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EXECUTIVE SUMMARY

Medicines Australia is the representative body for Australia's prescription medicines industry. The industry is now one of the largest exporters of elaborately transformed manufactured goods in Australia.

Medicines Australia, believes the successful negotiation of the Australia-US Free Trade Agreement (FTA) is a very significant outcome for Australia and it urges all parliamentarians to provide the bi-partisan support to deliver this historic once in a life time opportunity.

Medicines Australia recognises that Australia can secure billions of dollars worth of benefits in a FTA with the United States. This is a great result for Australia, offering big gains for local manufacturers, investors and professional services. The FTA will open up the US market of 290 million people to Australia.

The FTA is a win for Australian patients, the medical community and industry on several fronts.

The FTA commits Governments to facilitating high quality health care and continued improvements in public health for their communities.

The Government has consistently promised Australians that the Pharmaceutical Benefits Scheme (PBS) will remain in tact. This commitment has been honoured. The Regulation Impact Statement affirms that the Agreement does not impair Australia's ability to deliver fundamental policy objectives in healthcare and does not change the fundamental architecture of the PBS.

Medicines Australia supports the FTA because of the significant benefits that will accrue to the health of Australians and the wealth that will be created for the nation. The FTA builds on Australia's National Medicines Policy, previous and current Industry Development Plans (Factor f, PIIP and P3), the Government's Innovation and Biotechnology Strategies and the State Ministers' Australian Biotech Alliance.

The Senate Select Committee's terms of reference require it to examine the impacts of the agreement on Australia's economic, trade, investment and social and environment policies, including, but not limited to, agriculture, health, education and the media. Medicines Australia contends that the FTA has demonstrable benefits for Australian patients, the medical community and Industry.

These benefits include:

- Access to the world's largest economy and a market of 290 million people;
- Potential to secure billions of dollars worth of benefits that offer big gains for local manufacturers, investors and professional services;
- More efficient access to medicines when the Australian public needs them;
- Improved understanding by consumers and industry of the workings of the PBS , equipping them to become better, more informed participants;

- Heightened integrity of the system to ensure that the right decisions are being made on behalf of Australian patients;
- Greater certainty in access to medicines for patients;
- Protection and enhancement of the PBS system; and
- The potential to secure $1 billion of bio-pharmaceutical research activity, and manufacturing activity.

"Conventional wisdom has it that Australia's PBS is the world's best government system for subsidizing medicines. How many times have we heard that in the debate over the pending Australia-US free trade agreement? But although we have every reason to be proud of our health system, we should not be afraid of constructive criticism that could lead to its improvement especially in relation to access to medicines. Far from being near perfect, the PBS prevents much needed reform and baffles numerous medical specialists in virtually every discipline."

Professor John Zalcberg
Cancer specialist
The Australian
15/12/2003

INTRODUCTION

Medicines Australia is the representative body for Australia's prescription medicines industry. The broad industry has a turnover of approximately $12 billion, employs around 35,000 people and accounts for approximately 1 per cent of the global market. The industry *"backs Australia's ability"* and is an indispensable component of a high-tech, twenty-first century economy.

Over the last decade pharmaceutical exports have grown from $146 million to more than $2 billion and the pharmaceutical industry is now one of the largest exporters of elaborately transformed manufactured goods in Australia – neck and neck with the wine industry.

The industry's investment in R&D is $450 million and is in no small way associated with the very significant investment past and present governments have made towards building a highly respected R&D base in this country.

Medicines Australia, believes the successful negotiation of the Australia-US Free Trade Agreement (FTA) is a critically important outcome for Australia and it urges all parliamentarians to provide the bi-partisan support to deliver this historic once in a life time opportunity.

Medicines Australia recognises that Australia can secure billions of dollars worth of benefits in a FTA with the United States. This is a great result for Australia, offering big gains for local manufacturers, investors and professional services. The FTA will open up the US market of 290 million people to Australia.

The FTA is a win for Australian patients, the medical community and industry on several fronts.

The FTA commits Governments to facilitating high quality health care and continued improvements in public health for their communities.

The Government has consistently promised Australians that the Pharmaceutical Benefits Scheme (PBS) will remain in tact. This commitment has been honoured. The Regulation Impact Statement affirms that the Agreement does not impair Australia's ability to deliver fundamental policy objectives in healthcare and does not change the fundamental architecture of the PBS. [1]

The innovations to PBS systems and processes will ensure life-saving and life-enhancing medicines continue to be made available to all Australians.

These innovations will bring about a more transparent, improved PBS system, better equipped to assess the value of medicines and to ensure they are made available to Australians when they are most needed.

[1] This is affirmed in the Regulation Impact Statement for JSCOT which states: "Australia will make improvements to the transparency and timeliness of PBS processes and Australians will benefit from faster access to subsidies for new prescription medicines."

Industry, consumers and medical specialists can now rest assured there is a system of review to ensure the best decisions are made for all Australians, with access to the best therapies to treat and cure illness. This can allow patients, medical professionals and industry to be better informed and understand the importance of a new therapy or life saving medicine, while at the same time introducing greater transparency and certainty to important PBS processes.

Medicines Australia supports the FTA because of the significant benefits that will accrue to the health of Australians and the wealth that will be created for the nation. The FTA has demonstrable benefits for Australian patients, the medical community and Industry, which the Senate Select Committee should consider as positive impacts from the Agreement. These include:

1. The FTA facilitates more efficient access to medicines when the Australian community most needs them. This is better healthcare and will help achieve a healthier workforce with higher participation rates, as well as a viable local industry.

2. A more certain and predictable timeframe for PBS decisions will improve time delays in access to medicines for patients, enable the system to operate more efficiently, and allow prescription medicines companies to operate within normal business parameters.

3. The promise to disclose the procedures and rules of the system is a commitment to openness and transparency for what has until now been seen as an ill-explained process. This will enable the public and industry to better understand how the system operates and why a medicine has or has not achieved PBS listing, equipping them to be better, more informed participants in the process.

4. A system of independent review for decisions made by the PBAC is a safeguard for Australians to make sure that the right decision has been made for the community's needs. It is an appropriate acknowledgment of the importance of the system of providing subsidised medicines to the Australian community as part of Australia's world class health system. It also acknowledges procedural fairness considering the high level of investment industry makes in developing a new medicine and the need for timely access to critical medicines by the community.

5. Streamlining administrative steps required before a medicine is added to the PBS will result in efficiencies to the system and reduce the time between when a medicine receives PBAC approval and when it can be prescribed to Australian patients through the PBS.

6. Allowing industry to provide comments to the PBAC during the reimbursement process will allow a greater exchange of information crucial to a medicines' best chance of fair assessment. It will protect the integrity of the

system and ensure the right decisions are being made on behalf of the Australian community in addressing their needs.

7. The greater transparency and improved understanding of the way the PBS operates will increase the Australian public's understanding of the scheme, funded by their taxes, and presents an opportunity to increase their respect for the system and the way it is intended to operate. It will also provide a greater level of certainty and predictability for companies – a factor which underpins investment decisions by the global pharmaceutical industry.

8. The FTA has the potential to secure billions of dollars worth of benefits including attracting $1 billion worth of bio-pharmaceutical research activity and manufacturing activity to Australia. This will benefit local manufacturers, investors and professional services, and will convert a potential brain drain of talented young Australian scientists into a brain gain.

9. The FTA is a catalyst and a vehicle that can translate Australia's competitive advantages into positioning Australia as a major bio-pharmaceutical hub in the region. These advantages include an excellent medical research infrastructure, a high quality clinical research capability, innovative biotech companies and a highly skilled, high-tech, knowledge-based workforce – assets that through the FTA will foster better health outcomes and higher economic growth.

10. The Agreement will allow Australian medicinal exports to reach a market of 290 million people. It is vital for an industry that is the biggest employer of scientists outside Government.

11. The Agreement reinforces Australia's existing framework for intellectual property protection of pharmaceuticals and fulfils its international treaty obligations. The Therapeutic Goods Administration (TGA) marketing approval process will recognise the rights of patent holders through notification procedures as well as ensure that generic manufacturers have a rightful place in the market, once a patent has expired.

12. There is international recognition of the high standard of prescription medicine evaluation undertaken by the Australian TGA and the resultant high quality safety and efficacy of prescription medicines supplied in, and exported from Australia. Closer co-operation between Australia's TGA and the US Food and Drug Administration (FDA) will mean a more efficient registration process for medicines, ensuring Australians have a much better chance of accessing medicines they need when they need them.

Facts and Fiction

> *"Despite a campaign of misinformation picked up by some political figures throughout the past year, Australia was not forced to dismantle the PBS. What Australia was "forced" to do was to make the PBS more transparent and accountable, not to the US pharmaceutical industry but to the Australian people. The US pharmaceutical companies may have pushed this charge, but we should be pleased that they correctly pointed out that the PBS does not give sufficient weight to the benefits certain drugs may have on the quality of life of the person taking the drugs...".*
>
> ***Bryan Mercurio***
> Lecturer in international trade law
> University of NSW
> *The Australian*
> 11/2/2004

There are a number of fabrications which various groups have attempted to link to the FTA. Set out below are a number of more informed and objective responses to those myths:

1. The independent review system will not be able to force PBS listing. The final say and decision making on whether a medicine achieves PBS listing remains in the hands of the Executive Government and Health Minister. Whatever the PBAC or an independent review system may conclude the ultimate authority remains with the Government. The Minister retains the power to list or not list a medicine and to decide on the conditions that are placed for such listing. To suggest otherwise is misleading and mischievous.

2. Throughout the negotiations unsubstantiated claims were made that the FTA would increase the price of medicines to consumers. The suggestion for example that the FTA would result in the cost of a prescription for ordinary Australians jumping by 430% to more than $122, lacked any credibility or objectivity. These claims were refuted at the time and again following the release of the FTA text.

3. The FTA does nothing to alter the Government of Australia's right to determine what medicines it offers via subsidy to the Australian public. The FTA cannot dictate how much the Australian Government spends on medicines or how much medicines cost the Australian consumer. Governments, the Parliament and the community decide how much is ultimately spent on healthcare and this has nothing to do with a FTA.

4. Closer co-operation between Australia's TGA and the US FDA will not extend to the TGA having to accept the recommendations of the FDA on medicines or vice versa.

More detailed information is at Appendix A.

CONSIDERATION OF THE SPECIFIC ELEMENTS OF THE AUSTRALIA-USA FREE TRADE AGREEMENT

1. The principles

> 1. AGREED PRINCIPLES
> The Parties are committed to facilitating high quality health care and continued improvements in public health for their nationals. In pursuing this objective, the Parties are committed to the following principles:
> (a) The important role played by innovative pharmaceutical products in delivering high quality health care;
> (b) The importance of research and development in the pharmaceutical industry and of appropriate government support including through intellectual property protection and other policies;
> (c) The need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety and efficacy; and
> (d) The need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.

The FTA represents a real and unambiguous commitment by both Governments to facilitating high quality healthcare, through principles which give recognition to the important role played by innovative medicines, acknowledgement of the value of innovative medicines and the need for timely and affordable access. The role of research and development in the pharmaceutical industry is also seen as a central and abiding commitment.

Medicines Australia applauds the enunciation of these important principles, which builds on the commitments already made in Australia's National Medicines Policy.[2]

The FTA facilitates more efficient access to medicines when the Australian community most needs them. This will promote better healthcare and will help achieve a healthier workforce with higher participation rates.

[2] The National Medicines Policy is a well-established endorsed partnership framework. Governments – Commonwealth, States and Territories – the medicines industry, healthcare consumers, health educators, health practitioners, and other healthcare providers and suppliers work together to promote the objectives of the policy. The overall aim of the National Medicines Policy is to meet medication and related service needs so that both optimal health outcomes and economic objectives are achieved.
The National Medicines Policy focuses on four central objectives:

- Timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- Maintaining a responsible and viable medicines industry;
- Quality use of medicines; and
- Ensuring medicines meet appropriate standards of quality, safety and efficacy

The recently released Access Economics report[3] categorically demonstrated the major contribution that innovative medicines have made to the well being of Australians during the last decade, for example in the fight against cancer and cardiovascular disease.

The Government's Inter-Generational Report acknowledges that over the next 40 years the ratio of dependants to workers will rise and population factors will detract from GDP per capita. According to the Treasurer, higher participation among older Australians will have a more immediate and direct impact on GDP per capita than rising fertility rates.

The solution is about higher participation and increasing productivity. A key to such a cultural shift is maintaining and enhancing the health of Australians: that is, healthy ageing.[4] Access to innovative medicines will continue to be a major contributor.

It is both appropriate and important that access to innovative medicines has been included as a priority in the FTA principles, particularly because over the past few years, there has been mounting evidence of public concern regarding access to medicines (see Appendix B).

The FTA principles place priority on the importance of R&D in the pharmaceutical industry with appropriate Government support. This represents another building block in fostering the country's innovation agenda through developing a viable industry, helping the industry to compete in the global marketplace, which are both critical to increasing the flow of highly skilled jobs, high tech exports and higher economic growth (see Appendix C).

2. Transparency

<u>2. TRANSPARENCY</u>
To the extent that a Party's federal healthcare authorities operate or maintain procedures for listing of new pharmaceuticals or indications, or for setting the amount of reimbursement for pharmaceuticals, under its federal healthcare programs, it shall:
(a) Ensure that consideration of all formal proposals for listing are completed within a specified time;
(b) Disclose procedural rules, methodologies, principles and guidelines used to assess a proposal;
(c) Afford applicants timely opportunities to provide comments at relevant points in the process;
(d) Provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities;

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[3] For example, it demonstrated significant rates of return on investment in health research, as much as 800% in the case of cardiovascular disease. "Exceptional Returns – the value of investing in health R&D in Australia", prepared for the Australian Society of Medical Research, September 2003

[4] Leading Australian researcher Dr Paul Gross, the Director of the Institute of Health Economics and Technology Assessment, confirmed that better health outcomes obtained with modern innovative medicines lead to higher gross domestic product (GDP) by increasing both workforce participation and productivity. "The Economic Value of Innovation: measuring the linkages of pharmaceutical research, use of innovative drugs and productivity gains" Health Economics Monograph, No.80, March 2003

(e) Provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law; and
(f) Make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.

Transparency about how medicines are registered and reimbursed and the processes by which this is determined is important for community confidence in our health system as it relates to medicines; and recognition of the value that this delivers individual members of our community; and for business in its planning processes. It is far more than the publication of information.

The principles outlined in the FTA ensure that the decision making process for the reimbursement and pricing of medicines are timely, objective, fair and transparent and provide for meaningful consultation and accountability. These principles are reinforced by specific provisions in the Side Letter which outline the specific opportunities for consultation.

The greater transparency and improved understanding of the way the Pharmaceutical Benefits Scheme (PBS) operates will increase the Australian public's understanding of the scheme, which is funded by their taxes and presents an opportunity to increase their respect for the system and the way it is intended to operate. It will also provide a greater level of certainty and predictability for companies – a factor which underpins investment decisions by the global pharmaceutical industry.

The benefits of greater transparency have been noted by stakeholders and decision makers alike.

For example, the former Shadow Minister for Health Stephen Smith said at a pharmacy conference last year that when we look at the PBS we should look at the long-term, viable and sustainable measures: *"looking at (PBS) listing procedures for new medicines; making the scheme more transparent; more accountable both to the community and to the various professionals interested in it; making sure that we have evidence-based medicine and that we make sure that appropriate information goes to consumers and doctors so far as prescribing is concerned…".*[5]

In a recent opinion in the national media, one of Australia's leading cancer specialists Professor John Zalcberg said that, *"Far from being perfect, the PBS prevents much needed reform and baffles numerous medical specialists in virtually every discipline…many specialists, like me, are frustrated by unexplained delays that seem to be based on non-transparent, economic or bureaucratic processes dictating the PBS decision-making process".*[6]

[5] Australian Pharmacy Professional 2003, in Pharmacy Review April 2003.
[6] The Australian, December 2003.

The changes proposed in the FTA will build on the new arrangements - previously initiated by the Government - which apply from March 2004, with the introduction of the *"17 week schema"*. The *"17 week schema"* applies to PBAC applications and expands the opportunities for companies to provide comment on their applications.

The specific benefits which will flow from the FTA transparency provisions are as follows:

Certain and predictable timeframes for PBS listing

More certain and predictable timeframes for PBS decisions will improve time delays in access to medicines for patients, enable the system to operate more efficiently, and allow prescription medicines companies to operate within normal business parameters.

There is evidence of community concerns around access delays [7] as well as a number of references in Parliament relating to delays[8].

Recent examples show that the time between approval by the Pharmaceutical Benefits Advisory Committee (PBAC) and achieving PBS listing has for new chemical entities extended to between six months and three years. For example, in response to a question on notice from Senator O'Brien in October 2000, the Health Minister noted that the medicine Aricept had first been considered by the PBAC in December 1997 and received approval in December 2000, Similarly, Senator Carr in November 2002 noted that *"It is now 1 and a half years later and the government has failed to make the necessary decisions about the listing of these drugs (Avandia and Actos)."*

The TGA has a statutory timeframe for the registration process (255 days).

The issue of certain timeframes has been recognised by the Government and is currently under consideration as part of the review of post-PBAC processes which the Government had previously initiated. The goal of this review is to *"design a streamlined process/arrangement that is best positioned to deliver efficient, effective, certain and transparent outcomes for government, the pharmaceutical industry, prescribers and the community, including the achievement of a maximum 4 month timeframe from date of positive PBAC recommendation to available subsidy".*

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[7] For example, an investigation by the Daily Telegraph found that it could take up to five years for new break through drugs to attain Government subsidy. Daily Telegraph 24/11/03, p.3 .And commentator Alan Mitchell notes that "the PBS derives its bargaining power from its ability to effectively withhold drugs from the lucrative Australian market. This will become more difficult as the Australian population ages and the availability of new drugs becomes a national obsession." AFR 17/12/2003

[8] For example, Senator O'Brien – in October 2000- asked about Aricept and Exelon; Senator Murphy has asked about the glizatone drugs, in November 2002; Senator Lees asked about Enbrel and Remicade in September 2002.

The outcomes of this review, together with the FTA provisions relating to specified timeframes and reducing the time to implement PBAC recommendations are important initiatives towards improving systems and processes.

Disclosure of procedures, guidelines etc

The FTA provision relating to disclosure of the procedures and rules of the system is a commitment to openness and transparency for what has until now been seen as an ill-explained process.

This will enable the public and industry to better understand how the system operates and why a medicine has or has not achieved PBS listing, equipping them to be better, more informed participants in the process.

The industry acknowledges that many of the procedures and guidelines are publicly disclosed. However, there are still significant areas where disclosure would be beneficial and enhance the transparency of the process for everyone.

For example, the disclosure provisions will assist patients and industry to understand the process by which the PBAC chooses to consult specialists or patient groups on a particular medicine, how that consultation occurs and how it is used in assessing whether a medicine should be made available; and whether, for example, clinical practice guidelines play any part in the process.

Similarly, the disclosure provisions will assist in understanding how the expert evaluators - who are assigned to write an evaluation of a particular medicine for the PBAC and its sub-committees- assess the clinical and quality of life benefits of that medicine.

There is also a great need and desire for the public to understand the threshold which medicines must meet in order for them to be considered *"value for money"* by the PBAC. The industry agrees with and understands that it needs to demonstrate the value of its medicines. Clarity around the *"value for money"* threshold which medicines must meet will enable companies to better understand how to bring a product to market.

The need for greater disclosure and transparency has been recognised by others.[9]

Greater engagement by companies in the listing process

Allowing industry to provide comments to the PBAC during the reimbursement process will allow a greater exchange of information crucial to a medicines' best chance of fair assessment.

[9] For example, Dr Brendan Grabau, the chief assessor of the Pharmaceutical Continuing Education Program at Deakin University commented that The current lack of transparency sometimes baffles Australian patients/consumer groups," Canberra Times 28/1/04. Similarly Dr John Zalcberg asked the question:" ....are patients prepared to let this rationing continue behind closed doors" The Australian 15/12/03

It will protect the integrity of the system and ensure the right decisions are being made on behalf of the Australian community in addressing their needs.

The FTA provisions will enable a greater level of engagement by companies in the listing process than has been possible to date.

For example, the FTA provisions in the Side Letter (3(b)) will allow companies to fully respond to the lengthy evaluation reports which are provided as part of the process, rather than being limited from doing so, as has been the practice to date (maximum of four text pages, and 2 pages of tables/graphs).

Similarly, greater engagement will enable simple questions or inaccuracies to be answered or corrected early in the process, rather than having to wait for the PBAC to reject the submission 3-6 months later on the basis of incorrect or misinterpreted data.

The opportunity to appear before the PBAC – which is in the Side Letter at 3 (c) will measurably improve the current process where, to date, only written communication is permitted.

Earlier, more frequent and more wide-ranging opportunities for consultation and comment will improve the effectiveness and efficiency of the process and make it far more transparent for everyone.

In addition, increased interaction and dialogue between those involved in the evaluation and decision-making process and companies will increase industry's understanding of requirements and outcomes.

The intended outcome is to enable patient access to medicines when they need them by improving the success rate of submissions or reducing the rate of re-submissions, where there is justification and a demonstrated need.

In addition to the processes relating to the PBAC, Medicines Australia understands that the need for greater engagement has been recognised by the Government within the context of the previously initiated Review of post-PBAC processes.

A review of the Therapeutic Drugs Administration in 1991 resulted in very successful innovations to the systems and processes leading to the approval of medicines in a more transparent and timely manner.[10]

The Australian Government's own reviews, such as the 1996 Industry Commission inquiry into The Pharmaceutical Industry and the 1997 Australian National Audit Office review, have found that the administration of the PBS would benefit by greater transparency (see Appendix D).

[10] A Question of Balance. Report on the future of Drug Evaluation in Australia. Professor Peter Baume July 1991, AGPS.

Independent review process

A system of independent review of recommendations made by the PBAC is a safeguard for Australians to make sure that the right decision has been made in the community's best interests.

It is an appropriate acknowledgment of the importance of the system of providing subsidised medicines to the Australian community as part of Australia's world class health system.

It is also recognition of the need for procedural fairness considering the high level of investment industry makes in developing a new medicine and the need for timely access to critical medicines by the community.

The benefits of an independent review have been noted by stakeholders and decision makers outside the industry.[11]

The PBAC process is a technical, scientific process which involves subjective appraisals of large volumes of data arising from scientific studies and the exercise of discretion by PBAC members in some cases in complex areas of cutting-edge science. By its very nature, its outcomes are the product of a subjective decision making process. This is an area where new methodologies and approaches are continually being developed and refined, and where uncertainties around interpretation of evidence are prevalent. [12]

The independent review agreed to, is in line with the Government's stated approach to accountability and good governance - sentiments expressed by the Auditor-General and the Administrative Review Council.[13]

To ensure that the independent review process delivers true accountability to the public, the industry will support a process that:

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[11] For example, Dr Brendan Grabau noted that "this type of mechanism allows industry, doctors and patients to question how and why innovative medicines have failed to achieve a PBS listing." The Canberra Times 18/2/04.

[12] The Industry Commission noted this in its report: "The Commission finds that because economic analysis can only be approximate, undue reliance has been placed on its use in PBS listing and pricing decision-making." 10.7. Similarly the ANAO report recommended that the PBAC guidelines would benefit from incremental changes as improved techniques for economic analysis are accepted…." A full review of the PBAC Guidelines has not occurred for some years. The Guidelines have been essentially the same since 1995, with some tinkering around the edges.

[13] The Auditor General, Pat Barrett said in September 2000 in an address to the International Conference on Improving Oversight Functions: Challenges in the New Millenium: "The central element of democratic governance is accountability. The latter includes assurance that government and its institutions will conduct themselves with integrity,justly equitably and efficiently. In their wisdom, legislatures and governments have established independent bodies to oversight accountability and performance to help provide such assistance." In the Adminstrative Review Council report entitled "Better Decisions: review of the Commonwealth Merits Review Tribunal", the council said: "In the council's view, the overall objective of the merits review system is to ensure that all administrative decisions of government are correct and preferable. Achieving this objective involves more than ensuring that the correct and preferable decision is made in those cases that come before the review tribunals. It also means that all persons who might benefit from merits review are informed of their right to seek review and are in a position to exercise those rights and that the overall quality of agency decision making is improved."

a. Is conducted at arms length from the process which provides the original recommendation to Government;
b. Involves an independent objective appraisal of the matters dealt with in the initial process of arriving at a determination – the facts, all aspects of the recommendation. For PBAC submissions, this includes the scientific analysis/findings and economic analysis/findings;
c. Enables determinations to undergo review, where the original advice to Government is confirmed or can vary from the original determination;
d. Is conducted in such a way as to make public outcomes from the review process at the first opportunity; and
e. Is consistent with the currently agreed processes for the publication of negative decisions of the PBAC.

The mechanism for the operation of the review process needs to be finalised, reflecting the agreement reached by the Australian and US Government.

The independent review process around PBAC determinations is about access to medicines and their value to the community. However, it will not be able to force PBS listing. The final decision on whether a medicine achieves PBS listing, remains in the hands of the Executive Government and Health Minister. Whatever the PBAC or an independent review system may conclude the ultimate authority remains with the Government. The Minister retains the power to list or not list a medicine and to decide on the conditions for such listing.

The benefits of independent review processes are numerous and apply to the decisions of numerous government agencies (see Appendix E). The industry fully accepts that determinations which affect the health of millions of Australians should legitimately have an avenue for review.

3. The Medicines Working Group

<u>3. MEDICINES WORKING GROUP</u> (a) The Parties hereby establish a Medicines Working Group; (b) The objective of the Working Group shall be to promote discussion and mutual understanding of issues relating to this Annex (except those issues covered in paragraph 4), including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes; and (c) The Working Group shall comprise officials from federal government agencies responsible for federal healthcare programs and other appropriate federal government officials.

The establishment of the Medicines Working Group is similar to groups which have been set up under this and other Free Trade Agreements. Medicines Australia supports its focus on the important role of innovative medicines in delivering quality health outcomes. We assume that the Group's terms of reference will reflect the principles contained in Annex 2-C.

Composition of the MWG is a matter for the US and Australian Governments to determine. It should be made up of Government officials from central agencies, Health and Trade, to ensure a whole of Government approach on the part of both Governments.

4. Regulatory cooperation

4. REGULATORY COOPERATION The Parties shall seek to advance the existing dialogue between the Australian Therapeutic Goods Administration and the U.S. Food and Drug Administration with a view to making innovative medical products more quickly available to their nationals.

There is international recognition of the high standard of prescription medicine evaluation undertaken by the Australian TGA and the resultant high quality, safety and efficacy of prescription medicines supplied in, and exported from, Australia.

The rigorous evaluations conducted by the TGA, and the timeliness with which evaluations are conducted – on average a new prescription medicine is evaluated within 18 months from submission – means that Australian pharmaceutical companies can better convince their home offices overseas that Australia can be a regional or even global exporter of prescription medicines.

Closer co-operation between Australia's TGA and the US Food and Drug Administration (FDA) will mean a more efficient registration process for medicines, ensuring Australians have a much better chance of accessing medicines they need when they need them.

Closer cooperation between the TGA and FDA will also enhance the TGA's position as a significant regulatory agency in the Asia Pacific area.

5. Dissemination of information

5. DISSEMINATION OF INFORMATION Each Party shall permit a pharmaceutical manufacturer to disseminate to health professionals and consumers via the manufacturer's Internet site registered in the territory of a Party, and on other Internet sites registered in the territory of a Party linked to that site, truthful and not misleading information regarding its pharmaceuticals that are approved for sale in the Party's territory as is permitted under each Party's laws, regulations and procedures, provided that the information includes a balance of risks and benefits and encompasses all indications for which the Party's competent regulatory authorities have approved the marketing of the pharmaceuticals.

The FTA text articulates that any marketing and advertising to consumers must comply with existing laws. Current Australian law states that advertising direct to consumers by industry is prohibited. The prescription medicines industry adheres to this Government legislation and recognises this statement as a reaffirmation of existing policy.

6. The Side Letter on Pharmaceuticals

> 1. In order to enhance transparency, meaningful consultation, and accountability in the process of selecting, listing, and pricing of pharmaceuticals under its Pharmaceutical Benefits Scheme (PBS), Australia shall provide an applicant seeking to have a pharmaceutical listed on the PBS formulary:
> (a) An opportunity to consult relevant officials prior to submission of an application for listing, including on the selection of a comparator pharmaceutical;
> (b) An opportunity to respond fully to reports or evaluations relating to the applications that are prepared for the technical subcommittees of the Pharmaceutical Benefits Advisory Committee (PBAC);
> (c) An opportunity for a hearing before PBAC while it is considering reports or advice from the technical subcommittees to the PBAC regarding applications; and
> (d) Sufficient information on the reasons for its determination on an application, on an expeditious basis, to facilitate any application to the Pharmaceutical Benefits Pricing Authority.
>
> 2. Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list.
>
> 3. In order to make its process of selection, listing, and pricing of pharmaceuticals and indications under its PBS more expeditious, Australia shall:
> (a) Reduce the time required to implement recommendations of the PBAC, where possible;
> (b) Introduce procedures for more frequent revisions and dissemination of the Schedule of Pharmaceutical Benefits, where possible; and
> (c) Make available expedited procedures for processing of applications not requiring an economic evaluation.
>
> 4. Australia shall provide opportunities to apply for an adjustment to a reimbursement amount.

Points 1(a)-(d), 2 and 3(a), which relate to certain and predictable timeframes, greater engagement by companies in the listing process and the independent review process, have been addressed in earlier comments.

More frequent revisions and dissemination of the list of subsidised medicines – commonly known as the *"Yellow Book"* - and expedited procedures represent a streamlining of administrative and procedural steps which are required before a medicine is added to the PBS. This will result in efficiencies to the system and reduce the time between when a medicine receives PBAC approval and when it can be prescribed to Australian patients through the PBS.

Medicines Australia supports any measures aimed at streamlining procedures, as this is also in line with the intent of the Review of post-PBAC processes.

Point 4 of the Side Letter formalises an existing process whereby companies can ask for consideration of the value of their medicines.

7. Intellectual Property Chapter

ARTICLE 17.10 : MEASURES RELATED TO CERTAIN REGULATED PRODUCTS

5. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety or efficacy information, to rely on evidence or information concerning the safety or efficacy of a product that was previously approved, such as evidence of prior marketing approval in the Party or in another territory:
(a) That Party shall provide measures in its marketing approval process to prevent such persons from
  (i) Marketing a product, where that product is claimed in a patent; or
  (ii) Marketing a product for an approved use, where that use is claimed in a patent, during the term of that patent, unless by consent or acquiescence of the patent owner; and
(b) If the Party permits a third person to request marketing approval to enter the market with:
  (i) A product during the term of a patent identified as claiming the product; or
  (ii) A product for an approved use, during the term of a patent identified as claiming that approved use, it shall provide that the patent owner be notified of such request and the identity of any such other person.

Medicines Australia supports the intellectual property provisions of the Agreement which reinforces Australia's existing framework for intellectual property protection of pharmaceuticals and fulfils its international treaty obligations.

Australia's intellectual property regime is regarded as amongst the strongest in OECD countries and the FTA has reinforced this.

Most of the intellectual property provisions relating to pharmaceuticals clarify and reconfirm existing law. For example, the provisions on data exclusivity for new products do not impose any additional obligations.

Similarly, the provisions relating to the approval of generic drugs reinforce existing patent law. New provisions require measures in the marketing approval process to prevent a person from entering the market with a generic version of a patented medicine before a patent has expired; and notification to patent owners in certain circumstances. These provisions merely clarify that a generic medicine cannot be marketed while a patent is on foot – this is the existing law with an element of greater transparency.

These provisions will recognise the rights of patent holders through notification procedures as well as ensure that generic manufacturers have a rightful place in the market, once a patent has expired. There are no changes to pharmaceutical patent terms in the Agreement.

8. Side Letter on Intellectual Property

Notwithstanding Article 17.9.6, if a patent for a pharmaceutical product has been granted an extension of its term pursuant to Article 17.10.4, Australia may permit the export by a third party of a pharmaceutical product covered by that patent, only for the purposes of meeting the marketing approval requirements of Australia or another territory.

This provision confirms existing law which enables generic manufacturers to export a product for marketing approval purposes only, where that product is still protected by an extended patent in Australia. The industry believes that there should not be any differentiation between the protections provided pharmaceutical patents during the initial patent term or during the extension, as is the current practice in the US, but accepts the current Australian position.

APPENDIX A

FACTS AND FICTION SURROUNDING THE AUSTRALIA-USA FTA

To assist in separating fact from fiction on the PBS and FTA, Medicines Australia provides the following clarification on myths put forward about PBS changes:

Myth 1: The FTA will allow pharmaceutical companies to advertise directly to the public:
Fact: The FTA text articulates that any marketing and advertising to consumers must comply with existing laws. Current Australian law states that advertising direct to consumers by industry is prohibited.

Myth 2: There is a new element to the PBS where prescription medicines companies can demand price increases for their products:
Fact: There is no new process whereby companies can ask for higher prices for medicines. The FTA text formalises an existing process whereby companies can ask the Government to consider the value of their medicines.

Myth 3: The prescription medicines industry will be able to force the listing of medicines through an independent review system:
Fact: The independent review system will not be able to force decisions as the final say and decision making on whether a medicine achieves PBS listing remains in the hands of the executive Government and Health Minister. Whatever the PBAC or an independent review system concludes the ultimate authority still lies with the Government. The Minister retains the power to list or not list a medicine and to decide on the conditions that are placed for such listing.

Myth 4: Drug prices could double as a result of the FTA
Fact: As has been shown by the concluded negotiations, the suggestion by the Australia Institute[14] that the cost of a prescription for ordinary Australians would jump by 430% to more than $122 as a result of free trade negotiations lacked any basis in fact.

Their research shows a complete lack of understanding of who decides how much the Australian public pays for medicines. Their claims were refuted prior to the release of the FTA text[15][16][17] and again since.[18][19]

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[14] Australia Institute, www.tai.org.au Canberra 2004
[15] Mr Steve Deady Chief Negotiator 23 May 2003
[16] The Hon. Tony Abbott Sunday Sunrise 2 November 2003
[17] The Hon Mark Vaile ABC News 27 November 2004
[18] The Hon.Tony Abbott ABC Radio 10 February 2004
[19] The Hon. Mark Vaile The Advertiser 12 February 2004

The Government cannot realise a $1 increase in patient's contribution to medicines because of a block in the Senate, let alone the $120 price tag that is the fantasy of the Australian Institute.

No trade deal can dictate how much the Australian Government spends on medicines or how much medicines cost the Australian consumer.

The only change the FTA could mean for consumers is greater and timelier access to some of the worlds leading medicines that will save lives, treat and cure disease and reduce spending in more expensive and more invasive treatments involving surgery, hospitalisation and increased aged care.

Governments, the Parliament and the community decide how much is ultimately spent on healthcare – that has nothing to do with an FTA.

Successful implementation of the Free Trade Agreement will build the medicines industry into Australia's largest export business, create more jobs, keep young talented scientists in Australia and double the output of Australian research.

Myth 5: With drug company backing, the US wants to extend the patent life of drugs in Australia as a condition for the free trade deal. An extended patent life for drugs would ensure low-cost competitors could not edge into a market share by selling *"generic (cheaper) drugs"*.

Fact: There is no basis for this claim. Even the Australian Government's explanation of this confirms this. As the DFAT website notes, *"the Agreement reinforces Australia's existing framework for intellectual property protection of pharmaceuticals."*

According to DFAT, *"the Therapeutic Goods Administration (TGA) marketing approval process will ensure that a generic manufacturer is not able to enter the market with a generic version of a medicine before a patent covering that product has expired."* To do otherwise would be to flout the patent protection.

Myth 6: the FTA provisions will lead to the delayed entry of generic medicines, which could substantially increase the running costs of the PBS

Fact: The provisions relating to the approval of generic drugs reinforce existing patent law. New provisions require measures in the marketing approval process to prevent a person from entering the market with a generic version of a patented medicine before a patent has expired; and notification to patent owners in certain circumstances. These provisions merely clarify that a generic medicine cannot be marketed while a patent is on foot – this is the existing law with an element of greater transparency. It is unclear why critics are claiming that a notification procedure would delay the entry of generic medicines. Notification provisions on their own do not delay or impede the capacity of generic manufacturers to prepare for generic production. The rules for this are set out in the Intellectual Property laws, and these rules are unchanged by the FTA.

Myth 7: the FTA will curtail the supply of cheap and effective generic medicines /the deal on intellectual property will mean many drugs will stay expensive for longer

Fact: Generic medicines only exist because of innovative medicines. Generic medicines are copies of innovative medicines and become available once the patents on innovative medicines expire. There are no changes to pharmaceutical patent terms in the FTA. The only provisions relating to generic medicines are around measures to reinforce the existing law, the need for notification (see Myth 6) and the continued entitlement for generic manufacturers to export for marketing approval purposes during the extended patent period.

Myth 8: Efforts to improve the openness of PBS processes have been constrained by industry concerns about protecting proprietary information.

Fact: Transparency is a mechanism to enhance the openness and accountability of PBAC decision-making processes in order to improve the quality and consistency of PBAC decision-making, thereby benefiting all those who rely on the PBS process for access to innovative medicines.

Industry worked collaboratively with Government to enable the PBAC to publish its negative recommendations – without this collaboration, Government would have been unable to proceed. Industry's concern over the protection of their intellectual property is quite legitimate. The same concerns for protecting commercial in confidence information are held by universities and biotech companies as they develop and commercialise an innovation.

Myth 9: the FTA will lead to the dismantling of the PBS

Fact: There is nothing in the FTA which would lead to the dismantling of the PBS. The fundamental principles that underpin the PBS remain The Agreement does not impair Australia's ability to deliver fundamental policy objectives in healthcare and does not change the fundamental architecture of the PBS.

The Government has agreed to greater transparency in the listing process, and this is a good outcome for all. It has also agreed to greater ongoing engagement with the industry to ensure they have more certainty around their investment in Australia. These are both issues that have been previously identified in Government reports such as the 1996 Industry Commission Inquiry.

APPENDIX B

MEDIA COMMENT ON ACCESS TO INNOVATIVE MEDICINES

Five-year wait for price cuts on new drugs

By SUE DUNLEVY

PATIENTS are paying up to $20,000 a year for medicines but many simply can't afford new breakthrough drugs as it takes up to five years for a Government subsidy to cut the price.

Australians are also missing out completely on hundreds of new drugs for parkinson's disease, migraine and stomach cancer, as well as antibiotics and anti-depressants, which are available overseas.

They are not sold in Australia because experts won't approve them for subsidy, or because drug companies don't believe that our $5 billion-a-year medicines subsidy scheme, the Pharmaceutical Benefits Scheme, pays enough.

An investigation by *The Daily Telegraph* has found a requirement that Federal Cabinet approve subsidies on medicines costing more than $10 million a year.

This is adding up to a further two years to a three-year wait on the approval process and includes new asthma, diabetes and arthritis treatments.

Sick people are being forced to pay up for the treatments or miss out altogether.

Australian Consumers Association spokesman Martyn Goddard, who used to serve on the Pharmaceutical Benefits Advisory Committee, said in the past Cabinet used to quickly endorse experts' decisions but has now politicised the drug approval system to save money.

"It's crazy for politicians to step in and think they know better than their own medical and economic experts what is cost-effective," he told *The Daily Telegraph*.

"They are being held up purely as a political decision to save money."

The lengthy Cabinet process was making the "system open to pressure and manipulation by drug companies".

He added that the $10 million threshold that triggers Cabinet involvement was too low.

Diabetes Australian chief Brian Conway said many patients were forking out $90 a month for new diabetes drugs while it took Cabinet two years to approve them.

The Daily Telegraph investigation has found Cabinet took between six months and 2½ years to approve subsidies for four breakthrough drugs after its own experts said they should be subsidised.

It took Federal Cabinet 2½ years to approve subsidies for two new $90-a-month diabetes medicines Actos and Avanadia which delay the need for insulin. This was despite an expert committee stating they were cost-effective and should be subsidised.

Singulaire, the new $100-a-month asthma pill, was approved for use in Australia in 1999 but took until January 2002 for bureaucrats to agree to subsidise it.

Federal Cabinet then spent nine months before approving the subsidy, even then patients had to wait three months to get it.

The Federal Health Department refused to give an average time frame for Cabinet deliberations — "it would be misleading".

But it claims it takes around 5.4 months on average to list a new drug or a new use for an old drug after approval by experts.

Daily Telegraph 24/11/04

Subsidy row on cancer fight drug

■ By Dawn Gibson

THE Federal Government is sitting on a recommendation to extend subsidies for a revolutionary new cancer drug despite the Leukaemia Foundation claiming it could mean the difference between life and death.

MabThera is used with chemotherapy to treat people with an aggressive form of non-Hodgkin's lymphoma, the sixth most common form of cancer in Australia.

Patients who have relapsed or not responded to other treatments can get the drug at a subsidised rate through the Pharmaceutical Benefits Scheme, but other patients have to pay the unsubsidised cost of $24,000 for a one-off course of treatment.

Leukaemia Foundation chief executive Michael Lynch said MabThera could be of benefit to more than 1000 new patients a year.

"For every month that the treatment isn't available to patients, another five Australians will have a reduced life expectancy and their quality of life compromised," he said.

"Australia is one of the few developed countries in the world where patients with this aggressive form of non-Hodgkin's lymphoma do not have access to funded MabThera yet the treatment is available for this group in 45 other countries around the world."

According to the Leukaemia Foundation, the treatment was recommended for listing on the PBS in September 2002 but has since dropped down the Government's priority list.

A spokeswoman for Federal Health Minister Kay Patterson said the drug had been put on the PBS for some patients. The pharmaceutical benefits advisory committee recently recommended that the PBS subsidy be extended to include previously untreated patients aged 60 and over who suffered a specific type of non-Hodgkin's lymphoma.

The spokeswoman said the recommendation was an important step in the process but Federal Cabinet still had the final say on whether to approve the extension.

According to the drug's manufacturer, Roche, a large clinical trial had shown that adding MabThera to chemotherapy significantly reduced the risk of death by 36 per cent. The overall survival rate at two years was 70 per cent.

Non-Hodgkin's lymphoma is cancer of the lymph cells that have been made in the bone marrow but have travelled through the blood to other areas in the body, usually the lymph glands. Aggressive lymphomas, if left untreated, can be fatal within one to two years.

West Australian 30/5/03

Cancer patients denied life-saving drug

Julie Robotham
Medical Writer

Doctors are furious that a drug to treat a rare and otherwise incurable form of stomach cancer has been rejected for taxpayer funding.

The drug, Glivec, has a dramatic effect on gastrointestinal stromal tumours (GIST) and 80 per cent of patients who take it survive at least 18 months; without it, half die within one year.

But it costs $50,000 to treat each patient for a year with the drug, which is already available to some leukemia patients. Between 50 and 100 new patients a year might benefit from it – which would add millions of dollars to the politically-sensitive Pharmaceutical Benefits Scheme, already running at more than $4.5 billion annually.

"I'm very upset about it because I'm the person who's going to have to tell people they can't have the drug," said Professor John Zalcberg, director of haematology and medical oncology at Melbourne's Peter MacCallum Institute. "I accept absolutely the right of government to ration health-care but they need to look patients in the eye and tell them, 'We can't afford this' . . . the clinical community has lost confidence in the [Pharmaceutical Benefits Advisory Committee] to be able to provide drugs like this."

Professor Zalcberg contrasted the Glivec impasse with Herceptin, an expensive drug that can give extra months of life to breast cancer patients in the terminal stage of the disease. It was given public funding after a campaign by patient groups.

"[Glivec] saves lives. It doesn't just improve symptoms and make people feel better," he said. "It took a consumer advocacy group at the time of an election to change policy . . . Glivec is even more dramatic in its impact yet it's been rejected three times."

Despite refusing to fund Glivec in its most recent quarterly deliberations, PBAC's chairman, Lloyd Sansom, said the issue was "not dead in the water" and the committee was "entering a dialogue with oncologists on how to progress this issue".

Professor Sansom said the sticking point was how to decide whether the drug was working well enough in an individual patient for them to continue taking it.

Doctors say it is difficult to check the size of GIST cancers deep inside the body without using positron emission tomography (PET) scanning – a technology that is not widely available. As well, many doctors believe patients should be allowed continued Glivec even if their tumour does not shrink but only stabilises.

Euan Walpole, the chairman of the Medical Oncology Group of Australia, said Glivec had "a relatively low toxicity but an effectiveness we haven't seen before. Half of patients – at least – benefit from it."

For up to half of about 200 new GIST patients diagnosed each year in Australia, surgery was the most appropriate first therapy, Dr Walpole said. But if the disease was already too advanced or recurred after an operation, Glivec was the only real option.

About 140 Australians are currently using Glivec for GIST, either as part of a medical trial or through a compassionate-access program organised by the drug's manufacturer, Novartis.

'[Glivec] saves lives. It doesn't just improve symptoms and make people feel better.'

Professor
JOHN
ZALCBERG

Sydney Morning Herald

21/6/03

Drug move ruins boy's dream of a normal life

Daily Telegraph 12/6/03

By SUE DUNLEVY

IN SIX months 11-year-old Mathew Johnstone could be back in a wheelchair, unable to feed himself or roll over in bed when the charity funding for his arthritis drug runs out.

This week Cabinet delayed subsidising the $18,000-a-year drug Enbrel that has allowed Mathew and 181 other severe rheumatoid arthritis patients to walk and lead a normal life.

Another 4000 crippled Australians ...stimated to benefit from the drug, ...ch, if subsidised, would cost taxpayers between $72 and $140 million a year.

Mathew has been using Enbrel after *That's Life* magazine donated money o pay for a year's supply of the drug.

But his doctor Jeffrey Chaitow said yesterday the funding would run out in six months.

Mathew's mother Kate said the delay in subsidising the drug was "totally devastating" as there was no way her family could afford the $18,000 a year I needed to pay for it.

She is angry the Government could find money for waging war on Iraq but not for a medicine that has removed her son's pain and made him stop wanting to kill himself.

"I would like them [Cabinet] to have seen Mathew when he was critically ill," she told *The Daily Telegraph*.

Mathew, who is school captain and starts high school next year, was in a wheelchair two years ago, unable to roll over in bed or feed himself. He said he doesn't want to have to go back to "feeling sore and lying in bed".

Arthritis Research Trust chief executive Bridget Kirkhan said arthritis sufferers were being "held to ransom" in a political game.

Last November, the Government's Pharmaceutical Benefits Advisory Committee recommended the Federal Government subsidise Enbrel.

But Federal Cabinet waited six months before considering it. This week it delayed a decision on whether to fund it under the Pharmaceutical Benefits Scheme to seek "more advice from clinical experts".

A spokesman for Health Minister Senator Kay Patterson was unable yesterday to say which experts would be consulted or what information was being sought by Cabinet.

Enbrel is injected twice a week, is used only in severe cases of rheumatoid arthritis after other treatments have failed and it can compromise the immune system.

Mathew's mother said he would need a teacher's aide, which costs $12,000 a year, if he goes off the drug and his arthritis flares up.

Do you or your family use or need to use Enbrel? Let us know

» dailytelegraph.com.au

Valuable and expensive tool in treating arthritis

- **Enbrel** is used in severe cases of rheumatoid arthritis where the patient does not respond to other therapies
- **It works** by attaching to and switching off some of the body's naturally produced proteins that cause inflammation in joints
- **The drug** changes the immune system, one of the side effects being that patients can become very sick if exposed to some infections
- **It is** administered by an injection under the skin twice a week
- **It doesn't** work in all patients and paediatrician Dr Jeffrey Chaitow said only 10 to 20 per cent of the 1000 children with severe arthritis would benefit from taxpayers subsidising it
- **The Cabinet** proposal puts very strict conditions on Enbrel. Only around 200 specialists will be able to prescribe it, patients have to meet very defined criteria — and other drugs must have failed

Suffering the pain of paying for a miracle

Waiting for public subsidy of the miracle arthritis drug Enbrel could prove painful, ANNA PATTY reports

IT took 10 years to develop and has relieved millions of people across the world of debilitating pain.

But the task of creating Enbrel is not an easy one.

Americans Craig Smith, Raymond Goodwin and Patricia Beckmann of Immunex Corp were faced with the problem of how to copy the human protein that plays a role in regulating immune function and inflammation.

In some people, too much of a certain protein called tumour necrosis factor is produced in joints causing inflammation and swelling that is a major symptom of rheumatoid arthritis.

Enbrel mimics the structure in the immune system that naturally acts as a sponge to mop up excess protein and reduce inflammation.

The revolutionary drug is known as a TNF blocker because it neutralises the chemical, helping reduce pain, swelling and damage in the joints.

The drug is administered by injection under the skin twice a week, similar to insulin.

Its inventors were awarded the Intellectual Property Owners Association 28th annual Inventor of the Year Award for Enbrel, which has the scientific name of etanercept.

Enbrel has been available in Australia through Wyeth Pharmaceuticals for about two years for sufferers of rheumatoid arthritis who have been struck down by the condition in the prime of their lives.

For most, there are cheap subsidised medicines which relieve their suffering and allow them to lead reasonably normal lives.

For others there is only Enbrel, which costs $18,000 a year per patient.

Young mothers and children are the typical victims of the excruciating pain and disability rheumatoid arthritis brings.

Unlike osteoarthritis, which develops in old age as a result of bone-joint wear and tear, rheumatoid arthritis afflicts all ages.

It is an auto-immune disease where the body attacks its own tissue, causing inflammation, swelling and joint pain.

Sydney rheumatologist Dr Mona Marabani, vice-president of the NSW Arthritis Foundation said around 20,000 patients required Enbrel — but the cost was prohibitive.

Last year Enbrel was recommended for inclusion on the Pharmaceutical Benefits Scheme. If approved it would have brought the price down to $23.10 per script, or $3.70 for concession card holders.

The Federal Government this week delayed listing the drug on the PBS. It would cost taxpayers $70 million to $140 million a year to list and the Government said it wanted further advice on whether it should agree to a subsidy.

While the Government has not been specific about what advice it has received, Professor Lloyd Sansom, chair of the Pharmaceutical Advisory Committee which recommended its listing, suspects cost may be the overriding issue.

"You don't find that amount of money under the floor," he said.

"I suppose, to Cabinet, $140 million is a very large sum of money and it wants some points clarified.

"People shouldn't confuse our recommendation as guaranteeing government approval."

Dr Sansom said his committee had investigated the cost benefits of the drug for 12 months.

"It's a cost-effective drug in a severely disabling condition," he said. "It's part of the new generation of biotechnology drugs which stops the action of the factor which destroys the tissue in the joints."

Dr Marabani said she was confident strict protocols on the administration of Enbrel would ensure against a blowout in funding.

"Enbrel would not be necessary for everyone because up to 90 per cent of people will respond to cheaper therapies currently on the market," she said.

"We are only looking at 5 per cent of cases — the really hard cases — people who've failed to respond to standard therapy or who have had side effects.

"[redacted]heumatoid arthritis damages joints over a prolonged period and Enbrel could help prevent disability. However, it was not effective in all people.

"I know of one patient who has managed to keep a job because they are taking Enbrel. Their income from the job pays for the therapy," Dr Marabani said.

Arthritis Foundation NSW executive officer Philip Hopkin said he was puzzled by the Government's delay.

"We believe these are very important drugs," he said.

"They can prevent rheumatoid arthritis from destroying joints and they should be available through rheumatologists.

"We are very disappointed the Federal Government has put off the decision."

Nadine Garland, 34, said she had been counting on Enbrel because other therapies had damaged her liver.

"This was my next big hope because I failed on other drugs," she said.

Ms Garland worked as a nurse before rheumatoid arthritis forced her to stop.

She is now working part-time for a medical call centre.

"The disease is painful and I have limited mobility. I couldn't continue nursing because I couldn't lift.

"I was hoping Enbrel might reduce the pain and swelling in my joints, increase my mobility and possibly get me back into full-time work.

"I would like the people making these decisions to go a day with arthritis. It's hard to put a value on pain and limited mobility.

"That's where being human comes in. It can't all be about money, surely."

Daily Telegraph 14/6/03

Mum's last-gasp plea to federal MPs

Let me see my kids grow up

By JEN KELLY, medical reporter

A YOUNG Victorian mother fears she will be dead within months unless the Federal Government pays for a $40,000-a-month drug she needs to survive.

Tina Powney, 29, is in the last stage of an extremely rare lung disease and is afraid she will never see her children grow up.

In a desperate 11th-hour plea through the *Herald Sun*, the mother of four has called on federal politicians to find it in their hearts to fund the drug.

Ms Powney, from Kerang in the state's north, suffers from primary pulmonary hypertension and believes the drug, Prostacycline, is her last hope.

She breathes oxygen from a machine through tubes in her nose 24 hours a day and takes 22 pills a day to stay alive.

Her few outings include rare visits to her church on some Sundays, carting an oxygen tank. Friends and family help care for the children because she is unable to even dress herself without gasping for air.

Her husband, Scott Justin, is unable to work more than casual shifts because he must care for her and the children.

Ms Powney learnt this week she might have only months to live after battling the disease for 2½ years.

Her doctor, Alfred Hospital respiratory specialist Associate Professor Trevor Williams, said the drug was her best hope.

"From the available scientific information, Prostacycline is the most effective available drug," he said.

But he said the hospital could not cover the cost of almost $500,000 a year.

Professor Williams said Ms Powney was one of about 250 Australians who would benefit if the drug was subsidised.

Ms Powney is furious the Federal Government won't pay.

"They shouldn't have the choice whether people live or die," she said.

"Trevor would love to give me the drug but the hospital just doesn't have the money.

"I want the politicians to look in their hearts and realise this could happen to a member of their family or a friend.

"You look at your little kids, and you don't know whether it's going to be your last Christmas, and you don't want to say goodbye."

Ms Powney is ineligible for a lung transplant because she is 14kg overweight. Other drugs have failed to greatly improve her condition.

She believes if she received Prostacycline and her condition stabilised, she could exercise and lose weight to become eligible for a transplant.

Some patients taking the drug improve so much they no longer need a lung transplant.

If she dies, Mr Justin will be left to care for James, 12, Sharnah, 10, Kiarra, 4 and Tyron, 2, on his own.

Drugs can only be subsidised if drug makers apply to the Federal Government.

Professor Williams said it was well known that such high-priced drugs did not win subsidies so it was unlikely the drug's maker, GlaxoSmithKline, had applied. The firm could not confirm this yesterday.

"This drug is like liquid gold," Ms Powney said.

"I have a friend in Canada who has been on this drug for 10 months and she's doing wonderfully, and she's about to go back to work part-time."

Ms Powney's eldest son, James, suffers from hydrocephalus, or fluid on the brain. He spent most of his first five years at the Royal Children's Hospital and has endured 22 operations.

"I worry about the kids, and how James will cope in life without me," Ms Powney said.

"The only dream I have is to see my children grow up. My kids deserve to have a mum."

Herald Sun 18/6/03

Arthritis cure a victim of cost cutting

Australian Financial Review
18/6/03

The arthritis 'wonder drug' Enbrel is too expensive for the government to put it on the PBS list just now, writes Morgan Mellish.

Pharmaceutical manufacturer Wyeth began trying to get a government subsidy for its arthritis "wonder drug" almost five years ago.

On Tuesday, it was bitterly disappointed when the federal cabinet deferred making a decision, citing concerns about its cost.

The delay, which could mean that arthritis sufferers won't get Enbrel for many months, highlights the Howard government's battle to rein in the nation's rapidly growing scheme for subsidising drugs.

"We believe this drug is worthy of consideration of funding," says Lloyd Sansom, who heads the Pharmaceutical Benefits Advisory Committee, the independent group that recommends which medicines should be subsidised..

"We've looked at it for a long, long time. We've had ongoing consultations with the Australian Rheumatology Association. It's been a very good, co-operative effort.

"I know the Health Minister Kay Patterson would think exactly the same thing, but when you get a predicted bill of about $140 million, there is some fiscal uncertainty because we don't know what the pool of people is who will use the drug."

The pharmaceutical benefits scheme is one of the fastest growing areas of government expenditure. In the last five years, its cost has nearly doubled to $4.6 billion.

To try and save money, the government has attempted to increase the amount that patients pay for drugs in the scheme, but this has been blocked in the Senate by Labor and the minor parties.

As a result, Canberra is now cutting costs any way it can. This includes introducing strict rules on how drugs can be prescribed and, according to critics, lengthening the PBS listing process by adding more layers of bureaucracy.

For example, early last year it was decided that cabinet would have to approve any drug which could cost the PBS more than $10 million a year. Since then it has approved most of the big-name drugs which have come before it.

But in the past 18 months one product, Viagra, has been knocked back by cabinet and two others, the diabetes drug Avandia and Enbrel, have had their listing delayed.

"Companies say they are being made to jump through more hoops."

"Every nation in the world rations health because nobody can afford to buy everything," the Australian Consumers Association's health policy officer and former PBAC member, Martyn Goddard, says. "But when politicians impose their own judgement ahead of experts evaluating the evidence, then they are likely to get it wrong."

The intervention by cabinet – which was rare under previous governments – has prompted claims by drug companies that they are being made to jump through more hoops.

Wyeth Australia's director of corporate affairs, Rachael David, said the Enbrel proposal that went before cabinet this week had strict savings measures. Only specialists could prescribe it, and only to about 1300 patients in the first year.

"Given it's available in most of Europe, it's devastating to these people [arthritis sufferers] that we haven't been able to reach a conclusion," she says. "The process is becoming more and more lengthy every year. I've no doubt that it is in large part for cost control."

Health industry experts say the government was burnt several years ago by two subsidised medicines that cost taxpayers hundreds of millions of dollars more than expected.

These products – the anti-smoking drug Zyban and the arthritis pill Celebrex – were widely prescribed, and prompted the latest crackdown on who is eligible for newly-listed drugs.

The health minister makes no apologies for delaying Enbrel's listing, saying that the money at stake – about $140 million in the first year – was too big for the decision to be rushed.

"Clearly it is important that decisions of this nature are carefully considered," Patterson says. "Sitting back and doing nothing to tackle the growth [in the PBS] is not an option." Without a subsidy, Enbrel costs $18,000 a year per patient. If it was on the PBS, patients would pay $23 a script, and concession cardholders $3.70.

Sansom says the government's caution is understandable, given its experience with Zyban and Celebrex.

"The PBAC has been asked to try and improve the predictions about uptake and total cost," he says. "The government wants us to try and put into place those things which will actually prevent and minimise the risk of use outside the approved indications."

Krystle's pain over delay

Drug listing means relief from suffering

Daily Telegraph
13/6/03

By SUE DUNLEVY

KRYSTLE Brown is just 13, crippled with arthritis and can't walk or dress herself, but had to stop taking a drug that helped her because she couldn't afford it.

Krystle's mother Marilyn yesterday pleaded with the Government to list the drug, reducing its cost from $18,000 a year to as little as $3.70 a week for welfare recipients, or $23.10 a script.

Federal Cabinet this week delayed listing the drug on the Pharmaceutical Benefits Scheme, at a cost to taxpayers of between $70 million and $140 million a year.

Krystle is one of 181 people currently taking the drug Enbrel, but arthritis groups say up to 4000 Australians can benefit.

The Daily Telegraph reported yesterday that Mathew Johnston, 11, could be forced back into a wheelchair when charity funding for his Enbrel treatment runs out in six months.

A donor came forward yesterday offering to pay for a further six months of treatment.

The Daily Telegraph was yesterday contacted by many families whose children and adult relatives desperately need the medication but can't afford it.

Krystle has had rheumatoid arthritis since she was 15-months-old and the disease has affected her joints so badly she can only walk in a hydrotherapy pool.

She needs to have both hips replaced and until she began taking Enbrel was in severe pain.

"She has a wheelchair, and splints for her legs and arms, which help put her joints at a comfortable range," her mother Marilyn said yesterday.

A friend pushes Krystle's wheelchair for her at school and her mother had to give up work to care for her full-time.

Krystle tried the drug as part of a clinical trial, but when the trial ended, her family could not afford to pay for it.

Six months after stopping the drug, the Westmead Children's Hospital found the funds to pay for her treatment, but that funding is not guaranteed indefinitely.

Since Krystle began taking Enbrel she is not waking up in pain, she has more freedom of movement and her blood tests have improved.

The Government's expert advisory committee on the PBS recommended that Enbrel be subsidised last November, but Cabinet wants more information.

The Government does not want a repeat of the experience when arthritis drug Celebrex was listed and was widely prescribed, costing it hundreds of millions more than expected.

A spokesman for Health Minister Senator Kay Patterson said approval for the drug was "in no way being held up by the Government" and would be going before Cabinet again "very soon".

Sufferers' pleas

‘I have a sister who suffers from psoriasis plus a form of arthritis. I have seen her unable to get out of bed or unable to walk because of the pain. Still, she manages to go to work and pay taxes even though most days she is in so much pain. The Federal Government hasn't seen the pain people with these conditions go through.

My sister pays out about half of her wages on treatment that is in effect useless. She is an outpatient, putting more strain on an already strained health system.

I believe the cost spent on putting this drug on the PBS is far less then the cost to the government.’

— Jason Weston

‘My ex-husband has extremely severe RA which is not responding to the drugs available to him. He is often in severe pain and suffers from debilitating side effects of the drugs he takes.

Enbrel offers some hope for the future for him.

The cost of his ongoing medication, operations and his inability to rejoin the workforce would seem to be much greater than the $18,000 it would cost to supply him with a drug that would make an enormous difference to his health and economic situation.’

— Sue Blundell

I am 25-years-old and suffer from psoriatic arthritis. I have been on methotrexate for the past year and reached a maximum dosage of 25mg per week, this has since dropped due to side effects suffered. Unfortunately it is one of my last options as many of the other medicines make you sterile.

I believe that the government really needs to reconsider its position.’

— Niki-Jean Weston

Sydney Morning Herald 10/6/03

Put us out of our misery: woman's plea for arthritis medicine

Marian Vickery's arts marketing career spanned Australia's cultural icons, including the Museum of Contemporary Art and Opera Australia.

That was until rheumatoid arthritis took over her life. Now a disability pensioner, she fights off pain and immobility to turn her marketing skills to campaigning for a new drug.

It has taken Ms Vickery and others, including the manufacturer, Wyeth, five years to convince Australian officials that the $18,000-a-year cost is worthwhile. The drug, Enbrel, widely used in North America and Europe, is expected to get final Government approval for subsidies soon, but will be subject to unprecedented controls.

The Pharmaceutical Benefits Advisory Committee has recommended that the drug only be prescribed when a patient's rheumatologist meets a long list of conditions.

The chief executive of the Arthritis Research TaskForce, Bridget Kirkham, said the prescribing controls are the most detailed handed down by the committee and are likely to be followed in future for other high-cost drugs.

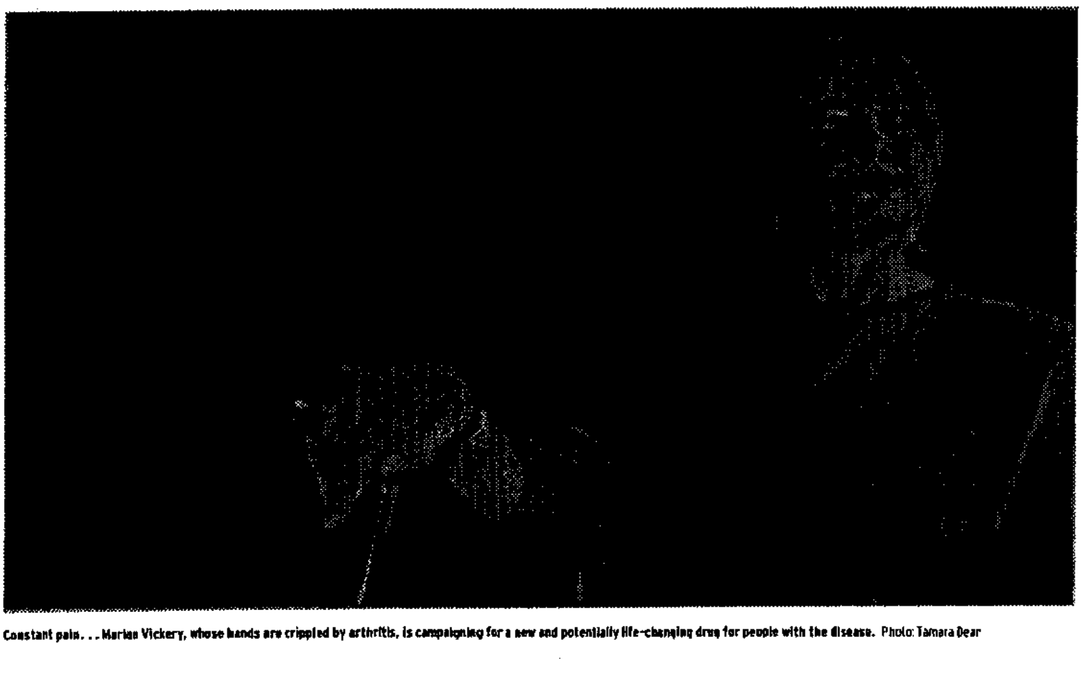
Rheumatoid arthritis hit Ms Vickery in her 30s. Normal life for her is now a memory. The joints in her fingers are under assault from constant inflammation and bone erosion. and domestic chores have become extreme challenges.

"The pain becomes background noise," says Ms Vickery, who has been hospitalised four times and had two operations to halt further damage to her hands.

She understands the aim to ensure there is no huge increase in costs. "But if Enbrel worked for me, it would reduce all those hospital and doctors' bills, and I could go back to work at least part time and pay taxes.

"While they are deliberating on criteria, I'm getting more frail and unwell... which makes it a more distant prospect to imagine I can become well enough to go back to work or function independently."

Mark Metherell



Constant pain... Marian Vickery, whose hands are crippled by arthritis, is campaigning for a new and potentially life-changing drug for people with the disease. Photo: Tamara Dear

Anger at rejection of leukemia drug

By Medical Writer
BARRY HAILSTONE

DOCTORS are angry that a drug to treat a rare and otherwise incurable form of cancer has been rejected for a third time for listing on the taxpayer-funded Pharmaceutical Benefits Scheme.

The drug known as Glivec is approved for treating leukemia-type cancers but not gastrointestinal stromal tumours (GIST), a form of stomach cancer which doctors say responds dramatically to its use.

A cancer specialist at Melbourne's Peter MacCallum Institute, Professor John Zalcberg, said 75 per cent of Australian GIST patients on Glivec in a trial were alive and well 18 months after starting a course.

"Without it half would die within one year," he said.

Prof Zalcberg and other specialists of the Australian and New Zealand Gastro-Intestinal Cancer Institute met in Adelaide last night to report on GIST and Glivec treatment to cancer patients, doctors and groups.

The drug costs $50,000 a year to treat one patient.

Prof Zalcberg said up to 100 new patients a year would benefit if the drug were approved for PBS listing by the "cost sensitive" Pharmaceutical Benefits Advisory Committee.

"There is no other known treatment and we are distressed, angry and confused why it has been rejected for the third time," Prof Zalcberg said.

"The clinical and cancer communities have lost confidence in the ability of the advisory committee to address the needs of cancer patients."

Committee chairman Professor Lloyd Sansom said the committee was trying to find Glivec's proper place in cancer therapy.

The committee had first to identify patients who would respond rather than maintain on very expensive drugs those who would not respond.

Adl Advertiser 25/6/03

Drug still not listed

By VANESSA McCAUSLAND

THOUSANDS of Central Coast people with diabetes are missing out on a "miracle drug" because the Federal Government has twice deferred its listing on the Pharmaceutical Benefits Scheme.

The wait is heartbreaking for local insulin-dependent diabetics, as they see France, Sweden, Spain and Asia join the US, the UK and Germany in introducing the drug.

Melissa McGarrity, 12, from Hardys Bay began to treat her type one diabetes with insulin Glargine, or Lantus, just three months ago.

The positive effects were immediate for someone who has been dealing with diabetes since she was a baby.

"I've had diabetes since I was 13 months old. But this new drug has changed my life. I can basically be a normal kid again. With this I can just have the one needle a day, instead of five. It keeps my blood sugar levels at a normal person's level," she said.

A spokeswoman for Lantus said the drug was different to other insulin because it didn't have the variability of other insulin in regulating blood sugar levels and had long-term health benefits in terms of kidney, heart and eye problems.

Melissa is now able to exercise and attend school camps — activities her mother, Christina Simpson, was hesitant about before her daughter began taking the drug.

"She has just started jazz, which she is very excited about," Mrs Simpson said. Melissa is also excited about the freedom she has gained since beginning Lantus.

"Because it delivers in a steady stream instead of peaking and troughing like conventional insulin does, I can eat food more normally and not worry about going for a run," Melissa said.

But that freedom has come at a cost. The family has to fork out $500 every three months.

This includes $200 for postage and handling and between $50 and $100 in customs duty.

The drug is made in Germany and only available over the internet.

The Lantus spokeswoman said the company had spent the past 18 months pushing for the drug to be listed on the PBS.

"But the Federal Government has deferred our application twice."

Toll of the illness

- **Diabetes** is a condition where there is too much sugar (glucose) in the blood because the body is not able to produce enough insulin
- **Type** one diabetes usually onsets during childhood and requires insulin dependence
- **Type** two diabetes is more common and usually occurs in adults aged over 45

Daily Telegraph 17/7/03

Aust Financial Review
6 May 2002.

Count PBS's benefits, not just its price

Budget 2002

The problem with the Pharmaceutical Benefits Scheme is not so much cost as a lack of transparency, maintains **Ben Harris**.

The Pharmaceutical Benefits Scheme is seen as a prime target in what will be – as the Treasurer reminded us yesterday – a tough federal Budget.

The PBS is viewed as a fat, "spiralling", and "unsustainable" program, one that cost taxpayers some $4 billion last year. The trend in expenditure growth of the PBS exceeds 15 per cent per annum. PBS expenditure hit $1 billion for the first time in 1988-89, grew to $2 billion in 1995-96 and $3 billion in 1998-99. At this rate it is likely to reach $5 billion by 2003-04 and $10 billion by the end of the decade.

We always need to keep a close watch on government expenditure. In my view, governments spending money is inherently wrong – it is implying that the Government knows better than the people it is governing, and is prepared to take our money to do things that individuals will not do without coercion. So it is vital that when governments spend our money, they tell us – we being the taxed and governed – what they are doing with it. I want a clear demonstration that the benefits to the community of government spending are greater than the costs.

Politicians, bureaucrats and other media commentators hysterically promoting the idea that taxpayer-funded PBS spending is "out of control" is not what I am looking for. I want more from my elected officials. I want to know what the PBS is doing for me and the community.

Pharmaceuticals allow thousands of people to make a better contribution to society – witness the many who were disabled by their illness, could not work before but who can now do so.

Due to pharmaceuticals there are fewer people relying on social security payments and more paying tax. Consequently, there is more money circulating in the community, which in turn accelerates economic growth.

Fewer people waiting in public hospital queues also reduces the general community burden to the health system. It also follows that carers, friends and family are able to do more work, thus paying more tax and increasing their own economic contribution to society.

The problem is one of transparency. Governments can count up to $4 billion in one program on just one hand. On the other hand, the benefits outlined above are hard for bureaucrats to define or quantify in a straightforward and meaningful way.

Another impediment is the make-up of the Pharmaceutical Benefits Advisory Committee, which approves drugs for PBS listing. Medical practitioners, professors and scientists dominate the committee, and so focus on the health benefits.

Sure, we need scientific advice to help determine if the drugs work, but decisions on subsidies need to be made in a more comprehensive and accountable manner. Economists, community members and social scientists should be making the call on public subsidy based on the effects of the drug for the community as a whole, rather than a medical model determining economic results. Results and discussions need to be public, to assure accountability and to provide information to medical practitioners prescribing the drugs.

The size of the PBS is not, of itself, a problem. The process may be. It's my hope that the Commonwealth rejects short-term, administratively complex "solutions" to the growth in PBS expenditure. Rather, the Government should look at why we subsidise drugs and engage the community through a transparent, representative process. If this process shows that a growing PBS is good for the community, then we can celebrate the rapid growth in the PBS rather than run around screaming that the sky is about to fall.

■ *Ben Harris is the vice-president of the Australian Federation of AIDS Organisations.*

Children failed by asthma bickering

By SUE DUNLEAVY

CHILDREN with asthma are missing out on a revolutionary new treatment because of bureaucratic wrangling over cost.

Subsidies for the breakthrough asthma tablet are being held up by a tough Federal Government approach to controlling the cost of its medicine subsidy scheme.

The drug, Singulaire, is expected to help around 20,000 Australian children who have frequent episodic and mild persistent asthma.

It replaces the current treatment, in which sufferers use a puffer to administer medicine, with a tablet that ensures a defined dose is delivered.

It was approved in January for listing on the nation's Pharmaceutical Benefits Scheme (PBS) but a dispute over how much the Federal Government is prepared to pay is delaying its listing.

Drug company Merck Sharp and Dohme believed it had reached a draft agreement with the Federal Health Department on the price of the drug at the end of February.

But the Finance Department is now insisting on a price volume agreement to prevent a blowout in the cost to the PBS similar to that caused by the listing of the new arthritis drug, Celebrex.

The Federal Government also introduced a rule in the May Budget requiring all drugs costing more than $10 million a year to get approval from Federal Cabinet.

Health Minister Kay Patterson yesterday said it was not true a price agreement was reached in February.

Senator Patterson's spokesman denied the Government was delaying the listing to save money, arguing it simply wanted to get the best value-for-money deal for taxpayers.

The drug company is understood to be keen to avoid a price volume agreement, which means it would have to repay the Government if the drug cost more than its agreed budget each year.

The Government is concerned about the ballooning cost of the $4.2 billion PBS and in the May Budget attempted to save $1.9 billion by raising the patient charge for drugs by $6.20.

This measure was rejected by the Senate and senior ministers suggested this might make it harder for the Government to list new medicines.

Singulaire is one of a number of medicines approved for listing that have been held up by disputes over the price the Government is prepared to pay.

Others include two drugs to treat type 2 diabetes, Avandia and Actos, and a drug to treat chronic obstructive pulmonary disorder, Spiriva.

Senator Patterson denied there was any link between the delay in approving Singulaire and the failure of the Budget measure to pass the Senate.

The drugs would be listed as soon as an agreement on price was reached, the Senator's spokesman said.

The listing on August 1 of five new drugs that treat schizophrenia, stomach ulcers, hypertension, glaucoma and hepatitis C was proof the Government was not delaying subsidising drugs to save money, he said.

"The Government is not going to cave into pressure from drug companies," she said.

"Drugs won't be put on [the PBS] without the best possible deal for taxpayers."

Pharmaceutical benefits scheme

NEW LISTED SINCE AUGUST 1

- **Solian:** treats schizophrenia
- **Nexium:** treats stomach ulcers
- **Bicor:** treats hypertension
- **Travatan:** treats glaucoma
- **Pegintron:** treats Hepatitis C

DRUGS APPROVED BUT AWAITING LISTING

- **Singulaire:** treats childhood asthma
- **Arandia** and **Actos:** treat type 2 diabetes
- **Spiriva:** treats chronic obstructive pulmonary disease

Daily Telegraph 14/8/02.

Flawed pharmaceutical system poses a health risk

The PBS can't be perfect if patients are denied access to valuable new drugs, says **John Zalcberg**

CONVENTIONAL wisdom has it that Australia's Pharmaceutical Benefits Scheme is the world's best government system for subsidising medicines. How many times have we heard that in the debate over the pending Australia-US free trade agreement?

But although we have every reason to be proud of our health system, we should not be afraid of constructive criticism that could lead to its improvement, especially in relation to access to medications. Far from being near perfect, the PBS prevents much needed reform and baffles numerous medical specialists in virtually every discipline.

Many specialists, like me, are frustrated by unexplained delays that seem to be based on non-transparent, economic or bureaucratic processes dictating the PBS decision-making process. So much for higher priority being given to health outcomes.

This often prevents specialists from being able to treat patients with life-saving or life-prolonging medications in a timely manner. It can take many months, and sometimes even years, for new-generation medicines to make their way through the system, and in this area we are at risk of increasingly falling behind other developed countries.

Not heard of such delays before? The media is rarely aware of the extent of the problem because of the confidential nature of the process by which medicines are subsidised. Often it takes a serious illness to alert you to the fact that there is a better treatment available, which you may or may not be able to access.

As cancer specialists, my colleagues and I are confronted by situations where cancer patients have difficulty accessing new-generation therapies that we believe would be to the patient's advantage. This restricted access to new medications that hold so much promise is the essence of our concerns about the PBS's ability to cope with the new generation of drugs. The question is: do patients want doctors to focus on the latest advances in treatment, or to accept the financial constraints that prevent the existing system from providing new medicines to the public?

Let me offer some examples. Eloxatin and Camptosar are among the important new drugs in the initial treatment of advanced colon cancer. Yet they are still not PBS listed, although they have been available for years in many other Western countries.

The PBS system, which was established to ensure cost-effective medicines are readily available to treat patients in need, appears increasingly to be used to ration healthcare. Imatinib is a new drug that targets a specific growth factor receptor in the rare gastrointestinal stromal tumour. This drug, which significantly prolongs life for victims of this disease, for which no other chemotherapy is effective, was rejected twice and deferred once by the Pharmaceutical Benefits Advisory Committee, which recommends therapies for PBS listing. It was approved only after 30,000 signatures were delivered to the consumer representative on the PBAC.

HERCEPTIN — arguably the most effective drug developed for advanced breast cancer in the past decade — was rejected three times by the PBAC. Ultimately, it was only made available outside the PBS after the then health minister Michael Wooldridge responded to legitimate concerns from physicians and consumer groups. Before this, less than 10 per cent of women who could have benefited from this important new drug had received it.

Is this really the perfect system? Given that about one-third of the community will develop cancer at some point during their lives, are patients prepared to let this rationing behind closed doors continue as health economists debate the value of their life?

Is the PBS such a perfect system when effective drugs are only approved after confrontation between the PBAC and angry lobby groups or frustrated clinicians? Is it such a perfect system when patients miss out on new drugs — drugs that work and are available overseas, yet are denied to patients in Australia because the PBAC and the pharmaceutical company can't agree on a price?

Is cost or benefit or value to be the principal determinant of the availability of new-generation medicines? Will access continue to be driven by arbitrary measures of cost-effectiveness that ignore the indirect health benefits of effective medicines such as a person's increased workplace productivity or the cost of more invasive therapies?

It's easy to accuse the federal Government or the PBAC of intentionally delaying the introduction of new medicines to limit costs. But how can the community deal with the increasing costs of new therapies? Short of reducing expenditure on wholesaling or pharmacy (which adds up to almost one-third of the $4.5 billion PBS budget), the available pool of funds needs to be increased — whether it's through higher co-payments or taxation — to pay for the drugs of the future.

The PBAC and the Government should talk with medical professionals and industry bodies as well as consumers. We need to focus on the significant benefits that medicines provide. And we need to look at improving the PBS, with or without a free trade agreement with the US. Too many lives depend on it.

Professor John Zalcberg, a Melbourne cancer specialist, has been an adviser to pharmaceutical companies. These are his personal views.

The Australian 15/12/03

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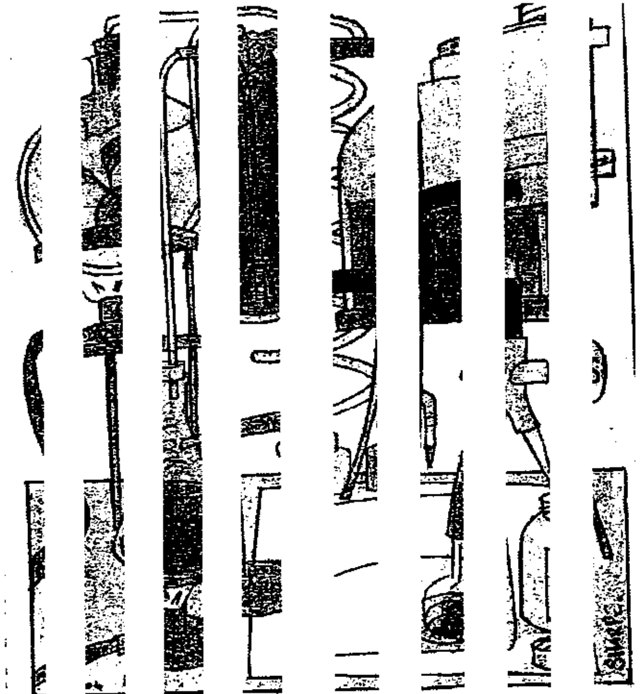

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Fed: FTA could attract $1 bln of research to Aust: MATrade US Drugs

CANBERRA, Feb 16 AAP –
A free trade deal with the United States could attract $1 billion worth of research to Australia, Medicines Australia said today.
The organisation's chief executive, Kieran Schneemann,said the deal and
changes to the Pharmaceutical Benefits Scheme (PBS) would act as an incentive for American firms to invest in Australia.
The trade deal, signed last week, commits Australia to greater transparency
in the decision-making process when listing drugs on the PBS.
Mr Schneemann said US firms spent $40 billion per year on pharmaceutical
research.
``If the Australian biotech-medicines industry attracts just two per cent of
that research expenditure, it will be worth more than $1 billion," he said in a statement.
``And we will see more partnership programs between Australian research
institutions and the pharmaceutical industry in the US and Australia, similar to the US-Australia partnership, that is developing a vaccine for cervical cancer."
Mr Schneemann said Australia had many advantages which could help the
country become a medical research hub, including excellent medical industry
infrastructure, high-quality clinical research capability and innovative biotech companies.

AAP sw/tma/br

Grim reapers off the mark

Not even facts convince doomsayers to change course on the trade deal

Janet Albrechtsen

WITH news of the Australia-US free trade agreement, it's time to revisit that vast gallery which houses the Left's growing collection of doomsday scenarios on free trade that proved wrong.

Start with Catholic bishop Pat Power who last November, without any detail before him, denounced any form of free trade agreement. As Trade Minister Mark Vaile headed to Washington to meet his US counterpart Robert Zoellick, the protectionist priest predicted on ABC radio that on health and social policy Australia's independence as a nation "very much is going to be swallowed up by big brother".

The scare campaign on health had already been ramped up with dire warnings by academic Clive Hamilton from the Australia Institute. Last August he predicted that prices for drugs for asthma, high blood pressure and arthritis could rise by more than 300 per cent under the FTA. Americans pay much more for their drugs, he said, and the Howard Government would trade off our cheap drug prices in return for Australian farmers gaining access to US markets.

"The devil is in the detail," Power warned. The Government released some devilish detail on Monday. Affordable medicines will be maintained under the FTA. There are no price increases to prescription medicines. There are much needed changes to make the system of approving PBS drugs more transparent. As the Howard Government made clear numerous times, slicing up the PBS was never on the negotiating table.

The media laps up these brothers grim because emotion is a bigger seller than economic literacy or even logic.

Martyn Goddard, the Australian Consumer Association's health policy officer, told one newspaper last year that without the PBS he would be dead. Diagnosed with HIV, Goddard said he could never afford the real cost of his life-saving drugs. A small dose of logic suggests that PBS is simply the vehicle for administering life-saving drugs. The drugs only exist because companies take significant risks on innovative research and development. They are more likely to do so now that the approval system is more transparent. Strange how Goddard is blind to this pro-consumer outcome.

The next exhibits include various predictions of cultural death Australia would suffer from a free trade agreement with the US.

Last November, at the Australian Film Institute awards, a long line of Australian actors, including David Wenham, Toni Collette and Geoffrey Rush, performed a very boring, very public political morris dance to the tune of Down With John Howard. Down With Free Trade.

A FEW days later, actor John Howard added: "We need to tell the US that we will decide now and in the future what stories will come into our country. If we won't protect our own culture, nobody else will."

No wonder Howard the actor is afraid of competition; these days he seems to trade more on mimicking his namesake than on his talents.

Protecting Australian culture makes sense, but beware film types who hide under the cover of culture as decreed by them whenever they churn out second-rate movies. In any case, those who predicted cultural terrorism predicted wrong. Culture has fared just fine under the FTA. Local content rules remain intact. And there is scope to impose more cultural limits as new media technologies emerge.

No tour of doom and gloom predictions is complete without hearing from the workers' friend, the unions. Joining Power and Howard at the same cosy press conference was Australian Manufacturing Workers Union national secretary Doug Cameron. Not to be outdone in the faux Grim Reaper stakes, he warned that the agreement "could threaten thousands of jobs" and Australia should not trade away its ability to decide industry policy for local employment.

More devilish detail unravels that tale of woe. More than 97 per cent of Australian exports to the US will be free of duty as soon as the FTA is up and running. As the Prime Minister said in his press conference on Monday, companies which, for example, produce utes were previously kept out of the US market by hefty 25 per cent tariffs. Now they can export them duty free. That means more jobs, not less, in this and other industries. And the FTA cements the right of both countries to enforce its own labour laws.

As Ford Australia notes, the FTA will impose competitive pressures on Australian industry, but some industries (film included) could do with a healthy dose of competition. If competition produces a more efficient industry, that is good for employment.

The only safe jobs are those in globally competitive industries. Hardly rocket science but it is beyond those like Greens Senator Bob Brown, who peddle in dishonest gloom rather than logic. He intends to vote against the FTA because "it's a disaster for Australia".

The FTA may not be perfect. There are sensible criticisms that can and will be made about insufficient tariff reductions in some industries and undue delays in how they are implemented in others, such as agriculture. However, madcap claims that the entire agreement should be scrapped because the US refused to budge on sugar quotas is just more bunkum.

The Australian 11/2/04

A chance to make PBS better

By Brendan Grabau

POTENTIAL changes to Australia's Pharmaceutical Benefits Scheme have emerged as a major sticking point in the Australia-United States Free Trade Agreement.

This has sparked panicked reactions from various parties.

Labor trade spokesman Steve Conroy has called on Prime Minister John Howard and Trade Minister Mark Vaile to stand firm and tell the US that the PBS is off the negotiating table.

The Greens, claiming the financial viability of the PBS is under threat, seem to want Australia to withdraw from negotiations altogether. Even US Democrats, seizing a political moment, have sounded alarm bells.

Yet the proposed changes to Australia's world-renowned drug-subsidy mechanism will not affect its essential character. Indeed they could leave the PBS in much better shape.

It seems that Australia has already fought and won the hard fight with the US to protect the essential nature of the PBS. The fundamental principles of the PBS, such as subsidised patient access to prescription medicines, co-payments based on patients' ability to pay, reference pricing, cost-effectiveness, pharmo-economic evaluation, and an evidence-based listing process are certain to remain untouched by an FTA.

It appears that recent negotiations on the PBS relate to the process — the way medicines and their respective merits are considered and treated in the PBS system.

This does not affect what the Government or Australians spend on medicines. This is reasonable and can only benefit Australian patients, doctors and industry.

The process of listing medicines on the PBS is in desperate need of improvement, with or without an FTA.

The ALP seemed to agree with this in 2003 when the former Opposition spokesman on health, Stephen Smith, wrote in *Pharmacy Review* that it was necessary to look at viable sustainable measures. He said that the listing process needed to be more transparent and to be more accountable to the community and the various professions within it.

This has also been the sentiment of various medical specialists who have lamented the delays in treating patients with the best technology available while medicines get caught up in the bureaucracy of the PBS. Patients too have often wondered why the PBS system can sometimes be frustratingly bureaucratic or make decisions that seem to be political, rather than based on merit.

Concerns about the future of the PBS may be misplaced — the FTA negotiations could well provide the catalyst to change the PBS listing process for the better.

For instance, a key element to the negotiations is the implementation of a PBS appeals mechanism, which would be open to industry whose medicines have failed to achieve a PBS listing.

Doctors, patients and industry in Australia have been calling for this type of mechanism for a long time.

Perhaps this is something that the Australian negotiators should carefully consider.

The Australian Government has long promised local industry and patient groups such a mechanism.

Given that the PBS spends $4.5 billion of taxpayers' money annually, it is reasonable that patients, doctors and industry understand how and why decisions not to list innovative and life-saving medications, available and used overseas, are made.

The current lack of transparency sometimes baffles Australian patients/consumer groups. The decision to list a medicine on the PBS needs to be seen to be based on merit, and not politics.

It is clear that with the current FTA negotiations, Australia has a real opportunity to make positive changes to the PBS that will improve its function and make it a more certain process for industry and consumers.

Howard has said that a trade deal would only proceed if it were in Australia's best interests. This is clearly the case with the PBS.

Dr Brendan Grabau is the chief assessor of the Pharmaceutical Continuing Education Program, Deakin Prime, Deakin University.

The Canberra Times 28/1/04

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Nation's health will benefit from US drugs

An accountable PBS is good news for everyone, suggests Bryan Mercurio

JUDGING from the reaction to the free trade deal with the US, one could be forgiven for thinking that those imperialist "Yanks have screwed Australia (again). *The Sydney Morning Herald's* front-page headline yesterday lamented "US gets upper hand in trade deal". Political scientist Ann Capling complains that Australia has been sold out. And according to Greens' senator Bob Brown: "The Howard Government has been slaughtered."

Yet contrary to these doomsayers, it is Australia that has fleeced the US. The Howard Government not only negotiated the best deal it could have possibly received from the US, but it secured most of what it wanted without giving any ground on the controversial issues of film and television quotas or investment. And despite a campaign of misinformation picked up by some political figures throughout the past year, Australia was not forced to dismantle the Pharmaceutical Benefits Scheme.

What Australia was "forced" to do was to make the PBS more transparent and accountable, not to the US pharmaceutical industry, but to the Australian people. The US pharmaceutical companies may have pushed this change, but we should be pleased that they correctly pointed out that the PBS does not give sufficient weight to the benefits certain drugs may have on the quality of life of the person taking the drugs.

For instance, let's say a drug listed on the PBS takes two weeks to heal a patient, but that during the two weeks the patient remains in pain. If a new drug comes along to compete with and possibly supplant an existing drug on the scheme and also takes two weeks to heal the patient but yet reduces the pain and improves the quality of life of the patient during the two weeks, that drug will likely be rejected by the PBS as not offering any medicinal improvement over the existing cheaper drug.

Such a decision hurts Australians and forces them to live in pain all because the bureaucrats that decide which drugs are on the scheme see no discernible improvement in the new drug. Thus, in order to save a few dollars, Australians suffer both physically and economically, as people in pain are more likely to miss work than pain-free people.

Now, as a result of pressure from US pharmaceutical companies, we'll know when such worthy drugs are rejected and we'll know when we are being forced to needlessly suffer. Information is power, and this is information that we should have been given a long time ago.

The US Government never wanted to dismantle the PBS. Instead, it wanted the process to become more transparent through the removal of barriers in the form of restrictive listings on the PBS and the "one size fits all" approach to drug-pricing. In essence, if the PBS refused their drugs, those companies wanted to know the reasons why such refusal took place. That is fair enough. The Australian public should want to know that as well.

The PBS, remember, is a government-run scheme that has to balance the budget. But if it refuses a drug that could help Australians on the basis of costs, we should be aware of it. Australians should have the right to know why certain drugs are rejected and have the right to lobby for the inclusion of certain rejected medicines in the scheme.

Trade Minister Mark Vaile assured us that the PBS will not be dismantled as a result of the FTA. Early in the negotiations, he stated: "We're not going to negotiate away our ability to implement good public policy in terms of providing these public services like the PBS, like education and other services. Of course we're not."

Not many opposition leaders or members of the media believed Vaile then, but they have been forced to eat their words. The Government not only safeguarded our local content requirements in the film and television industries, but they also protected the social fabric of our society by not dismantling the PBS.

Not many issues outweigh the benefits of free trade, but the cultural and social survival of our nation is just such an issue. In the final reckoning, not only did Australia secure a free trade agreement on very favourable terms, but it also protected the cornerstones of our social system. Labor and the minor parties should put aside the frivolous politicking and recognise that this deal is good for the future of Australia.

Bryan Mercurio is a lecturer in international trade law at the University of NSW.

The Australian 11/2/04

Letters to the Editor

FTA will not affect costs

IN RESPONSE to David Jarvis (Letters, January 5) a free-trade agreement will not affect the cost of medicines to consumers.

It remains difficult to predict what the US Government or the Australian Government will finally bring to the negotiating table in relation to medicines and the Pharmaceutical Benefits Scheme.

However, some things are certain. It is the sovereign right of Australia to decide how much it spends on health and subsidised medicines in Australia and not the right of other Governments.

Spending on health is considered in the context of the Federal Budget, which the Government must pass through both the House of Representatives and the Senate. Similarly the amount consumers must contribute towards the cost of medicines on the PBS must also be passed through both the Senate and House.

One only has look back to 2002 when the Federal Government tried to introduce a Budget measure to increase the consumer co-payment contribution. It was defeated twice in the Senate.

Each year on January 1, the amount that Australians contribute to the price of medicines through co-payments is adjusted in line with the CPI. For 2004, it has risen from $23.10 to $23.70 and, for those who hold concession cards, from $3.70 to $3.80.

These annual price increases are not related to the free-trade agreement.

Consumers should take comfort in the fact that 2004 is an election year and that the Prime Minister has categorically stated that the essential character of the PBS will not change with an FTA.

(Dr) BRENDAN GRABAU
Deakin University, Melbourne

The Canberra Times 7/1/04

Time to get the facts right about medicines

Brendan Grabau outlines the astonishingly high cost of producing new medicines and supplying them to the Australian public.

PRESCRIPTION medicines are a major media focus in the context of the US-Australia Free Trade Agreement as debate intensifies on whether there should be changes in Australia's Pharmaceutical Benefits Scheme (PBS).

However, there can be no sensible debate until there is an end to the inaccurate information reported in the media in relation to the costs and benefits of medicines, the PBS and the global industry.

The PBS was established in 1948 and was intended to provide pensioners with subsidised medicines. In addition, it provided access to 139 life-saving and disease-preventing medicines to those who required them urgently.

As of May 1, 2003, the PBS covers 593 substances available in 1451 forms and strengths (items) that are marketed as 2558 different products (brands).

Restrictions apply to 778 of the items, 288 of which require an authority prescription from the Health Insurance Commission.

The PBS subsidises about 80 per cent of all prescription medicines available at pharmacies. A subsidy is provided to a consumer each time a prescription is filled.

The co-payment made by consumers is up to $23.10 for most PBS medicines, or $3.70 for concession-card holders.

Subsidising medicines on the PBS is costly but relatively inexpensive compared with the cost of not listing effective medicines on the scheme.

The benefits of medicines have been well documented. Every $1 of increased spending on prescription medicines is associated with a $3.65 reduction in hospital expenditures. If the Government funded both there would be no argument about the cost-effectiveness of medicines.

Further Australian research has confirmed that better health outcomes obtained with modern innovative medicines lead to higher gross domestic product (GDP) by increasing both workforce participation and productivity.

A Yale University study has shown conclusively also that significant workplace benefits accrue from the use of prescription medicines because they reduce absenteeism among chronically ill workers.

In the world's largest study of people at high risk for heart attack or stroke, cholesterol-reducing drugs such as statins reduced the risk safely by a third.

If 10 million high-risk patients

The Canberra Times 26/12/03

[illegible]

PBS needs new diagnosis

Alan Mitchell
Economics editor

The federal government's advertising and Intergenerational Report warns about the potentially unsustainable cost of the pharmaceutical benefits scheme. And yet the government's reforms are stuck in the Senate and there is no consensus about where we should go from here.

Maybe the next step should be an independent inquiry into the PBS.

I can hear the groans now. And it is true that the PBS has been looked at in the course of several recent inquiries and the problems and possible policy responses have been well rehearsed.

No doubt the last thing the people who run the PBS think they need is another inquiry. Yet another inquiry could be precisely what they do need.

The main point of an inquiry would not be to uncover some hitherto unsuspected answer to the PBS's problems. Rather, it would be to focus the public's attention on the problems and the possible answers.

The public's attitude is crucial, and not just because ministers pay too much attention to talkback radio.

The idea of the sustainability of the PBS is based on an assumption about what the public is prepared to pay.

Similarly, the policy responses to the increasing cost of the PBS are likely to involve a trade-off of the scheme's main objectives: the comprehensive availability of drugs, universal access and cost containment.

In the end that trade-off must be the public's decision.

Of course, it is tempting for ministers and public servants to avoid debating tough options "in front of the children". But that is not a sustainable long-term strategy. And this is a long-term problem that will involve many tough decisions.

The Intergenerational Report has been criticised for merely projecting past PBS per-capita cost trends (by age and gender) into the long-term future.

Perhaps, as some critics have argued, the report has overstated the future costs of the PBS. But it is also possible that it has missed important future cost pressures.

For example, it seems likely that the PBS will lose some of its bargaining power as the population ages in Australia and in the United States and Europe.

The PBS derives its bargaining power from its ability to effectively withhold drugs from the lucrative Australian market. That will become more difficult as the Australian population ages and the availability of new drugs becomes a national obsession.

At the same time, population ageing will also increase the cost of health care in the US and Europe and generate political pressure to cut the cost of drugs in those economies.

US politicians have already attacked the system of international price discrimination that has delivered cheaper pharmaceuticals to countries like Australia.

A number of American states have passed or are considering passing legislation requiring that the pharmaceutical manufacturers charge US customers no more than the lower prices charged in Canada, or a weighted average of prices charged in Canada and other countries. Related legislation has also been introduced in the US Congress.

The government should respond to these kinds of pressures in ways that do the least harm to the key PBS objectives of providing all Australians with access to necessary and life-saving medicines at an affordable price.

But that is not guaranteed. Crude cost-capping can be politically easier. The government has already been caught economising on the availability of an expensive new cancer drug, potentially leaving a small number of patients exposed to bills of up to $55,000 a year.

There are no simple, easy answers to the cost problems facing the PBS.

The higher patient co-payments and safety net thresholds sought by the government could be part of the answer. But without a more comprehensive means test, there are serious concerns about the impact on some non-concessional patients.

Reducing or even removing the subsidy for non-essential drugs is another option. But it too is problematic. The PBS spends $40 million a year on common analgesics. But while delisting these drugs seems a simple way to save a lot of money, nearly all of the analgesic subsidy goes to concessional patients.

Moreover, if the subsidy were withdrawn, doctors would prescribe substitute drugs still listed on the PBS. If these substitutes were more expensive, the result could be an *increase* in the cost to the taxpayer.

Other options include budget-holding arrangements and strategies to encourage more cost-effective prescribing.

The optimal solution almost certainly is a sophisticated combination of several of the above, plus higher taxes.

But that solution will be intrusive and involve higher health-care costs for large numbers of people.

To get it right, governments will need the understanding, if not the enthusiastic support, of the public.

Aust Financial Review 17/12/03

Free trade? Go America

Alan Mitchell
Economics editor

When I hear that the Americans are trying to bully Australia's brave free-trade negotiators, my first thought usually is that I hope the Americans succeed.

The reason, as every economist would know, is that most of the economic benefits from pulling down trade barriers accrue to the country cutting the barriers, not to the country gaining the market access.

A few weeks ago an economics professor rang to say excitedly that he'd heard that the Americans were suddenly demanding free access to the Australian university market.

Could this be true? Could an old economic rationalist's Christmases all be coming at once?

Alas, even if the Americans were interested in such a reform, it would be so good for Australian students that our negotiators would be bound to resist it to their last breath. But, as it happens, America's politicians are as determined as the Australian government to maintain the status quo.

Australian universities can relax. The government's subsidies for tertiary students will continue to discriminate in favour of the established, publicly owned universities, and against new private and foreign universities.

There will be no economic rationalist nonsense such as fully transferable vouchers that university students could use to help finance the cost of tuition in any university of their choosing, in Australia or elsewhere.

Any uppity students with ideas of studying at the feet of a US Nobel Prize winner can think again. Any Australian university that feared it might have to lift its game to compete with American universities can relax. And any enterprising university that thought it might attract adventurous US students to do their degrees in Australia can just put their enterprising ideas away.

Perhaps the public interest will be better served when it comes to films. There the US negotiators seem to be making some headway.

The film industry bleats about protecting our culture, but the local content rules serve mainly to protect local jobs. Television stations are forced to run Australian programs whether their Australian audiences want to watch them or not.

Applying the same rules to broadband internet or digital television would just extend the tyranny.

A feature of local content rules is that they provide the greatest assistance to the programs that the television stations value least but still buy or make to fill the local-content quota.

There is now a healthy debate about the quality of the output of the local film industry. One obvious way to improve the local product would be to force our industry to compete more openly with imports.

The government would still subsidise the production or purchase of Australian programs to offset their cost disadvantage. But television stations would be free to buy or not buy Australian programs according to their judgement of what the public wanted to watch.

No doubt the industry would be smaller. But our actors would know they were telling stories in Australian accents to people who actually wanted to listen.

My other great hope for the free-trade agreement is the reform of the pharmaceutical benefits scheme.

I presume the US negotiators want more profits for American pharmaceutical companies.

What I want is a PBS better able to meet the needs of an ageing Australian population.

Here's the problem. The cost of the PBS is projected to grow dramatically as expensive new drugs become available and as the population ages and the demand for all drugs increases.

But expensive new drugs are not necessarily a problem if they save lives or improve people's quality of life or are a substitute for less cost-effective forms of treatment. We will *want* to spend more on cost-effective new drugs.

But what is in the public interest is not necessarily in the government's interest. Governments will always be tempted to judge the costs and benefits of new drugs in terms of the effect on the federal budget.

A government might be quite happy to restrict the supply of an expensive new drug through the PBS simply to save itself the cost of the subsidy. The political trick is to restrict those expensive drugs that mean a lot to a small number of people.

To avoid a tiresome debate, the government might also try to hide the real reason for its decision behind opaque walls of confidential negotiations and complicated technical advice.

Hopefully what will emerge as a result of the pressure from US negotiators is a process of selecting drugs for the PBS that is more transparent and less susceptible to distortion by political decision makers.

Aust Financial Review 10/12/03

No side-effects in trade deal

CHRISTINE Wallace's feature (31/10) contains inaccurate claims and assumptions about how a Free Trade Agreement with the US would affect the Pharmaceutical Benefits Scheme.

No trade deal can dictate how much the Australian Government spends on medicines or how much medicines cost the consumer. This is a matter for the Government to decide. The only change the FTA would mean for consumers is greater and timelier access to some of the world's leading medicines — reducing spending on more expensive and invasive treatments involving surgery, hospitalisation and aged care.

It beggars belief to suggest that Australia would sign on to an FTA that has a net cost for taxpayers; there has to be a net benefit. What Australians need to be assured of is that the PBS is here to stay. However, everyone would benefit from it being strengthened to mean a fairer, more transparent, consultative and consistent process.

There would be very few Australians who would not want access to the latest medical discoveries because of a process-driven PBS. There will soon be new classes of medications available — in areas such as cancer and HIV/AIDS. We need to provide them as soon as they become available, which at the moment does not necessarily happen.

One cost this article did not calculate was the cost of new medical therapies not being made available to those who need them when they need them. How do you calculate that cost?

Kieran Schneemann
Medicines Australia

The Australian 1/11/03

Anti-FTA views bunkum

Scaremongering is distorting the benefits of a free-trade deal, writes **Michael Baume**.

So a free-trade agreement with the United States is bad for your health, according to the latest tabloid media scare story. Recently newspapers around Australia trumpeted the headlines: "Drug costs to triple", "Drugs rise in trade-off", and "US trade deal could triple the price of drugs". Then came the follow-up stories such as "Drug prices to treble under free trade: study", which kept the farce going.

This invented news story was based on no more than the patently absurd rehash by a left-wing think tank, the Australia Institute, of its earlier incompetent study based on a disingenuous comparison between drug prices in the US and Australia, along with a predictable response by the politically oriented Doctors Reform Society.

Official denials were either ignored altogether, or buried in the last paragraphs.

As the Australian Associated Press news wire story put it: "New figures showed life-saving asthma and cholesterol drugs could become unaffordable for some patients under a US-Australia agreement, doctors warned. US drug companies are lobbying for the price of Australian pharmaceuticals to come in line with those available in America [so] the price of common prescription drugs would triple."

It was all bunkum. Apart from the false inference that the Doctors Reform Society equates with doctors (rather than a small group of opinionated radicals with a medical degree who in no way represent their profession), the government has repeatedly stressed, as Health Minister Kay Patterson repeated last week, that the Pharmaceutical Benefits Scheme is not up for grabs in the proposed free-trade agreement with the United States. Very few of the newspapers that were happy to succumb to the anti-FTA propaganda felt any need to run the response that not only was the government absolutely committed to the PBS but also that the US negotiators had not requested changes to be made to it.

And naturally, none reported that the association of pharmaceutical companies in the United States, PhRMA, stated in its submission to the US Special Trade Representative that it was not a goal of the US industry to see the Australian PBS dismantled. The US industry simply is not lobbying to raise Australian pharmaceutical prices under an FTA to US levels.

This was the latest instalment of the strange campaign of fear and loathing against an FTA that rests on the "if pigs had wings" school of analysis. The Australia Institute did no more than compare Australian and US prices for the same drugs and then conclude that price increases of this order would be expected if the pharmaceutical companies are successful in eliminating or undermining the reference pricing system of the PBS. Nowhere in this purported study was there evidence either of any US official intent to do so or of the Australian government being likely to give way. In fact, there is none.

But the problem for industry is that the multinationals dominating the sector believe that not only have the prices set by the monopoly purchaser (the PBS) been too low to justify larger-scale development here, but that the basis on which decisions have been made to include or exclude items in the PBS has not been sufficiently transparent. It is the transparency point that is very much on the table in the FTA negotiations, not the rights of Australia to determine a price under the PBS.

The problem is not about the prices of existing drugs, which are clearly not under threat from the FTA, but on the policy issues of how the government is to deal with its PBS cost dilemma. This is in the face of a pig-headed opposition that has prevented the government from restoring the patient share of PBS costs to Labor's 25 per cent from the present 16 per cent. And then there's the problem of how to offset the PBS budget benefits — of screwing down pharmaceutical prices versus the benefits of having a drugs price base that provides an incentive for the pharmaceutical industry to invest enough in local manufacture.

The Australian government's view is that the two issues of PBS price and industry incentives should be separate, and so is providing specific investment incentives rather than allowing PBS prices to provide market incentives. Whether the industry will consider the government's incentives good enough and whether the FTA does bring enough transparency will be seen in future decisions about the size and structure of the Australian pharmaceutical industry — issues that are far more relevant than incompetent research by the Australia Institute and polemical posturing by the Doctors Reform Society.

■ *Michael Baume is a former investment editor of* The Australian Financial Review *and a former Liberal MP.*

Aust Financial Review 11/8/03

Grim reapers off the mark

Not even facts convince doomsayers to change course on the trade deal

Janet Albrechtsen

WITH news of the Australia-US free trade agreement, it's time to revisit that vast gallery which houses the Left's growing collection of doomsday scenarios on free trade that proved wrong.

Start with Catholic bishop Pat Power who last November, without any detail before him, denounced any form of free trade agreement. As Trade Minister Mark Vaile headed to Washington to meet his US counterpart Robert Zoellick, the protectionist priest predicted on ABC radio that on health and social policy Australia's independence as a nation "very much is going to be swallowed up by big brother".

The scare campaign on health had already been ramped up with dire warnings by academic Clive Hamilton from the Australia Institute. Last August he predicted that prices for drugs for asthma, high blood pressure and arthritis could rise by more than 300 per cent under the FTA. Americans pay much more for their drugs, he said, and the Howard Government would trade off our cheap drug prices in return for Australian farmers gaining access to US markets.

"The devil is in the detail," Power warned. The Government released some devilish detail on Monday. Affordable medicines will be maintained under the FTA. There are no price increases to prescription medicines. There are much needed changes to make the system of approving PBS drugs more transparent. As the Howard Government made clear numerous times, slicing up the PBS was never on the negotiating table.

The media laps up these brothers grim because emotion is a bigger seller than economic literacy or even logic.

Martyn Goddard, the Australian Consumer Association's health policy officer, told one newspaper last year that without the PBS he would be dead. Diagnosed with HIV, Goddard said he could never afford the real cost of his life-saving drugs. A small dose of logic suggests that PBS is simply the vehicle for administering life-saving drugs. The drugs only exist because companies take significant risks on innovative research and development. They are more likely to do so now that the approval system is more transparent. Strange how Goddard is blind to this pro-consumer outcome.

The next exhibits include various predictions of cultural death Australia would suffer from a free trade agreement with the US.

Last November, at the Australian Film Institute awards, a long line of Australian actors, including David Wenham, Toni Collette and Geoffrey Rush, performed a very boring, very public political morris dance to the tune of Down With John Howard. Down With Free Trade.

A FEW days later, actor John Howard added: "We need to tell the US that we will decide now and in the future what stories will come into our country. If we won't protect our own culture, nobody else will."

No wonder Howard the actor is afraid of competition; these days he seems to trade more on mimicking his namesake than on his talents.

Protecting Australian culture makes sense, but beware film types who hide under the cover of culture as decreed by them whenever they churn out second-rate movies. In any case, those who predicted cultural terrorism predicted wrong. Culture has fared just fine under the FTA. Local content rules remain intact. And there is scope to impose more cultural limits as new media technologies emerge.

No tour of doom and gloom predictions is complete without hearing from the workers' friend, the unions. Joining Power and Howard at the same cosy press conference was Australian Manufacturing Workers Union national secretary Doug Cameron. Not to be outdone in the faux Grim Reaper stakes, he warned that the agreement "could threaten thousands of jobs" and Australia should not trade away its ability to decide industry policy for local employment.

More devilish detail unravels that tale of woe. More than 97 per cent of Australian exports to the US will be free of duty as soon as the FTA is up and running. As the Prime Minister said in his press conference on Monday, companies which, for example, produce utes were previously kept out of the US market by hefty 25 per cent tariffs. Now they can export them duty free. That means more jobs, not less, in this and other industries. And the FTA cements the right of both countries to enforce its own labour laws.

As Ford Australia notes, the FTA will impose competitive pressures on Australian industry, but some industries (film included) could do with a healthy dose of competition. If competition produces a more efficient industry, that is good for employment.

The only safe jobs are those in globally competitive industries. Hardly rocket science but it is beyond those like Greens Senator Bob Brown, who peddle in dishonest gloom rather than logic. He intends to vote against the FTA because "it's a disaster for Australia".

The FTA may not be perfect. There are sensible criticisms that can and will be made about insufficient tariff reductions in some industries and undue delays in how they are implemented in others, such as agriculture. However, madcap claims that the entire agreement should be scrapped because the US refused to budge on sugar quotas is just more bunkum.

The Australian 11/2/04

A chance to make PBS better

By [illegible]

P[illegible]

[illegible]

... and an evidence-based listing process are certain to remain untouched by an FTA.

It appears that recent negotiations on the PBS relate to the process — the way medicines and their respective merits are considered and treated in the PBS system.

This does not affect what the Government or Australians spend on medicines. This is reasonable and can only benefit Australian patients, doctors and industry.

The process of listing medicines on the PBS is in desperate need of improvement, with or without an FTA.

[illegible]

... and not politics.

It is clear that with the current FTA negotiations, Australia has a real opportunity to make [illegible] changes to the PBS that will improve its function and make it a more certain process for industry and consumers.

Howard has said that a trade deal would only proceed if it were in Australia's best interests. This is clearly the case with the PBS.

The Canberra Times
28/1/04

PBS needs new diagnosis

Alan Mitchell
Economics editor

The federal government's advertising and Intergenerational Report warns about the potentially unsustainable cost of the pharmaceutical benefits scheme. And yet the government's reforms are stuck in the Senate and there is no consensus about where we should go from here.

Maybe the next step should be an independent inquiry into the PBS.

I can hear the groans now. And it is true that the PBS has been looked at in the course of several recent inquiries and the problems and possible policy responses have been well rehearsed.

No doubt the last thing the people who run the PBS think they need is another inquiry. Yet another inquiry could be precisely what they do need.

The main point of an inquiry would not be to uncover some hitherto unsuspected answer to the PBS's problems. Rather, it would be to focus the public's attention on the problems and the possible answers.

The public's attitude is crucial, and not just because ministers pay too much attention to talkback radio.

The idea of the sustainability of the PBS is based on an assumption about what the public is prepared to pay.

Similarly, the policy responses to the increasing cost of the PBS are likely to involve a trade-off of the scheme's main objectives: the comprehensive availability of drugs, universal access and cost containment.

In the end that trade-off must be the public's decision.

Of course, it is tempting for ministers and public servants to avoid debating tough options "in front of the children". But that is not a sustainable long-term strategy. And this is a long-term problem that will involve many tough decisions.

The Intergenerational Report has been criticised for merely projecting past PBS per-capita cost trends (by age and gender) into the long-term future.

Perhaps, as some critics have argued, the report has overstated the future costs of the PBS. But it is also possible that it has missed important future cost pressures.

For example, it seems likely that the PBS will lose some of its bargaining power as the population ages in Australia and in the United States and Europe.

The PBS derives its bargaining power from its ability to effectively withhold drugs from the lucrative Australian market. That will become more difficult as the Australian population ages and the availability of new drugs becomes a national obsession.

At the same time, population ageing will also increase the cost of health care in the US and Europe and generate political pressure to cut the cost of drugs in those economies.

US politicians have already attacked the system of international price discrimination that has delivered cheaper pharmaceuticals to countries like Australia.

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The government should respond to these kinds of pressures in ways that do the least harm to the key PBS objectives of providing all Australians with access to necessary and life-saving medicines at an affordable price.

But that is not guaranteed. Crude cost-capping can be politically easier. The government has already been caught economising on the availability of an expensive new cancer drug, potentially leaving a small number of patients exposed to bills of up to $55,000 a year.

There are no simple, easy answers to the cost problems facing the PBS.

The higher patient co-payments and safety net thresholds sought by the government could be part of the answer. But without a more comprehensive means test, there are serious concerns about the impact on some non-concessional patients.

Reducing or even removing the subsidy for non-essential drugs is another option. But it too is problematic. The PBS spends $40 million a year on common analgesics. But while delisting these drugs seems a simple way to save a lot of money, nearly all of the analgesic subsidy goes to concessional patients.

Moreover, if the subsidy were withdrawn, doctors would prescribe substitute drugs still listed on the PBS. If these substitutes were more expensive, the result could be an *increase* in the cost to the taxpayer.

Other options include budget-holding arrangements and strategies to encourage more cost-effective prescribing.

The optimal solution almost certainly is a sophisticated combination of several of the above, plus higher taxes.

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To get it right, governments will need the understanding, if not the enthusiastic support, of the public.

Aust Financial Review 17/12/03

APPENDIX C

THE FTA AS A CATALYST FOR WEALTH CREATION THROUGH AUSTRALIA'S INNOVATION AGENDA

Over the next decade innovation in science and medical research will be one of the key drivers for developed nations in achieving strong knowledge-based economies and economic growth. This is recognised in a political partisan manner at Federal and State level. The Australian pharmaceutical industry is and will continue to be a major player in innovation.

The Australian pharmaceutical industry is a knowledge intensive industry and its outstanding performance, now a benchmark for growth, employment and competitiveness, was highlighted by the Centre for Applied Economic Research.[1]

The Australia- US FTA will be a vital cog in the development of the Australian pharmaceutical industry and its contribution to wealth creation for the nation. The FTA builds on previous and current Industry Development Plans (Factor (f), PIIP and P3), it *"backs Australia's ability"*, will help facilitate the Government's Innovation and Biotechnology Strategies and the State Ministers' Australian Biotech Alliance and is a catalyst that can help action Labor's pharmaceutical innovation statements.

The FTA will add further impetus to achieving the goal of the Pharmaceuticals Industry Action Agenda (PIAA), which is to double Australia's share of the global pharmaceutical market. (The PIAA is the Government-Industry strategic plan developed by Medicines Australia, the Federal Government, universities, research institutions, AusBiotech and the generics medicines industry).

The future of the research-based pharmaceuticals industry will continue to be that of a global marketplace with advanced economies competing for a slice of the pie.

Australia must be presented internationally as a competitive, high-technology country in which to do business if local affiliates of multi-national companies (MNCs) are to successfully compete to bring research and development and manufacturing investment to Australia.

Australia has existing strengths (for example, its performance in clinical trial activity) that position the industry to capitalise on growth in the global pharmaceuticals industry.

[1] Centre for Applied Economic Research (CAER) "The Economic Performance and Contribution of the Pharmaceutical Industry in Australia: 1985-95", Working Paper No. 1, 1998

However, changes in the global market, including increasing globalisation of this sector, will mean that Australia must make an active choice for growth. Other countries- such as Singapore, Ireland and Canada are demonstrating that they are prepared to take necessary actions to strengthen their competitiveness, to proactively offer incentives to attract the pharmaceutical industry and to make their countries a better place for doing business.

Failure to act will therefore result in a decline in the pharmaceuticals industry, with increased flight of researchers and their research to markets which offer greater opportunity, limitations to the abilities of Australian start-up companies to pursue medicines development, and dissipation in manufacturing activity and exports.

Australia would be in danger of losing a significant part of a $12 billion industry with all the consequential adverse impacts on employment and the trade balance. It would also be losing one of its pre-eminent chances to build a globally competitive knowledge-intensive sector.

Pharmaceuticals, with the stimulus of the Australia- US FTA, can be positioned into Australia's biggest export business, create more jobs, double the output of Australian research and turn a potential brain drain into a brain gain.

The pharmaceutical industry can play a vital role in helping to commercialise the output from research scientists and institutions in Australia and leverage the benefits of the Government's extensive investment in R&D.

The FTA can help enable the full potential of the local biotech industry to be realised through partnerships and alliances with locally based multi-national companies and ensure the products of Australian research are placed on a world stage.

There is currently a global shortage in capacity for the manufacture of new-wave biological products. It is estimated that the establishment of one *'biological'* plant can require an investment of up to US$500 million. Given Australia's strengths in scientific research, our highly skilled workforce and demonstrable capabilities in manufacture, Australia has the ability to be a player in this market, which has huge export potential.

The local bio-pharmaceutical industry spends more than 10 times the amount of venture capital injected into medical R&D, spending $450million a year against a venture capital expenditure of $25million: the global spend on R&D is $60 billion, $40 billion of which is in the US.

Although Australian research is cited in 2.5 per cent of US patents, Australia, constitutes only 1.2% of the world market, with Australian researchers holding just 0.5% of world patents themselves. This represents a failure to translate academic ideas into commercial outcomes.

The FTA can help deliver increased research, greater commercialisation of research and an increased proportion of development activity occurring in Australia. Australia can also gain a larger share of the global market, particularly with global development activity and manufacturing, as hubs are located here.

The resultant increase in critical mass could increasingly position Australia to benefit from growth in the global pharmaceuticals industry.

The Government's recent innovation mapping report notes that:
"The global nature of decision making by multinational corporations about the location of research and manufacturing, presents challenges for Australia to link into these international networks."

Australia is a significant market for many MNCs, but a degree of dissatisfaction has been expressed in relation to some aspects of Australia's operating environment, largely relating to the reimbursement systems and processes associated with the PBS.

A survey of senior executives at MNC headquarters, undertaken by the PIAA provided a better understanding of how they view Australia when making international investment decisions.[2]

In terms of R&D investment decisions, PBS related issues were ranked as the most important factors influencing decisions to invest.

For manufacturing, the taxation environment, along with PBS related issues were ranked as most important.

Conclusively, in the area ranked as most important for decisions to invest, that is PBS related issues, Australia was considered poor. This negative perception applies to the transparency and predictability of the process.

The greater transparency and improved understanding of the way the Pharmaceutical Benefits Scheme (PBS) operates as a result of the FTA will provide a greater level of certainty and predictability for companies – a factor which underpins investment decisions by the global pharmaceutical industry. Similarly the recent announcement by the Federal Opposition of its strong support for a pharmaceutical industry development program is also important.

These messages have very positive impact on perceptions overseas of Australia as a sensible place to invest.

Australia only has to attract 2% of the global spend on pharmaceutical research and development to realise an investment inflow of an addition $1billion. This is the stated goal of the PIAA. The FTA brings this possibility much closer to reality.

[2] "Local priority- Global Partner" Pharmaceuticals Industry Action Agenda, 2002, p. 45

APPENDIX D

GOVERNMENT REPORTS WHICH HAVE RECOGNISED THE NEED FOR IMPROVED TRANSPARENCY AND INDEPENDENT REVIEW:

1. Industry Commissions Inquiry into the Pharmaceutical Industry, Volume 1: The Report; Report No. 51, (3 May 1996): (9.2.6 Consultation, transparency and appeal processes)
"The Commission acknowledges that PBPA price negotiations, by their very nature, are not amenable to formal review. However, the lack of administrative appeal processes for recommendations of the PBAC reduces transparency and accountability."

2. Industry Commissions Inquiry into the Pharmaceutical Industry, Volume 1: The Report; Report No. 51, (3 May 1996): (9.2.4):
"The criteria for reviewing prices outlined by the PBPA do not provide sufficient guidance for companies facing review, and may, in practice, be inconsistent with the criteria applied in the initial pricing decision...The Commission that the criteria applied in pricing reviews lacks specificity and may be inconsistent with those applied in the initial pricing decision."

3. Industry Commissions Inquiry into the Pharmaceutical Industry, Volume 1: The Report: (9.2.2 Delays)
"The Commission finds that a significant proportion of Pharmaceutical Benefits Scheme listing applications fail to meet the time limits adopted by the Pharmaceutical Benefits Branch. The Commission finds that the Pharmaceutical Benefits Branch should take greater account of the costs unnecessary delays impose on consumers and industry.

- *Supporting positions cited within the Commission's report: (9.3.2 A review of the PBS listing process)The Victorian Government supported the recommendation for an urgent review and stated that the 'current difficulties and delays with the PBS listing process are a cause of concern from the viewpoint of the consumer as well as the industry' (sub. 182, p. 3).*
- *Among health professionals and consumer representatives, the Royal Australasian College of Physicians supported 'any moves to increase the transparency and predictability with which applications to bodies such as the PBAC are handled (sub. 140, p. 1).*
- *The Australian Nursing Federation supported the review and noted that it had...received comment from members relating to delays in the PBS listing... A review of the PBS listing process should give a single body overriding responsibility for the outcome so that accountability rests somewhere (sub. 111, p. 1).*
- *The Consumers' Health Forum (sub. 139, p. 8) and the AIDS Council of NSW (sub. 196, p. 1) also agreed with the Commission's recommendation that there should be a review of the PBS listing arrangements."*

4. Australian National Audit Office (ANAO) Report of the Pharmaceutical Benefits Scheme (13 November 1997)

"ANAO recommends that DHFS explores ways to reduce the average time taken to list drugs on the PBS insofar as this is consistent with rigorous evaluation and value for money, through avenues such as:

- *Avoiding delays to correct relatively minor inadequacies in sponsor's applications for (PBS) listing;*
- *Increasing the proportion of applications accepted for listing in the first cycle of evaluation;*
- *More effectively using IT resources to support the operations of the listing process; and*
- *Reducing the time taken to produce the PBS schedule."*

5. Industry Commissions Inquiry into the Pharmaceutical Industry, Volume 1: The Report: (9.2.6 Consultation, transparency and appeal processes)

"The Commission finds that it is appropriate that the basis for decisions made in the Pharmaceutical Benefits Scheme listing process be made clear to companies. The Commission finds that current processes, particularly review processes, may not provide companies with adequate opportunities for consultation."

6. Australian National Audit Office (ANAO) Report of the Pharmaceutical Benefits Scheme (13 November 1997) Recommendation 6 (4.38)

"ANAO recommends that DHFS consider initiating more effective face-to-face consultations with companies following initial assessment of their more complex submissions in order to:

- *Provide companies with more knowledge of the listing process; and*
- *Clarify as many issues and data requirements as possible before they are provided to the Department's advisory committees."*

APPENDIX E

INDEPENDENT REVIEW MECHANISMS IN OTHER AREAS OF GOVERNMENT AND THE BENEFITS WHICH ACCRUE

The following are some of the independent bodies who are involved in reviewing the decisions of various Government agencies:

- Administrative Appeals Tribunal – an independent body established to provide aggrieved persons and agencies with an independent review of a wide range of administrative decisions of the Government and some non-government bodies;
- The Commonwealth Ombudsman – investigates complaints about the administrative sectors and procedures of federal and ACT government departments and agencies, to seek redress for errors in administration, to identify systemic issues and to improve the quality of public administration;
- Veterans' Review Board – an independent statutory authority that reviews decisions of the Repatriation Commission on various matters relating to war veterans; and
- Social Security Appeals Tribunal – an independent statutory authority established as the first tier of external review of social security and students assistance decisions.

Providing an independent review mechanism, against decisions of Government agencies:

- Ensures that a factual basis for disputed decisions can be properly considered;
- Ensures that independent analysis of facts can be undertaken;
- Act as a valuable management tool to assist Government agencies with feedback and quality control;
- Ensure that proper reasons for recommendations are provided; and
- Improve the quality and consistency of Government decision making.