranteed savings, this framework for joint monitoring of PBS expenditure, growth trend and drivers is the appropriate mechanism for Government to assess PBS sustainability. This collaboration should continue and is far more likely to produce good social and economic policy outcomes than knee jerk decisions to find short term savings in an already efficient program.

Transparency

The Government has stated that the deferral of these medicines is temporary and normal practice will be resumed 'when the fiscal situation allows'. As yet there has been no clarification of when this is likely to be, leaving patients and those treating them in limbo.

GSK hopes that Government will reverse the short sighted decision to defer PBS listing of cost effective medicines as soon as possible. Continuing deviation from the past practice of listing all medicines meeting the strict cost effectiveness criteria fundamentally changes the nature and purpose of the PBS. We strongly believe that it is unacceptable and unnecessary for Cabinet to unilaterally alter the PBS in this way.

Changing the PBS from an uncapped program facilitating universal access to cost effective medicines to a cost containment program that rations healthcare, is a fundamental shift that must not occur without full public discussion, debate and decision by Parliament.

Recommendations

- The Government should overturn its previous decisions to defer the PBS listing of recommended medicines and move to facilitate the listing of medicines subject to deferral as soon as possible.

- The Government should ensure the PBS can properly fulfil its objective of providing access to cost effective medicines by observing long standing past practice of listing medicines recommended by the PBAC.

- The Government should honour the intent of the MoU and continue to collaborate with industry to establish an agreed, factual basis for ongoing policy discussions concerning the sustainability of the PBS.