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Sent: Monday, 19 April 2004 9:53 AM
To: Committee, Treaties (REPS)
Subject: Medicines Australia Submission

Please find attached an electronic copy of our submission to the Joint Standing Committee on Treaties, which has been hand delivered on the 13 April now that the Committee has resolved to make the submissions public.
Kind regards

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US-Australia Free Trade Agreement

Submission to the Joint Standing Committee on Treaties

MEDICINES Australia

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

The preparation of this submission to the Joint Standing Committee on Treaties was coordinated by Medicines Australia on behalf of its member companies.

Consistent with existing protocol, this submission is not to be made public until such time as the Joint Standing Committee on Treaties so resolves.

Medicines Australia 13 April 2004

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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.

As the National Interest Analysis notes, the Agreement improves access to and facilitates trade with Australia's largest trade and investment partner; helps to preserve Australia's competitiveness in the US market; signals strong support for trade liberalisation and has important flow-on benefits by stimulating economic activity and further trade and investment.

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 intact. 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 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.

As the National Interest Analysis notes, the Agreement improves access to and facilitates trade with Australia's largest trade and investment partner; helps to preserve Australia's competitiveness in the US market; signals strong support for trade liberalisation and has important flow-on benefits by stimulating economic activity and further trade and investment.

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 intact. 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.

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.

This is affirmed in the Regulation Impact Statement 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.

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 medicine 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 have further interaction with 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's (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. One suggestion was 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. The Australian Government, 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.[1]

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.

[1] 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[2] 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.[3] 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

2. TRANSPARENCY

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;

[2] 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

[3] 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..."[4]

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".[5]

[4] Australian Pharmacy Professional 2003, in Pharmacy Review April 2003.
[5] 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 [6] as well as a number of references in Parliament relating to delays[7].

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".

[6] 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

[7] 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.[8]

Greater engagement by companies in the listing process

Allowing industry to further interact with the PBAC during the reimbursement process, will allow a greater exchange of information crucial to a medicine's best chance of fair assessment.

[8] 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.[9]

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).

[9]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 interest.

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.[10]

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. [11]

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.[12]

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[10] 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.

[11] 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.

[12] 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."

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

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

> 3. MEDICINES WORKING GROUP
> (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[13] 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[14][15][16] and again since.[17][18]

[13] Australia Institute, ~~www.tai.org.au~~ Canberra 2004
[14] Mr Steve Deady Chief Negotiator 23 May 2003
[15] The Hon. Tony Abbott Sunday Sunrise 2 November 2003
[16] The Hon Mark Vaile ABC News 27 November 2004
[17] The Hon. Tony Abbott ABC Radio 10 February 2004
[18] 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 that there is no basis for this claim. 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

Press clippings that were included
have not been scanned

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 'biologicals' 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.