



NATIONAL ASSOCIATION OF PEOPLE LIVING WITH HIV/AIDS

**SENATE SELECT COMMITTEE ON THE FREE TRADE
AGREEMENT BETWEEN AUSTRALIA AND THE UNITED STATES
OF AMERICA**

**Submission from
the National Association of People Living with HIV/AIDS**

April 2004

Executive Summary of NAPWA's submission

Overall

- NAPWA's comments are restricted to those clauses in the draft AUSFTA relating to health care systems and the pharmaceutical industry.
- NAPWA is not opposed in principle to an Australia-US Free Trade Agreement, which we believe can be potentially beneficial, particularly to health and medical research, and need not be detrimental to Australian public health policy.
- However, we believe the AUSTFA draft text emphasises a commercial agenda and the needs of industry more than it does considerations of public health. The primacy of the public health interest underpins the philosophy of both the Pharmaceutical Benefits Scheme, and the Australian health care system more generally. We are concerned that the AUSTFA draft text does not unambiguously acknowledge the centrality of the public health interest to this system, nor take sufficient account of the need to sustain this into the future.

Language of the FTA

- NAPWA is concerned that the language of the AUSTFA draft text is frequently ambiguous and non-specific. Given this is a legally binding document and of considerable domestic political significance, we believe this should be urgently addressed as part of the ratification process.
- In particular, we believe the draft text mystifies, rather than clarifies, key agreements relating to: the Pharmaceutical Benefits Advisory Committee; the proposed Medicines Working Group; and intellectual property rights.

An "independent review process"

- NAPWA is not convinced of the advantages of an independent peer review process attached to the Pharmaceutical Benefits Advisory Committee, given that there is already latitude for unsuccessful applicants to resubmit, and to take advice from the PBAC on this.
- NAPWA believes the description of the independent review process in the AUSFTA draft text is inadequate. In particular, NAPWA is concerned about the potential for costly and time-delaying legal action should the

“independent review process” return a decision ultimately not upheld by the PBAC. This could delay Australians’ access to important new pharmaceutical agents and potentially life-saving treatments.

A Medicines Working Group

- While not opposed in principle to such a bilateral group, we believe the AUSTFA is unnecessarily vague as to its remit, authority and composition.
- In order to best reflect the partnership approach to public health policy in Australia, and to further in practice the “transparency” which the AUSTFA enshrines, NAPWA believes the composition of this group should extend beyond bureaucrats and representatives of government, to others with an unarguable interest in Australia’s public health policy, including: medical practitioners; health consumers; and the pharmaceutical industry.
- NAPWA questions why such a group needs to be specifically located within a legally binding free trade agreement.

Intellectual property rights

- The necessary balance between the rights of intellectual property owners and the need to protect appropriate access to pharmaceuticals for citizens of both partners to this agreement is not well-reflected in the AUSTFA draft text.
- The Doha Declaration of 2001 captures that need for balance, but its philosophy seems absent from the draft text.
- It is crucial that people living in Australia continue to be able to access cost-effective treatments, including generic drugs from overseas through parallel importing schemes. Anything less, we believe, is absolutely contrary to ethical, clinical and public health good sense.
- The requirement that patent holders be notified of any requests for marketing approval for generic drugs pending the expiry of the existing patent would, we believe, have a negative effect on the Australian health care system. Experience in the United States shows that manufacturers routinely use this requirement to take legal action against would-be competitors in a bid to protect prices and market share. NAPWA cannot see any advantage to this outcome.

1. Introduction: NAPWA's interest in the Australia-US Free Trade Agreement (AUSFTA)

1.1 Who we are

NAPWA is the peak, community-based organisation advocating for and providing policy advice on behalf of the 14,000 Australians currently living with HIV/AIDS. In partnership with the Australian Federation of AIDS Organisations (AFAO), NAPWA works to ensure a national continuum of community-based advocacy and service delivery, from prevention, to care and support. Our 20 years of engagement, aligned with the singular challenge that HIV has offered, has given us a significant depth of experience in and with health delivery in Australia, and also with the full range of stakeholder interests engaged in its provision.

NAPWA will restrict its comments on the AUSFTA to those sections which relate directly to the pharmaceutical industry.

1.2 The Pharmaceutical Benefits Scheme (PBS)

Current data (*National Centre in HIV Epidemiology and Clinical Research Annual Report 2003*) suggests that around 50 percent of all HIV positive Australians currently take antiretroviral treatments: usually combinations of three or more drugs. All of the currently licensed HIV antiretrovirals are provided through Section 100 of the Schedule of Pharmaceutical Benefits. In addition, many people with HIV require additional drug treatments to manage treatment side effects, or other complications of HIV such as opportunistic infections. In a population whose average income is substantially lower than the national average (*HIV Futures III: Positive Australians on Services, Health and Well-Being, Australian Research Centre in Sex, Health and Society, 2003*), this means many people with HIV/AIDS view the Pharmaceutical Benefits Scheme (PBS) as a virtual lifeline.

Revision of Australian clinical guidelines in relation to HIV prescribing (largely brought about by evidence that early treatment intervention does not present significant long-term benefit over and above later intervention) has resulted in a decline in treatment uptake, down from the 70 percent recorded in 1997-98, but the

fundamental fact remains: the lives of HIV positive Australians – like many others with serious acute or chronic illness – are utterly dependent on continuing access to affordable medicines.

1.3 Importance of research

Equally essential is the identification, development and production of new therapeutic agents targeting different areas of the HIV replication process and compensating for the fact that most people with HIV will develop resistance to one or more available treatments over time. According to the HIV Futures III study, three quarters of people who were tested for resistance to HIV treatments were resistant to one or more currently available drugs.

Given this imperative, we recognise that an innovative, profitable, research-based pharmaceutical industry is vital to new drug development. In fact, the lives of the majority of our constituency have been and will continue to be, dependent upon it.

1.4 Timely access to new treatments

Finally, NAPWA maintains a very specific interest in drug approval and listing processes given our origins in the late 1980s HIV/ AIDS epidemic experience. Effective HIV treatment didn't emerge until the mid-1990s, and the urgent need to supply new treatments to affected populations initiated overhauls of existing drug approval processes, both in Australia and across the western world.

Our experience has given us a continuing appreciation not only of the importance of the PBS, but also of the need to foster and maintain pragmatic, collaborative engagement with all those involved in the Australian response to HIV – government, industry, medicine, consumer health. NAPWA's own ongoing commitment to that philosophy is evidenced by the fact that NAPWA-based nominees have filled the consumer representative position on the Pharmaceutical Benefits Pricing Authority (PBPA) continuously since 1999.

2. General concerns : the language of the AUSFTA draft

The Australia-US FTA negotiations were accompanied by a great deal of scrutiny and speculation — some comments, admittedly, less justified, helpful or informed than others. In particular, much attention was obviously focused on the potential for an AUSFTA to have a deleterious effect on the long-term sustainability of the PBS, by skewing the balance of interests in favour of industry. This anxiety was not helped by unambiguous messages from the powerful US medicines industry lobby, PhRMA, that it saw the PBS as a legitimate area of negotiation for the AUSFTA. This has been made abundantly clear in its submissions through the AUSFTA negotiations, and other publicly available material.

This, combined with the speculation in the press, caused some disquiet among the NAPWA membership.

When successful negotiations were concluded, NAPWA, like many other organisations, was relieved by initial assurances from both the Trade Minister and Prime Minister that the PBS had been protected, and would be effectively untouched by the AUSFTA. However, early on, it was noted that officials representing the US appeared to have a somewhat different version of the outcome, and seemed to be claiming that significant concessions had been won in relation to pharmaceuticals, citing as particular improvements an additional review process attached to the PBS, and the establishment of Medicines Working Group to “provide for continued dialogue between the United States and Australia on emerging health care policy issues”.

Given these versions seemed to sit uneasily, NAPWA keenly awaited the full draft text of the AUSFTA. It is disappointing, then, that the text itself is couched throughout in frequently ambiguous and open-ended terms, which offer considerably less clarity than might be hoped about the proposed new arrangements in practice. In particular, as this submission will detail, NAPWA is concerned about a lack of specificity and clarity in the sections of the Agreement relating to the proposed PBAC review process, and the Medicines Working Group.

NAPWA has no wish to interpret this vagueness as necessarily deliberate or sinister. However, we do note with disappointment that the document mystifies, rather than clarifies, many significant questions about the PBS arrangements, which we believe is a major deficit in a legally binding agreement. It is an open invitation to further speculation as to the advantages, disadvantages, and short or long term implications of many aspects of the Agreement — for both Australia and the US. We also suggest this systemic elusiveness increases the risk of lengthy and unhelpful legal confrontation arising as the Agreement is implemented.

3. Operation and implementation of the Agreement: the need for practical clarity

Broadly, we welcome any initiative that offers a potentially positive accrual to Australia's economic wellbeing. We see no necessary reason why the tenets of a bilateral free trade agreement can't co-exist with a regulatory environment maintaining those areas of our national infrastructure deemed essential to securing the health and wellbeing of Australians. We accept, in that respect, that the PBS represented a specific challenge for Australian negotiators, and to the extent that its principles have been preserved in the AUSFTA draft, we applaud the negotiators' efforts.

Nevertheless, we do have concerns about implementation, and the future direction that agencies and regulatory authorities might take. Central to this is the need to be clearer how the various clauses relating to the PBS might be practically enacted, and – as far as possible – some informed insight into the downstream effect that ratification might have. We fully acknowledge the “work in progress” reality here, and view this Inquiry as the prime vehicle for contributing to that process.

We don't share the frequently-enunciated and overly-pessimistic view that the AUSFTA is a deliberate means to a government end whose net effect would be that Australia pays more for the pharmaceuticals it purchases. Our faith in the innate tendency towards fiscal prudence in government – regardless of ideological colouring – is nigh unshakeable. We do, however, understand the market reality within which the pharmaceutical industry works, and understand that return to their shareholders is – and will be – a clear priority. Operating within a purchasing environment like the PBS will, quite understandably, be seen by industry as a constraint on this.

Equally, an ever-burgeoning range of pharmaceutical solutions on offer to a population increasingly expectant of swift and effective pharmaceutically-derived outcomes places a continuing pressure on the PBS.

Given this conflation, the balancing act required of government is significant. It becomes potentially more so if we enter a bilateral trading agreement with an economically powerful partner whose philosophical approach to nationalised health care is very different from our own. We therefore see a clear and unmistakable commitment to preserving the operating basis of the PBS as an essential ingredient in successful implementation of AUSFTA.

This shouldn't be read as a desire on our part to set the current operating parameters in stone. Flexibility and adaptability are crucial ingredients in the mix. However, the principle whereby the government has responsibility for purchasing and supplying essential medicines via cost-effectiveness assessment criteria and 'best price' reference benchmarking is a cornerstone of Australian health delivery, and needs to be clearly articulated as such if confidence in the government's commitment is to be maintained. We acknowledge that a variety of government spokespeople have already alluded to the integrity of the PBS as a key consideration in the AUSFTA negotiations and development of the draft. The test is a continuing commitment to upholding and reinforcing that position against the reality of implementation in the fundamentally different operating environment that an AUSFTA would create.

We note that the soon-to-commence P3 program provides for up to \$300,000,000 to be delivered to the pharmaceutical industry over the three years of the program. By any measure, this represents a generous investment in industry-specific research and development — particularly so when the AUSFTA commits the parties to identifying even greater opportunities for research and development growth.

We observe that continuing commitment to upholding and reinforcing the position of industry features prominently and transparently and arguably, in inverse proportion to the degree of transparency attaching to the need for upholding and reinforcing the public health primacy upon which the PBS is based. Some clarity as to how this primacy is to be maintained and strengthened over the life of the AUSFTA would go some distance towards allaying our concerns over what we currently perceive — in terms of overall impression — as an imbalance in treatment between the public health and the pharmaceutical provider interests in the current AUSFTA draft.

4. Specific Analysis

4.1 An “independent review process”

Parties shall...

(f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination

– Paragraph 2(f) Annex 2-c

This clause, which provides for a new applicant-initiated review of Pharmaceutical Benefits Advisory Committee (PBAC) recommendations or determinations, has been characterised in some quarters as an assault on PBAC’s ability to make binding recommendations that might impact adversely on an industry applicant. NAPWA can certainly see advantages to any processes which increase the transparency and robustness of PBAC processes. However, it is not clear that there is any advantage to an additional review process, given that there is already a capacity to review decisions, and that the PBAC already has the latitude to meet with unsuccessful applicants to discuss outcomes and future prospects for resubmission.

An ongoing agenda for greater transparency has been in train across the drug approval and listing processes for some time, and we welcome this development. We note further that the review process proposed in the AUSFTA will not be able to overturn PBAC’s sole right of recommendation to the Health Minister. Minister Abbott, in responding to a question during House of Representatives Question Time on 8 March 04, depicted the process as follows:

“To increase the transparency of the PBS and to build on the good work that the PBAC has been doing, there will be a transparent independent review process – a formal peer review – that can only make our existing system stronger.

This review process will be determined by the government after consultation with the industry, stakeholders, the PBAC and consumers.”

(Hansard, 8 Mar 04, p 51)

“Formal peer review,” in this context, would appear to us to require a virtual mirror image of the PBAC, but somehow acting as an advisory group adjunct to that body. It would logically require the same mix of interests (pharmacology and medicine, industry, government, and consumer) as those which currently comprise the PBAC, in order to be true to its ‘peer review’ role.

Presumably, a decision by the review body that was at odds with the original PBAC decision might provide a catalyst for legal action on behalf of the listing applicant, if the review decision is perceived as less adverse to applicant than that of PBAC. That potential might become a likely eventuality if PBAC finally recommends to the Minister on the basis of its earlier decision, despite the second ‘review process’.

It is unclear to us as to who might be currently envisaged as the having the right to initiate a review at this point. Obviously, we’d expect that industry would be the major potential review applicant, but the medical interest and consumers, too, might arguably be interpreted as “directly affected”. It would be useful to have some clarification on the meaning of “applicant” within these clauses. Clarifying these questions would also seem prudent to avoid the potential scenario that appealing negative PBAC recommendations becomes a routine, rather than exceptional, part of the drug listing process.

Although it would require some reworking of the concept of “independent,” one way to ameliorate the potentially negative effects of litigation and delays might be to envisage PBAC as a two-tier process, with an initial recommendation going forward automatically to a second-tier review panel that would frame the final PBAC position. This would necessitate more frequent PBAC meetings in order to expedite the process without simply causing delays, but we note that the AUSTFA draft already provides for an increase in PBAC meetings and more frequent updates of the Schedule of Pharmaceutical Benefits (The Yellow Book), reflecting changes in process now.

We believe that the fundamental importance of the comparative cost-effectiveness analysis as the basis for PBAC decision-making needs to be retained and reinforced. While industry has long-argued a case for greater attention to be paid to quality of

life indicators — and in our experience “quality of life” is an undeniably important accrual from many emerging therapies — the appraisal balance should remain with the robustness of the cost-effectiveness case.

The wording of this paragraph lacks specificity and clarity. It is frustrating to us that the purpose and intent of this review mechanism is not more obvious, particularly given the considerable latitude already available to applicants to consult with the PBAC, Pharmaceutical Benefits Branch Staff, and obtain advice to assist resubmission.

As is it stands, however, it is unclear as to what will be achieved by this additional mechanism. We have serious concerns that this process, coupled with the ordinary processes of submission, might have the very real effect of adding delays to access to urgent and important new treatments for Australian health consumers. This outcome would be unacceptable, and counter to good sense from both an industry and health consumer perspective.

4.2 A Medicines Working Group

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 health outcomes.

(c) The Working Group shall comprise officials from federal government agencies responsible for federal healthcare programs and other appropriate federal government officials.

— Paragraph 3 of Annex 2-c

We note that other areas of activity within the AUSFTA draft text have provision for similar Working Groups to be created, presumably to monitor the ongoing effectiveness of AUSFTA. We acknowledge the obvious logic behind this. There is, however, a fundamental difference between the way that 'medicines' are understood in the broader context of Australian health delivery and the way that a specific agricultural product might be understood. In short, a group whose membership was restricted to members of government and its agencies would not begin to be totally representative of the broad polity that shares ownership of Australian health delivery – of which pharmaceuticals policy is an integral part.

The Medicines Working Group, on initial appraisal, appears to negate the principle of collaborative stakeholdership in favour of bilateral, bureaucracy-to-bureaucracy discussions. NAPWA has no problem with the principle of an AUSFTA-derived Medicines Working Group as part of a broader health relationship, but we believe that it must be representative of the health culture in which pharmaceuticals are utilised, if it's to be viewed as consistent with the fundamental principles which underpin the Australian health care system. To that end, we see it as absolutely essential that there is appropriate representation from healthcare consumers, the medical profession, and industry.

There seems no immediately apparent reason as to why this couldn't happen, apart from the fact that no mention is currently contained in the draft. Australian pharmaceuticals policy isn't constructed or administered in a medical and consumer-free vacuum, and NAPWA would not support any attempt to introduce such an approach. For instance, pharmaceutical manufacturers have every right to lobby government on an ongoing basis – and do so quite energetically and successfully.

Clearly, there's a risk that those excluded from the process will view this exclusion in a negative light, and inevitably question the fundamental motivation behind the arrangement. There is significant value in a trans-national health working group aimed at harmonising, where appropriate, a wide range of health-related matters including the separate, often labyrinthine and time-consuming, therapeutic approval

processes that each jurisdiction duplicates. The AUSTFA draft actually refers to the need to consider this broader aspect, and NAPWA is fully supportive of this.

Given this, the rationale for setting up a separate group specifically about medicines, and apparently exclusive to government, isn't immediately obvious to us.

NAPWA is disappointed that the AUSTFA does not spell out more precisely the nature and intent of the Medicines Working Group. For example, what authority will that group hold, to whom is it answerable, and how and on what basis is it proposed that it will consider Australian health policy? Does Australia have rights in return to consider US health policy? What is the purpose of placing such a group within a legally-binding Free Trade Agreement?

In summary we support the concept of formalised, inclusive trans-national health issues discussion on an ongoing basis but see limited benefit to the pharmaceuticals dimension, within the broader Australian health polity, from the construct currently envisaged as the Medicines Working Group, nor why it needs to be placed within the legally binding AUSTFA.

4.3 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 the 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 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 pharmaceuticals.

– Paragraph 5, Annex 2-c

This, in essence, represents no change to the current situation in relation to direct-to-consumer advertising of pharmaceutical prescription drugs. We welcome this. The

stress given to “truthful and not misleading” information in the extract is also welcomed, though we note in passing that making intent reality, in this particular context, is perhaps more of a challenge than it might first appear.

Nonetheless, the ambiguous wording of this paragraph unfortunately leaves it open to speculation as to the spirit and intent of this clause, which has been interpreted by some groups as paving the way for script drug advertising in Australia in the future. Certainly, the emphasis on the Internet recognises a major shift in the technology of information delivery, where individual countries’ legislative frameworks governing advertising are obviously less meaningful.

NAPWA does not support direct-to-consumer advertising of prescription pharmaceuticals. We believe any claimed benefits (such as information about options for consumers) are outweighed by the very real possibility that information may not be balanced, and the potential for artificial demand for new drugs, which could have a serious effect on the sustainability of the PBS.

4.4 Intellectual Property Rights

Chapter 17 of the AUSFTA

Chapter 17 deals with intellectual property rights. Our fundamental concern here is less with the content and more with a perceived omission. A single reference is made – albeit obliquely – to the Doha Declaration, which states, *inter alia*, that:

we stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines.
(Doha World Trade Organization Ministerial 2001, section 17)

However, the balance between ownership and access implicit in this section of the declaration isn’t reflected within the AUSFTA, which appears to be slanted with greater favour towards of the rights of intellectual property owners. We have no difficulty, in many circumstances, in accepting the obvious case for protecting intellectual property rights. We also accept that the parties may have considered the

place of the Doha Declaration when drafting the AUSFTA text, but if so, it's not immediately apparent.

We believe that it's essential to address the question of balance between competing interests in a clear and transparent manner. In our view, the public health interest merits a considered primacy that it doesn't currently enjoy within AUSFTA draft text.

4.5 Parallel Importing Restrictions

17.9 Patents – Paragraph 4

Each party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on import by contract or other means.

We acknowledge that the United States pharmaceutical industry has a particular issue with parallel importing, as it's become a widespread practice amongst Americans wishing to access pharmaceuticals cheaper than those available from the domestic market. (We also recognise, however, that for the many US citizens with HIV who may be unable to access affordable antiretroviral treatment, parallel importing is absolutely necessary to their health).

There are many people in Australia with HIV who do not currently have access to antiretroviral treatment through the PBS. This includes people who are here on student visas, and people awaiting migration review who do not have access to Medicare. It is absolutely crucial that the capacity for these people to obtain cost-effective treatment, including the purchase of generic drugs from overseas, is maintained. Anything less would be fundamentally contrary to ethical, clinical and public health 'good sense'.

We acknowledge that our position here might conceivably be depicted as somewhat bleak. However, in the absence of any stated commitment to the Doha position outlined above, we're left with the impression that the possible outcome, – if not the intent – here is to privilege industry rights above the broader public health interest.

It's not obvious to NAPWA why both interests can't be addressed concurrently. We certainly believe that they can and should be.

4.6 Notification of Marketing Applications to Current Patent Holders

Chapter 17-10 paragraph 5 of the AUSFTA

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.

In practice, these clauses would require the Australian government to notify a current pharmaceutical patent holder if a third party – possibly a generic manufacturer – requests marketing approval pending the expiry of the existing patent. Experience in the US shows that pharmaceutical manufacturers routinely use this requirement to take legal action against would-be competitors in a bid to protect their existing price and market share for as long as possible.

It's difficult to perceive anything other than a potentially negative effect from this inclusion, from an Australian perspective, with particular reference to the continuing ability of the PBS to restrain price to the greatest extent. There would clearly be little initial impact here post-ratification but this provision, combined with other IP and parallel importing provisions, does create a fairly clear context for the view that the

pharmaceutical industry has gained significant momentum in terms of its future prospects in relation to the AUSFTA regime. Once again, the perceived need — from our perspective — for more assurance around the public health interest point of balance, is pressing.

4.7 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;*
- (e) provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law;*

— Annex 2-c 2

We endorse the commitment to greater transparency, noting also that, for the most part, the provisions outlined are either current – or about to be current – practice. We also note that transparency of process doesn't equate to guaranteed satisfaction about outcome, *vide* comments above.

Summary

We support the principle of free trade and acknowledge its crucial importance to Australia's economic future. We also acknowledge the efforts of the Australian AUSFTA negotiators in preserving the integrity of the Pharmaceutical Benefits Scheme, to an extent that many informed commentators might not have anticipated.

We have outlined a number of concerns that emerge. Some of them might be easily addressed in terms of clarification and the emergence of an operating structure for AUSFTA innovations, such as the PBAC review process.

Nevertheless our overall impression is indelibly one of the weight of an AUSFTA being slanted away from the public health interest generally, towards a more industry-focused perspective. It's therefore crucial that some sense of equilibrium should be restored in the ratification process.

This shouldn't have to involve significant changes. Rather, it's more a matter of providing some firm assurances about the will and the means to commit to preserving what is, in the PBS, a very important part of our national fabric. Further, we believe it is absolutely essential, if the AUSFTA is to enjoy the support of the Australian community, that the ambiguous language around clauses relating to the PBS and the Medicines Working Group is reworded to ensure that the obligations and implications of these clauses are as clearly spelled out as possible.

A number of the changes wrought by AUSFTA ratification will take some years to have significant effect upon the PBS but there's no doubt from our perspective that pressure on the public health interest will increase as a result of it.

We have offered some suggestions that might perhaps restore the sense of equilibrium between the various stakeholders and forestall any erosion of the principles upon which the PBS is based and we recommend them to the Committee for its consideration.

