National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 – Senate Inquiry

Submission of Dr Thomas Faunce

Senior Lecturer College of law and Medical School

Australian National University

Contents

Executive Summary 3

Background 3

Background to PBS Reference Pricing 4

AUSFTA and Policy Changes to PBS 5

Adverse Impact of the Bill on PBS Fundamentals 7

Need to Repeal or Amend this PBS Legislation 8

Comments on the Minister's Second Reading Speech 9

Recommendations 14

References 16

Executive Summary

The creation through these amendments of a special F1 category for new medicines on the basis that their 'innovative' claims are related to their single 'brand' status in relation to competitors, represents a fundamental shift of Australian medicines policy away from valuing pharmaceutical innovation against traditional PBS evidence-based criteria of 'objectively demonstrated therapeutic significance' toward valuing it through nominally 'competitive markets' (the US position under Annex 2C.1 of the AUSFTA).

Seven specific recommendations are set out at the conclusion of this document.

Background

The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 was introduced into the House of Representatives on 24 May while the Senate was not sitting. It is expected that the Bill will be formally referred to the Committee for inquiry when the Senate next sits on 12 June. The reporting date will be early the following week as the Bill is scheduled for passage that week.

Due to the expected very short timetable for the inquiry, the Committee is providing advance notification of the inquiry to enable some extra time to provide a written submission.

This submission has been lodged prior to 13 June 2007, electronically as an attached document – email: community.affairs.sen@aph.gov.au – also by fax (02 6277 5829).

I understand that submissions become Committee documents and are made public only after a decision by the Committee. I also understand that publication of submissions includes loading them onto the internet and their being available to other interested parties including the media and that persons making submissions must not release them without the approval of the Committee. I understand that submissions are covered by parliamentary privilege but the unauthorised release of them is not protected.

I am aware that information relating to Senate Committee inquiries, including notes to assist in the preparation of submissions for a Committee, can be located on the Internet at http://www.aph.gov.au/senate/committee/wit_sub/index.htm

The Committee anticipates holding a public hearing in Canberra on 15 June 2007 and I am available on that date if required and have communicated this to the Committee Secretariat on (02) 6277 3515.

Background to PBS Reference Pricing

The PBS is an internationally respected system under which the federal government reimburses to pharmacists (and thence to manufacturers), from public funds, the 'health innovation' value of listed medications as proven by a hierarchy of scientific evidence assessed by pharmaco-economic experts on the Pharmaceutical Benefits Advisory Committee (PBAC). This allows Australian citizens, oblivious to that price negotiation, to generally pay at or below a standardised, relatively low, co-payment ($30.70 from 1 January 2007) for all PBS medicines, patented and generic alike. Under the current PBS system, once expert assessment has established that a new patented drug has better efficacy or safety (in terms of incremental cost per life year gained or modelled surrogate outcomes) than a different off-patent comparator for the same main clinical indication, it is recommended by the PBAC for listing and the price is negotiated by the Pharmaceutical Benefits Pricing Authority (PBPA). If that transparent and accountable analysis merely establishes eqi-effectiveness of dose, then, in a fundamental cost-minimisation process, the newly listed drug's initial reimbursement price is linked to the lowest of comparitor(s) grouping price reference groups. This initial cost-minimisation is distinct from that reference pricing which limits (after listing) the amount our government pays for drugs in six 'therapeutic groups' to that of the lowest therein; patients having to pay an additional therapeutic group premium (TGP) when their doctor prescribes the more expensive group members. For example, of the dihydropyridine derivative calcium channel blockers, Zandip 10mg has a TGP of $1.07 and Norvasc 10mg a TGP of $6.48. In this system, "interchangeable" is a conclusion made on established technical grounds only about different brands of a particular strength of the same item. It is not a concept used to compare different drugs. Thus, reference pricing is an important institutional manifestation of science-based community health value required to underpin public expenditure on expensive medicines under section 101(3B(a)) of the National Health Act, as well as the principle of equity of access under the Australian National Medicines Policy.1

PBS reference pricing values pharmaceutical innovation transparently and accountably. It links the price of a patented medicine to that of a suitable comparitor proven to provide merely an equivalent health outcome after expert assessment against

objective criteria of its differential effectiveness. Reference pricing is not value neutral, it has a philosophical basis in the evidence-based distributional justice required to underpin public expenditure on medicines (a fair connection between price and proven community benefit) by section 101 (3A&B) of the *National Health Act 1953 (Cth)* and the principle of equity of access under the Australian National Medicines Policy.[1] Reference pricing has many forms in the present PBS system, but it applies after cost-minimisation determinations at the time of initial reimbursement and later when new competitors (with lower prices) enter the market.

Multinational pharmaceutical companies prefer to have 'innovation' 'valued' by the operation of markets that are nominally competitive but readily distorted by collusion and advertising.

AUSFTA and Policy Changes to PBS

The last few years have been a turbulent policy period for the PBS. Annex 2C of the AUSFTA[2], which specifically focused on the PBS, lead to positive changes including public summary documents.[3] It also produced, however, a new review mechanism for Pharmaceutical Benefits Advisory Committee (PBAC) decisions,[4] and increased opportunities for industry pre-hearings and consultations with technical staff. Annex 2C established a Medicines Working Group (MWG) comprising high level officials on medicines policy from both countries.[5] In the last few months policies have been produced for full PBAC cost-recovery from industry.[6] This is despite such 'user fees' and increased liaison mechanisms being criticised as creating dangerous conflicts of interest for the US Food and Drug Administration (FDA) and strong calls being made for their removal.[7]

Perhaps most significantly, Annex 2C.1 of the AUSFTA emphasised the principle of valuing pharmaceutical 'innovation' through either the operation of 'competitive markets' [the US position] or by 'adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical' [the Australian position].[8] The potential importance to Australian medicines policy of this ambiguous definition of 'innovation', has been highlighted by the author in this journal,[9] and elsewhere.[10]

The US negotiators to the AUSFTA, who previously worked very closely with senior members of the US patented pharmaceutical industry on the IFAC3 committee, had an explicit legislative mandate to seek the 'elimination' of PBS reference pricing[11] (see box 1).

The same legislation also required the US Department of Commerce to investigate the dismantling of reference pricing in OECD countries.[12] On 1-2 December 2005, in Paris, the US sought to implement this agenda through an OECD 'Project on Pharmaceutical Pricing Policies and Innovation'.[13]

Australian AUSFTA negotiators provided these reassurances about the Annex 2C.1 innovation principles before a Senate Select Committee:

> "We went into these negotiations with an absolutely clear mandate to protect and preserve the fundamentals of the PBS. This is what this agreement does...There is nothing in the commitments that we have entered into in Annex 2C or the exchange of letters on the PBS that requires legislative change."[14]

The AUSFTA MWG met for the first time in Washington on 13 January 2006 and Australia's Trade Minister Mark Vaile stated:

> "The core principle that we both agree on in this area…is recognising the value of innovation."[15]

This statement represented a radical reorganization of priorities under the Australian National Medicines Policy. Documents obtained under a Freedom of Information application[16] reveal that the first AUSFTA MWG meeting only discussed one Op-Ed. This argued: "Truly innovative cures should be referenced against innovation in other classes, rather than against generics."[17] The second meeting of the MWG on 30 April 2007, discussed the remarkably similar F1 PBS category.[18] The official Australian government website, however, only disclosed that MWG "discussions were constructive and informative".[19] This evidence of a possible, non-transparent MWG link between 'innovation' in the AUSFTA Annex 2C.1, the new F1 PBS category and the vague precondition of 'interchangeable of an individual patient basis' before reference pricing, has disturbing implications for sovereignty over Australian public health policy.

The South Korean government was so impressed by the socially and scientifically sound economic incentives offered by Australian PBS evidence-based cost-effectiveness and reference pricing system, that it demanded a similar process in its free trade negotiations with the United States.[20] Article 5.2 of the KORUSFTA indicated that if South Korea did establish a reimbursement system for pharmaceuticals or medical devices where the amount paid was not based on 'competitive market-derived prices', then amongst other things it had to 'appropriately recognise the value of patented pharmaceutical products' (article 5.2 (b) (i)). Article 5.1 (c) and (e) respectively mentioned PBAC-type 'sound economic incentives' as a method of facilitating access to patented medicines and 'transparent and accountable' procedures as a means of promoting innovation. Article 5.7 of the KORUSFTA creates a similar Medicines and Medical Devices Committee to the AUSFTA MWG. Such international interest is one reason why the debate over the PBS Bill, introduced to the federal House of Representatives on 24 May (the draft legislation issuing one week previously), is globally significant.

Adverse Impact of the Bill on PBS Fundamentals

The PBS Bill proposes amendments (new sections 85AB, 85AC) to the National Health Act 1953 (Cwlth) that will divide the current PBS formulary into two: F1, for patented or 'innovative' medicines; and F2, for generic medicines.

Once adopted, price cuts and disclosures will be imposed only on F2 generic medicines. Reference pricing as it operates after PBS listing to produce therapeutic group-wide 'flow-on' price drops will be problematic between the F1 and F2 classes. New therapeutic groups (in addition to the existing six) will have to meet the additional high standard (undefined in legislation) that they are "interchangeable on an individual patient basis" (proposed sections 84AG and 101[3BA]). This phrase needs precise definition and clarification of its non-interference with (1) the initial choice of cost-effectiveness comparitor (2) initial cost-minimisation and (3) the creation of therapeutic relativity sheets that are used by the PBPA to assess post-listing industry requests for price rises. Without such clarifications, this change and the creation of F1 and F2 clases, threaten a shift away from the fundamental PBS evidence-based method of valuing the

'health innovation' of a patented pharmaceutical after listing, toward one which values F1 products over their time more through the operation of markets that are nominally competitive but readily distorted by collusion and advertising.

The Bill proposed amendments (new sections 85AB, 85AC) to the *National Health Act 1953 (Cth)* fracture the unitary PBS formulary into two: F1 for patented or allegedly 'innovative' medicines and F2 for generic medicines. Price cuts and disclosures will be imposed *only* on F2 generic medicines (new Division 3A of Part VII). Reference pricing will be limited to a few existing F1 therapeutic groups, or to where initial comparitors have met the imprecise standard that they are 'interchangeable on an individual patient basis' (proposed sections 84 AG and 101 (3BA)). The latter amendment inserts a highly capricious and idiosyncratic test into the heart of every PBAC listing recommendation. Individual patient (or clinician) reasons for asserting non-interchangebility may relate more to advertising and 'branding' of products, than efficacy or safety. The section 101 (3BA) 'individual interchangeability' requirement for all PBAC listing recommendations will easily be exploited in the new hearings process and review mechanism by 'innovator' manufacturers who wish to avoid price reductions through any initial choice of comparitor.

Need to Repeal or Amend this PBS Legislation

It is likely that creating an F1 PBS category insulated from reference pricing against generics and required price drops will, in the short term, tempt governments to increase the extent of patient cost sharing (perhaps through differential means-tested co-payments) for high cost patented F1 medicines. It will also provide additional arguments for lobbyists of the patented pharmaceutical industry to claim that the PBS is "unsustainable" and we need to move to a privately financed pre-paid insurance system, such as medical savings accounts (a form of medicines superannuation).[21]

If a future Australian government, however, wants to retain public funding of patented medicines and contain PBS expenditure, it could remove, or more rigorously define, the vague criteria of 'individual interchangeablility' clouding the certainty of comparative cost effectiveness in initial PBS pricing mechanism determinations. It will protect and support the independence of officials involved in pharmacoeconomic analysis

and vigorous price negotiations with patented manufacturers, both on first listing and over time.

The danger is that the mechanics of the PBS are so arcane that this choice might be delegated to technical experts in finance, rather than made part of a systematic public debate about the kind of health care system all Australians want to have and the trade-offs they are prepared to make against strategic objectives of trade or international public policy.

The incentives for products to remain in the protected F1 class will lead to much more aggressive pharmaceutical patent battles in Australia. These will be fought in a regulatory environment restructured by AUSFTA article 17.10.4-required amendments to the *Therapeutic Goods Act 1989 (Cth)*, creating a potential "evergreening" notification system for patented drug manufacturers about impending generic market entry, as well as increased opportunities for patent extensions for delayed marketing approval.[22] Without a period of market exclusivity for first generic entrant, expedited patent hearing process, or a single list of pharmaceutical patents overseen by a specialist multidisciplinary body (as in Canada), the thin profit margins allowed by these changes are unlikely to create a high value-added generics industry in Australia capable to linking with our emerging bio/nanotechnology strengths and efficiently responding to a compulsory license in a public health emergency.[23] Such a series of outcomes will make the Australian regulatory and policy environment for medicines resemble the inequities of the US system: low price generics, but unaffordable innovator products and worse health outcomes for citizens lacking private insurance with extensive coverage.

Comments on the Minister's Second Reading Speech

House of Representatives 24 May 2007. **National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007**

Second Reading

The Pharmaceutical Benefits Scheme (PBS) is an excellent system for funding access to medicines and has served the Australian people well for many years.

The PBS provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. Patients normally pay only standard copayments to access medicines which often would otherwise be unaffordable. Doctors and patients can often choose between a variety of medicines and brands to treat a particular condition. Medicines that are listed on the PBS are assessed by experts to be clinically effective and cost effective.

> ***Comment: This explanation fails to emphasise that the PBS was established by Constitutional referendum and has been supported by each major party over 50 years. It also fails to discuss the reasons why Australia was prepared to allow the PBS, as a core item of Australian health policy, to be included in the AUSFTA. This is particularly important given the secretive nature of the AUSFTA Medicines Working Group and its presumptive influence in creating the aspects of these amendments that undermine reference pricing.***

In 2005-06, the government provided $6.2 billion to subsidise access to medicines listed on the PBS. More than 168 million prescriptions across a wide range of PBS listed medicines were dispensed, ranging from relatively low-cost, high-volume medicines for the treatment of long-term chronic conditions to highly targeted, expensive medicines for acute and life threatening illness.

Every year important new medicines are listed on the PBS. Since August 2006, more than $1.3 billion has been committed to fund access to new medicines: medicines such as Herceptin for early breast cancer, Lantus and Levemir for the management of diabetes and Raptiva for the treatment of psoriatic arthritis. This is good news for patients, more of whom now have access to the latest medicines.

Other PBS listed drugs have recently had their criteria extended so they are now available to more patients. These include the statin group of drugs, including extensions

to the listing of Ezetrol and Vytorin, and broadened eligibility for alendronate for the treatment of osteoporosis.

It is our responsibility, however, to continue to scrutinise schemes like the PBS to ensure that we are getting good value for taxpayers. The structures we have in place must be able to continue to provide access to new and expensive medicines for future generations.

The integrated package of reforms to the PBS I announced on 16 November 2006 delivers this dual aim. It puts in place structural changes to the pricing of medicines to achieve good value for listed medicines, while delivering long-term savings to support the continued listing of cost-effective medicines into the future.

> ***Comment: The problem with this approach is that its strategy about facilitating access to expensive patented medicines is predicated chiefly on making more citizen money available to fund whatever excessive price is set by the multinational patented pharmaceutical industry. The approach should have emphasised that Australia emphasized during the AUSFTA negotiations and remains committed to an evidence-based approach to valuing health innovation, which is (this difference of opinion being set out in Annex 2C.1 of the AUSFTA) opposed to the US position of valuing innovation in pharmaceuticals through the operation of markets that are nominally competitive, but readily distorted by collusion and advertising.***

The reform package includes:

- a new structure to the PBS schedule with new pricing arrangements for listed medicines, including statutory price reductions and greater transparency through price disclosure requirements;
- a pharmacy support package to help community pharmacists to adjust to the new arrangements;
- streamlined authority approvals for a large number of medicines, which will give doctors more time to spend with their patients;

- establishing a working group to consider issues of continued access to innovative medicines through the PBS; and

  Comment: there is particular concern with allowing Medicines Australia (the patented pharmaceutical manufacturers association, representing foreign multinationals) to have this key policy role alone on a committee with the Department of Health and Ageing. In effect this is 'out-sourcing' policy development. The AUSFTA Medicines Working Group (and the US pharmaceutical interest there represented through US officials) was specifically excluded from this function, but now it is being given to them anyway. It is hard to see how such a body will develop any policies that emphasis the principle of access to essential medicines mentioned in the national Medicines Policy.

- a public awareness campaign to increase knowledge and usage of generic medicines.

  Comment: Without some fiscal encouragement to generic purchase (a small co-payment reduction) or market entry (a period of market exclusivity for the first generic market entrant, such an advertising campaign is a tokenistic gesture.

Key industry stakeholders, particularly Medicines Australia, the Pharmacy Guild and the Australian Medical Association, have indicated their general support for these reforms.

Comment: The Pharmacy Guild is actually very angry it was not consulted in advance about these PBS changes before signing its new contract with the government. The AMA supports low cost generics but not at the expense of removing reference pricing and its capacity to ensure value for public money in long term access to innovative drugs (soon to include gene and nano-based medicines)

The bill contains amendments to the National Health Act 1953 that will change the pricing arrangements for medicines to make sure that the government pays better prices for multiple brand medicines, without increasing the costs for patients and taxpayers.

These changes are forecast to save more than $580 million over the next four years, growing to $3 billion over the next 10 years.

The fundamentals of the PBS will not change. Patients will continue to meet only the standard copayments, currently $4.90 for concessional patients and $30.70 for general patients. In some cases, where the price of a medicine falls below the general copayment, patients will pay less. The Pharmacy Guild has estimated that about 400 brands will fall into this category.

The government will continue to list only those medicines that the Pharmaceutical Benefits Advisory Committee (PBAC) has assessed as safe, effective and cost effective. The legislation does not amend those sections of the act that set out the basis on which the PBAC provides advice on the listing of medicines.

Comment: The final sentence above is fundamentally incorrect once one considers that a new section 101 (3BA) requires the PBAC to specify in each new listing recommendation the new standard that that a comparitor is "interchangeable on an individual patient basis." It is difficult to see any public benefit from this new standard.

The main changes will be in the way that the government prices medicines that are operating in a competitive market. In recent times, the government has been paying too much for many multiple brand medicines where there is a competitive market operating. These medicines will take price reductions in the short term, and eventually will move to a more transparent system where the price the government pays is much closer to their market price.

The Formularies

The first major reform enacted by this bill is to divide medicines on the PBS into separate formularies, F1 for single brand medicines and F2 for multiple brand medicines. A medicine can be listed on only one formulary. Importantly, there will be no price links between these formularies.

Comment: The latter sentence if taken broadly represents a fundamental change in PBS cost-effectiveness processes and contradicts the Minister's assertion that such fundamental changes are not involved.

This classification of medicines into formularies is an important step in tackling a problem that has arisen in the current system of PBS pricing, where the price of single brand and multiple brand medicines that provide similar health outcomes has been linked.

In this environment, it has been difficult to impose price reductions on those multiple brand medicines which the government knows are being discounted to pharmacies. This is because, in many cases, the reductions flow directly on, through price linking, to single brand medicines that are not being discounted. This has caused some difficulties for industry and places patients at risk of losing subsidised access to many worthwhile medicines.

Classifying medicines into formularies with no price links between them allows the government to reduce the price paid for medicines operating in a competitive market while protecting single brand medicines from unsustainable price reductions.

Comment: It is incorrect to say that the main problem with PBS sustainability will be access to cheap generics. The main problem will be restraining the unaccountable costs of new patented medicines. These changes, by undermining reference pricing, fundamentally alter that important fiscal lever for community value from patent medicines prices.

Recommendations

1. There should be an immediate systematic inquiry into the manner in which these changes were developed and the extent to which they will adversely impact on the national interest long term. This inquiry should particularly focused on the extent to which encouragement of domestic manufacturing capacity in pharmaceuticals may be in the national interest with respect to subsequent compulsory licensing in national public health emergencies (particularly in response to emergent infections disease and bioterrorist threats) and also with regard to developing a high value-added biotech, sector emphasising gene and nano-based medicines in the future which will attract the top graduates in science and other relevant disciplines from Australia's educational sector.
2. The Government should restate that one of these changes were required by the AUSFTA. We made it clear in the AUSFTA negotiations that whilst the US wishes to value innovation in pharmaceuticals through the operation of competitive markets, the Australia system (which were assured would not change as a result of the AUSFTA values innovation scientifically through transparent and accountable expert assessment of 'objectively demonstrated therapeutic significance.'

3. National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007. Schedule 1- Amendments to the PBS. Part 1-Amendments National Health Act 1953. 34 At the end of Division 1 of Part VII

4. To the new section 84 AG Therapeutic Groups: delete these words from subsection (3) "to the effect that a drug or medicinal preparation should or should not, be treated as interchangeable on an individual patient basis with another drug or medicinal preparation"

5. 82 After subsection 101 (3B). Delete the new subsection (3BA) in its entirety. Replace with new subsection (3BA) "The members of the Pharmaceutical Benefits Advisory Committee shall receive such remuneration as is determined from time to time by the Minister and shall not receive payment for their official duties from sources other than public funds."

6. Also add new subsection (3BB) "Adjustments may be made to the evidence-based pharmacoeconomic processes utilised by the Pharmaceutical Benefits Advisory Committee in its assessments and price recomendations to properly adjust for the creation of the new F2 category. This shall not preclude forms of reference pricing continuing between the F1 and F2 categories established by sections 85AB and 85AC.
7. Add new section 101 (3BC) "Australian representatives to the Medicines Working Group established under the Australia-United Sates Free Trade Agreement shall publish in full the minutes of that groupon a website accessible to the Australian public.

References

[1] Australian Government Department of Health and Ageing, 2000, *National Medicines Policy*, available at http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/nmp-objectives-policy.htm/$FILE/nmp2000.pdf (last accessed 19 April 2007).
[2] Australia-United States Free Trade Agreement (AUSFTA), 18 May 2004, [2005] ATS 1, available at: http://www.dfat.gov.au/trade/negotiations/us.html (last accessed 15 March 2007).
[3] Australian Government. Department of Health and Ageing. PBAC Outcomes and Public Summary Documents. Available at: http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pbac-outcomes-and-public-summary-documents (last accessed 4 June 2007)
[4] Australian Government. Independent Review (PBS). Available at: http://www.independentreviewpbs.gov.au/ (last accessed 4 June 2007)
[5] US Department of Health and Human Services, 2006, *Australia-U.S. Medicines Working Group Holds First Meeting*, available at http://www.globalhealth.gov/Australia_meds_011406.shtml (last accessed 14 January 2006).
[6] Australian Government. Department of Health and Ageing. PBS News. Available at: http://www.pbs.gov.au/html/healthpro/news/article?id=NEWS-2007-04-18-Cost_Recovery.xml (last accessed 5 June 2007)
[7] Ray WA, Stein CM. Reform of drug regulation-beyond an independent drug-safety board. *NEJM* 2006; 354(2): 194-201.
[8] Lopert R, Medical Adviser, Pharmaceutical Benefits Brach, Dept. Health and Ageing. Senate Select Committee on the Free Trade Agreement between Australia and the United States of America. Official Committee Hansard Monday 21 June 2004; 18, 19, 24. Available at: http://www.aph.gov.au/Senate/committee/freetrade_ctte/hearings/index.htm (last accessed 1 Feb 2007)
[9] Harvey KJ, Faunce TA, Lokuge B, Drahos P. Will the Australia-United States Free Trade Agreement undermine the Pharmaceutical Benefits Scheme? *Medical Journal of Australia* 2004; 181(5): 256-259
[10] Faunce TA, Doran E, Henry D, Drahos P, Searles P, Pekarsky B, Neville, W. Assessing the impact of the Australia-United States Free Trade Agreement on Australian and global medicines policy *Globalisation and Health* 2005: 1; 1-15
[11] *Medicare Prescription Drug Improvement and Modernization Act 2003* 21 U.S.C. conference agreement House Report 108-391 Title XI-Access to Pharmaceuticals.. *Bipartisan Trade Promotion Authority Act 2002* (US), 107-210 §2102 (b) (8) (D).

[12] US Department of Commerce, 2004, "Pharmaceutical Price Controls in OECD Countries: Implications for US Consumers, Pricing, Research and Development and Innovation", available at http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf (last accessed 7 April 2006).
[13] Scherer P, Head Health Division. *Delegates to the OECD Group on Health*. Pharmaceutical Pricing Policy. Organisation for Economic Co-Operation and Development 20 September 2005 (letter in author's possession).
[14] Deady S, Special Negotiator, Office of Trade Negotiations. Dept. Foreign Affairs and Trade. Senate Select Committee on the Free Trade Agreement between Australia and the United States of America. Official Committee Hansard Monday 21 June 2004; 12 and 16. Available at: http://www.aph.gov.au/Senate/committee/freetrade_ctte/hearings/index.htm (last accessed 1 Feb 2007)
[15] Vaile, M, Deputy Prime Minister and Minister for Trade, 2006, Joint press conference at the office of the United States Trade Representative, Washington DC, 7 March.
[16] Organised by Pat Ranald. Australian Fair Trade and Investment Network 2007.
[17] Laming A. Let's Overhaul the Pharmaceutical Benefits Scheme *The Australian* 2006; 10 January 10.
[18] Comments by panellists and speakers Australian Government Attorney-General's Department, International Trade law Symposium 4 May 2007. University House, Australian National University.
[19] Australian Government. Department of Health and Ageing. AUSFTA-Medicines Working Group-2007 Meeting Statement. Available at: http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-ausfta-statement-2007 (last accessed 5 June 2007).
[20] Office of the US Trade Representative. Korea-United States Free Trade Agreement Chapter Five. Pharmaceutical and Medical Devices. Available at: http://www.ustr.gov/Trade_Agreements/Bilateral/Republic_of_Korea_FTA/Draft_Text/Section_Index.html (last accessed 26 May 2007)
[21] Will Delaat, Chairman of Medicines Australia. National Press Club speech 2005 reported in *Pharma in Focus* 8 August 2005 . Available at: http://www.pharmainfocus.com.au/news.asp?newsid=825 (last accessed 5 June 2007).
[22] Faunce TA and Lexchin J 'Linkage' pharmaceutical evergreening in Canada and Australia *Australian and New Zealand Journal of Health Policy* 2007: 4:8 Available at: http://www.anzhealthpolicy.com/ (last accessed 5 June 2007)
[23] Faunce TA Challenges for Australia's bio/nanopharma policies: Trade deals, public goods and reference pricing in sustainable industrial renewal *Australia and New Zealand Journal of Health Policy* 2007; 4:9 Available at: http://www.anzhealthpolicy.com/ (last accessed 5 June 2007)