



PUBLIC HEALTH ASSOCIATION
of Australia Inc
ABN 41 062 894 473

7 May 2004

The Secretary
Brenton Holmes
Senate Select Committee on the Free Trade Agreement
Between Australia and the United States
Senate Foreign Affairs, Defence and Trade Committee
Parliament House
Canberra ACT 2600

Dear Sir/Madam,

Pharmaceutical Benefits Scheme (PBS) and the Australia and United States of America Free Trade Agreement (FTA)

The Public Health Association of Australia (PHAA) is Australia's leading advocate for public health policy, practice, research and training. The PHAA provides a forum for the exchange of ideas, knowledge and information about public health issues and concerns both nationally and internationally. PHAA members contribute to the development and implementation of public health policy by bringing their expertise to the development of policies, providing representation on government boards, committees, and other decision-making bodies, providing submissions to government inquiries and providing access to informal and professional networks. The membership of the PHAA is currently drawn from over 40 public health related occupations.

The PHAA expressly supports the submissions provided by the Australian National University and Dr Ken Harvey. In addition we would like to make the following comments about the potential effect of the Australia United States Free Trade Agreement (FTA) on the Pharmaceutical Benefits Scheme (PBS).

PHAA's interest in the Pharmaceutical Benefits Scheme (PBS) and (FTA) lies in our concerns that neither the provision of health infrastructure nor the health of individuals should be subordinated by trade, and in particular by the FTA. We note that the US is obliged under its *Trade Promotion Authority Act (2000)* US to ensure its trade agreements facilitate 'affordable' access to 'essential' medicines under the Doha declaration of the convention on Trade Related Intellectual Property Rights (TRIPS).

In this case, we are concerned that the proposed FTA will directly provide for changes to the PBS, and provide for changes in other areas, such as intellectual property rights, that will affect the PBS and consequently the affordability and access to many essential medicines.

Australian medicinal drug policy is held in high regard by countries and governments across the world. Australia's PBS is widely regarded as one of the most efficient schemes in the world at controlling the cost growth of pharmaceuticals as a percentage of health care expenditure, while providing all Australians with equitable and affordable access to pharmaceuticals: *"Australia...is the one country which seems to have got it right, that what you want to do in controlling costs is to pay what the drugs are therapeutically worth. And the PBS does that..."*^{i, ii}

Should the Australian Government agree to include the proposed clauses and side letters regarding the PBS in the FTA, the FTA will undoubtedly undermine the effectiveness and success of the PBS, and potentially lead to the Australian Government and individual citizens paying two to three times more for medications.. This will almost certainly result in some sick people not being able to afford their prescribed treatments. In the longer term this will impose a greater burden on the hospital system.

In comparison with Australia, pharmaceutical costs are much greater in United States of America, with some sectors of the community, such as the elderly and uninsured, having to forego unaffordable medications.ⁱⁱⁱ This is not a model that Australia should emulate.

PBS decision-making has previously been, and continues to be, openly discussed in international journals^{iv,lv}, which in general have found it to be consistent with the concept of economic efficiency.^{vi} Yet the Australian Government is under pressure from the US to explain the mechanisms of the scheme and provide "transparency" of its dealings.

The PHAA strongly endorses transparency in decision-making. However, transparency under the FTA needs to be explicitly spelt out. It must not just mean that the Australian Government has to provide information to pharmaceutical companies and others about aspects of how, and on what evidence, the Pharmaceutical Benefits Advisory Committee (PBAC) has made its recommendations and the Government has made its decisions. Rather, it must explicitly include both this and transparency from the pharmaceutical companies of the submissions they have made to the PBAC, the government and any review mechanism, such that only material that is truly "business in confidence" is not made public.

The PHAA also regards the current FTA text on the review mechanism for the PBS to be too loose. It is difficult to see how, as a ‘review mechanism’, not an ‘appeals mechanism’, it will provide a satisfactory outcome for either the pharmaceutical companies or consumers, advocates or the Australian Government. Should it become an appeals mechanism, it will undermine the effective, internationally admired, evidence-based, independent decision-making process, and will lead to inappropriate drugs being placed on the PBS. In turn this will lead to less than optimal clinical expenditure, and could lead to unnecessary bureaucratic costs and undermine the efficiency of the already stretched PBAC.

The Pharmaceutical Research and Manufacturers Association (PhRMA) of the United States of America directly lobbied for the FTA to “promote pharmaceutical and biotechnology and genomic discovery in both the US and Australia”.^{vii} The links between PhRMA and the US government are strong.^{viii} PhRMA lists a number of what it claims to be “anti-competitive” practices of the PBS on its website, such as restrictive listings, reference pricing, “spring-boarding” (which is the authority for a generic manufacturer to embark on trials to ensure its drug is given immediate regulatory approval when a patent ends) and stockpiling.

PhRMA has applied to have Australia added to the annual “Special 301” report that is mandated by the US Trade Act of 1988 and is a review of global intellectual property rights (IPR) protection. In this report, the US Trade Representative (USTR) is required to identify countries considered to have inadequate intellectual property rights, to provide a warning to improve, and if not to apply unilateral trade sanctions.^{ix}

The USA Department of State is committed to a policy of promoting increased intellectual property protection and “*is making progress in advancing the protection of these rights through a variety of mechanisms, including through the negotiation of free trade agreements*”.^x

The PHAA believes that the intellectual property provisions in the FTA can undermine access to medicines^{xi} and contravene the 2001 Doha Declaration which states that public health should hold primacy over patent rights.^{xii} This issue must be resolved before the FTA is agreed and signed, or PhRMA will have the capacity to use the threat of trade sanctions to ensure that the decisions that it is seeking on pharmaceuticals are made. The Australian Government must not leave itself exposed to the possibility of such a threat.

In addition, **the PHAA notes that the changes to the intellectual property laws proposed in the FTA will inevitably lead to delays in the entry of generic medications onto the market** in Australia. Hence the higher prices paid for drugs under patents will be extended for a number of years, thus retaining high prices when a lowering of prices could be anticipated under the PBS as it currently stands. Inevitably, this increase in overall PBS costs will be passed onto consumers, directly and/or as taxpayers. The PHAA recommends that these provisions be removed from the FTA.

It is also critically important to note that the efforts of PhRMA and its members are not confined to direct lobbying in the United States and in Australia. Rather they extend to the use of the internet as a means of direct to consumer marketing of individual drugs. This is contrary to Australian law on the advertising of drugs. **The PHAA believes that this inappropriate use of the internet will lead to unnecessary demand for specific drugs, thus increasing the costs of the PBS.** There have been notable examples of such cost “blowouts” in recent years.

The Public Health Association of Australia affirms the following principles:

1. The PBS is an essential mechanism for providing equitable and affordable access to medicines for all Australians.
2. The PBS should be protected or excluded from any agreement that weakens the ability of the government to maintain the current operating mechanisms of the scheme.
3. As endorsed by the 2001 Doha Declaration, governments of the world have the right to make public health decisions without breaching trade agreements.

The Public Health Association of Australia believes that the following steps should be undertaken:

- The Federal Government should commit to maintaining the PBS as a means of providing the Australian community with universal, affordable and equitable access to essential medicines.
- The PBS should be protected or excluded from this and any other free trade agreement.
- Should the Government refuse to remove the provisions outlined above as being of concern, then it is recommended that the Federal Government establish mechanisms to monitor the effects of each of these changes on the functioning of the PBAC, drug prescribing and usage, drug costs and the overall cost of the PBS. It is also recommended that if the provisions are retained, a ‘sunset clause’ of a maximum of five years be included allowing the Australian Government to rescind these provisions.
- This position should be maintained by this and subsequent Australian Federal Governments.
- Full disclosure and public accountability should be maintained by the Australian Federal Government at all times in relation to any negotiations with foreign governments, organizations and companies regarding the PBS.

The PHAA notes that we have a number of other concerns about the FTA text. In particular we are concerned about the provisions relating to **quarantine and food safety standards**. These issues have been well addressed in other submissions, notably the Australian National University submission. PHAA reiterates its support for the stance taken in the ANU submission.

I would be happy to discuss this matter with you should that be useful. I can be contacted on (20) 62852373 or at plaut@phaa.net.au

Yours faithfully,

Pieta-Rae Laut

Pieta-Rae Laut

ⁱ Laing, R. (2001), Transcript, Australian benefits scheme upsets US drug companies, 7.30 Report, ABC, 27/2/2001, <http://www.abc.net.au/7.30/s252447.htm>

ⁱⁱ Australian Productivity Commission. "International pharmaceutical price differences : research report". Published Melbourne : Productivity Commission, 2001" (ISBN 1740370414)

ⁱⁱⁱ Lokuge K, Denniss R. The Australia Institute. "Trading in our health system? The impact of the Australia-US Free Trade Agreement on the Pharmaceutical Benefits Scheme". Discussion paper 55, May 2003. ISSN 1322-5421.

^{iv} Birkett DJ, Mitchell AS, McManus P. "A cost-effectiveness approach to drug subsidy and pricing in Australia". Health Affairs, Vol 20(3), 2001 pp 104-114.

^v Hill SR, Mitchell AS, Henry DA. "Problems with the interpretation of pharmacoeconomic analyses: a review of submissions to the Australian Pharmaceutical Benefits Scheme". JAMA 2000, Apr 26; 283(16):2116-21.

^{vi} George B, Harris A, Mitchell A. Cost effectiveness analysis and the consistency of decision making: evidence from pharmaceutical reimbursement in Australia (1991-1996). Pharmacoeconomics, 2001; 19(11):1103-9.

^{vii} Pharmaceutical Research and Manufacturers Association (PhRMA) www.phrma.org/international/resources/04.03.2003.353.cfm Accessed 01/04/2003

^{viii} Consumer Project on Technology. www.cptech.org/ip/health/politics/revolvingdoor.html, Jan 2001, version 2.0. Accessed 16/07/2003.

^{ix} Oxfam Briefing Paper No 33, November 2002.

www.oxfam.org.uk/policy/papers/33bullying/33bullying.html Accessed 01/04/2003.

^x US Department of State. www.usinfo.state.gov/topical/econ/ipr/03050101.htm Accessed 15/07/2003.

^{xi} Oxfam. www.oxfamamerica.org/advocacy/art5635.html Accessed 15/07/2003.

^{xii} World Trade Organisation. Ministerial Conference, Doha, 9-14 November, 2001. WT/MIN(01)/DEC/1