Dr Thomas Faunce, BA LLB(Hons) B Med. PhD.
Associate Professor College of Medicine and Health Sciences and College of Law, Director
Globalisation and Health Project

College of LawBdg 5 rm 284
CANBERRA ACT 0200

T: +61 2 6125 3563
F: +61 2 6125 3971
E: Thomas.Faunce@anu.edu.au

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Senate
Community Affairs Committee

Submission by Assoc. Prof. Thomas Faunce
College of Law and College of Medicine and Health Sciences
Australian National University
And Timothy Vines, Research Associate, College of Law
Australian National University

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Executive Summary

This submission argues that

- Partial cost-recovery from industry submissions by the Pharmaceutical Benefits Advisory Committee (PBAC) is an important factor in ensuring the intergenerational sustainability and survival of the Pharmaceutical Benefits Scheme (PBS).
- The proposed amounts to be charged for partial PBAC cost-recovery grossly underestimate the hourly rates of the expert professionals (many at Professorial level) who give up their other paid employment to perform pharmacoeconomic assessments on the PBAC. The amounts proposed to be charged should at least be doubled and supplemented with the maintenance of existing government support calculated on an in-kind hourly rate for DOHA staff in the PBAC secretariat.
- Partial PBAC cost-recovery is opposed by Medicines Australia as an industry lobby group chiefly because their long term agenda is the collapse of the PBS and its replacement with Medicines Savings Accounts in which citizens achieve access to medicines in proportion to their capacity to take out private health insurance.
- Partial PBAC cost-recovery supports a conception of pharmaceutical innovation defined by scientific evidence of 'objectively demonstrated therapeutic significance' (the Australian approach mentioned in Annex 2C.1 of the AUSFTA) assessed through cost-effectiveness systems such as the PBS; these don't impede market access or patent rights, but aim to ensure maximum community value from the expenditure of public monies.
- China, India and Korea will soon be replicating the PBS and are likely to also introduce partial cost-recovery. It is likely that with a Democrat president US Federal legislation preventing Federal drug cost-effectiveness systems will be removed and the FDA

model of cost-recovery from industry will then commence there also.

- Partial PBAC cost-recovery needs to be introduced with legislative protections for the independence of PBAC assessors, which should include prohibiting industry positions on PBAC management committees, no industry involvement in PBAC assessor appointment, dismissal or remuneration (Fixed terms, directly appointed by the Minister in consultation with the PBAC chair).
- Mechanisms for funding cost-effectiveness assessment (including partial or full cost-recovery from industry) would be worthwhile issues to be negotiated in the context of an international treaty on the safety and cost-effectiveness assessment of new health technologies. Australia could play a lead role in the creation of such a treaty, by alliances with nations such as China. India and Korea.

This Submission in Relation to Terms of Reference

(1) That the National Health Amendment (Pharmaceutical and Other Benefits-Cost Recovery) Bill 2008 be referred to the Community Affairs Committee for inquiry and report not before 18 August 2008, together with the following matters:

(a) the impact of the Pharmaceutical Benefit Scheme (PBS) cost recovery on:

(i) patients' timely and affordable access to medicines,

(ii) the Australian pharmaceutical industry,

(iii) new products and innovation, and

(iv) the independence of the Pharmaceutical Benefits Advisory Committee;

(b) cost recovery mechanisms in other countries;

(c) how cost recovery will improve the timeliness and effectiveness of the current PBS process for listing new medicines; and

(d) the modelling and consultation underpinning the decision.

(2) That, in conducting its inquiry, the committee hear evidence, inter alia, from the pharmaceutical industry, generic medicines industry, consumer and patient health groups, the Department of Health and Ageing, the PBS Evaluation Units and the Australian Medical Association and other medical bodies.

Background and General Comments

National Health Amendment (Pharmaceutical and Other Benefits - Cost Recovery) Bill 2008 (Cth) was originally designed to come into force on 1 July 2008, now defered to a committee for hearing.

Shld. 1 of the Bill aims to insert a new *Division 4C - Cost Recovery* into the *National Health Act 1953* (Cth) which, *inter alia,* allows for the making of regulations requiring the payment fees for PBS service: clause 99YBA(2)(b).

A further regulatory power allows a minister to refuse to exercise a power where the applicant has failed to pay the prescribed fee: clause 99YBB(1).

The financial impact of these changes has been estimated as $9.4m in fees (ex-GST) in 2009 rising to 'around $14m' (ex-GST) in 2010. [Explanatory Memorandum to the Bill, 1].

Impact on patients' timely and affordable access to medicines

The PBS has unquestionable democratic legitimacy. It is one of the few pieces of public policy in Australia that has been approved in a Constitutional referendum by a majority of citizens in a majority of States. It has survived challenges to its implementing legislation in the High Court of Australia and been improved by a series of federal governments over more than fifty years of intense health policy debate.

The core regulatory component of the PBS system is section 101 (3A&B) of the *National Health Act 1953 (Cth).* This, in broad terms, requires that pharmacoeconomic experts on the PBAC, recommend PBS listing (after a central government price negotiation) of a pharmaceutical submitted by its manufacturer after a positive determination of its cost-effectiveness in relation to alternative therapies (whether or not involving drugs).

Australia's PBS is highly respected nationally and internationally as a successful articulation of a scientific approach to ensuring maximum public benefit from government expenditure on medicines. Now solidly based on principles of the *National Medicines Policy*, it has been operating for over half a century to provide evidence-based, cost-effective and equitable access to healthcare for Australians. Efficient operation of the PBS in the present rapidly changing regulatory environment and with much more problematic claims to innovative status by orginator companies, requires a well-financed cost-effectiveness regulatory system with robust protections of its independence.

Before a new patented drug is listed, it must obtain safety, quality and efficacy marketing approval from the Australian *Therapeutic Goods Administration* (TGA). Once this is done, the supplier may apply to have it listed on the PBS, to an independent statutory committee – the *Pharmaceutical Benefits Advisory Committee* (PBAC) set up under the *National Health Act 1953*. The PBAC is required to consider applications against certain criteria set out in the legislation. The PBAC cannot recommend a new drug for listing if it is 'substantially more costly than an alternative therapy' unless it 'provides a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies' (*National Health Act 1953* (Cth), section 101(3B(a))). This is an onerous public responsibility on the highly expert members of the PBAC who to date have been inadequately compensated financially for their substantial effort.

The PBAC must now operate in a highly complex regulatory environment. In August 2007 (after minimal parliamentary debate lasting no more than two week for both houses combined), the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007* was passed, amending key provisions of the *National Health Act 1953*. In implementing what I have called 'in substance, the Medicines Australia policy proposals' for changes to the PBS reference pricing system, the legislation effectively created two PBS pricing formularies.

F1 comprises single brand, mostly patented and 'innovative' drugs and F2 comprises multiple brand, mostly generic medicines. Reference pricing no longer occurs between the two formularies. The pricing of new 'innovative' medicines in the F1 formulary risk diminishing the extent to which the PBS processes now can be said to be based on objectively demonstrated therapeutic significance. In outlining the changes late last year, the then Australian Health Minister Tony Abbott admitted that 'Generics Medicine Industry Association is not, as I understand it, especially happy with these changes.'

Although explained as derived from the need to allow lower cost generic medicines into Australia, these F1-F2 legislative changes to the PBS appear to substantially reflect the position on the PBS articulated by US negotiators during the AUSFTA negotiations (and in the AUSFTA Medicines Working Group (MWG)) on the 'elimination' of PBS reference pricing mechanisms (as supervised by the PBAC) has been successful to a significant degree, altering a core aspect of the Australian national medicines system that provided Australian citizens with timely and affordable access to medicines.

Further the anti-evergreening amendments introduced with the AUSFTA implementing legislation, provide in the the new 26C and 26D in the *Therapeutic Goods Act* 1989 (Cth) the capacity of the Commonwealth Attorney-General to join an application for an injunction by a brand name patent holder against a generic medicines manufacturer and to claim damages where an 'evergreening' injunction has caused a price rise under the PBS. This legislative mechanism allows Australia under article 32 of the *Vienna Convention on the Law of Treaties* to claim that its actionable legitimate expectation was that the 'linkage evergreening' system in article AUSFTA 17.10.4 would not increase medicines prices under the PBS.

In this contentious climate and with the price of brand name patented medicines continuing to rise in ways which forbid any rational understanding of their marginal costs of production, it is crucial that a strong PBAC system be maintained in Australian

citizens are to obtain timely and affordable access to medicines. This means the capacity of PBAC assessors to have the time and resources to do their job properly, but also to be protected from undue political or industrial interference with their tasks.

Impact on new products and innovation

PBAC cost-recovery (with proper protections of PBAC independence) will allow the PBAC processes to work more effectively in a drastically changed regulatory environment for new and innovative pharmaceutical products in Australia.

Working through a hierarchy of evidence, the PBAC and its and its advisory subcommittee assess the cost-effectiveness of the submitted product against its best already marketed comparitor. This is the core of the PABC's evidence-based approach to assessing the community value of health technology innovation, a concept known as 'health innovation' to distinguish it from lobbying and advertising-based approaches to establishing the innovation credentials of new health technologies. If the product is deemed not cost-effective by the PBAC, then in a cost-minimisation exercise, its price is reduced to that of the comparitor. Reference pricing, in its most fundamental sense, used (before the F1-F2 categories were established) to apply post-listing when new competitors (with lower prices) entered six groups established under the Therapeutic Group Premium (TGP) Policy. In this TGP system, the unusual criterion of "individual interchangeability" assisted patients wishing to obtain an alternative to a drug in one of these groups whose price has a high additional premium. Under the new F1-F2 changes this unusual, subjective and vague standard will become a more important part of PBAC work, also increasing its complexity and risks.

If the PBAC recommends against listing a particular pharmaceutical, the manufacturer can still access the market and promote its product, however the consumer will have to pay a higher out-of-pocket price. The PBS process is thus not a non-tariff barrier to

trade. It also facilitates a more science-based approach to pharmaceutical pricing. The Pharmaceutical Benefits Pricing Authority (PBPA) uses the PBAC recommendation to negotiate a maximum amount the government will reimburse to pharmacists. It, as mentioned, is an evidence-based system of evaluating pharmaceutical 'health innovation' on the basis of objectively demonstrated therapeutic significance, in line with the four main objectives of Australia's ***National Medicines Policy***:

- *timely access to the medicines that Australians need, at a cost individuals and the community can afford; [the latter phrase is often deleted by representatives of Medicines Australia when they cite the National Medicines Policy]*
- *medicines meeting appropriate standards of quality, safety and efficacy;*
- *quality use of medicines; and*
- *maintaining a responsible and viable medicines industry.*

In addition, the 'transparency' provisions under AUSFTA Annex 2C.2 now add to PBAC workload by containing requirements that listing PBS proposals are completed within a specified time, that procedural rules, methodologies, principles, and guidelines used to assess a proposal be disclosed, and that applicants are given opportunities to provide comments. Furthermore, PBS applicants and the public are to be provided by the PBAC with detailed information about the determinations made, and an 'independent review process' is to be available to an applicant directly affected by a recommendation or determination. The legislative form that this review process took framed it more as a quality assurance exercise for PBAC decisions, with no new evidence and no overturning of PBAC decisions permitted.

AUSFTA Annex 2C also established a 'Medicines Working Group' (MWG) which is to 'promote discussion and mutual understanding of issues relating to this Annex' (Annex 2C 3(b)). This has been viewed as creating the potential for patented pharmaceutical companies to lobby for or against changes to the PBS and PBAC

process, for example, through the role of Medicines Australia, the lobby group representing the so-called 'innovative' (often on market-based (advertising and lobbying) rather than scientific criteria) medicines industry in Australia.

Drug patent "evergreening" will also create major problems for PBAC work. 'Evergreening' is an important strategy that multinational pharmaceutical companies have been using since 1983 in the USA (and since 1993 in Canada) to retain rent-profits over "blockbuster" (high sales volume) drugs by extending patent monopolies for as long as possible. In Canada, to be discussed in more detail subsequently, the government has funded a specialised body to oversee 'evergreening' claims and their cost on the public purse. "Evergreening" is more a multifaceted strategic and tactical process. A central method is use of the patent system by innovator companies to delay the appearance of generic competitors. In terms of the PBS this would involve strategies to keep drugs in the F1 PBS category and prevent them being transferred to the F2 category. The PBAC may be heavily involved in such PBS category disputes. Briefly, other evergreening tactics the PBAC may encounter include introducing once a day versions of a drug just before patent expiration to replace a three times a day form or bringing a single isomer version of a drug that was previously marketed as a racemic isomer (e.g., esomeprazole replacing omeprazole). Recently drug companies have used doctors to attack generic products in academic journals. Another recent development involves contractual agreements in which the generic manufacturer agrees not to enter the market in return for financial remuneration from the brand name manufacturer. Brand name companies will sometimes enter into agreements with a single generic company to allow that company to produce a generic version ("authorised" generics) of a drug that is soon to go off-patent.

Data exclusivity may end up being another evergreening strategy. Generic companies are unable to use the original safety and efficacy data for a period of time. If they want to bring a product to

market while data exclusivity is being enforced they would have to conduct their own set of clinical trials to establish safety and efficacy. The cost of these trials would be prohibitive. Making data exclusivity long enough could significantly delay the appearance of generics.

Impact on the Australian pharmaceutical industry

The proposal is unlikely to adversely impact on the price or willingness of pharmaceutical companies to list products on the PBS. Pricing of new pharmaceuticals is non-transparent at best, and an exercise in global profit-gouging in the name of innovation at worst. The Australian Government has done a vast amount to encourage innovation in the pharmaceutical sector in Australia, with little reward.

Between 1990 and 2004, a succession of Australian governments funded a variety of regulatory initiatives, to obtain greater public benefit from pharmaceutical R&D and the pharmaceuticals sector. These have largely been unsuccessful and have too often resulted in wasteful subsidy of inefficient originator industries with Australian taxpayer funds.

On 29 May 2001, for example, the then Minister of Industry, Tourism and Resources announced a Pharmaceuticals Industry Action Agenda with an Implementation Group under the Chairmanship of Dr Graeme Blackman. Its key policy recommendations were to “promote increased investment and exports of pharmaceuticals goods and services” (action 2); “identify opportunities and facilitate growth in the export of pharmaceuticals industry” (action 7) “promote two-way movement between industry and academia” (action 11) and “align industry activity with the National Innovation Awareness Strategy” (action 14).[1]

As part of this Action Agenda, and following on from similar programs dating from the late 1980s, the Department of Industry, Tourism and Resources between 1999 and 2004 operated the $300 million Pharmaceutical Industry Investment Program which rewarded

manufacturers undertaking research and development in Australia. This program channelled support to nine companies, including one generics firm, FH Faulding & Co Limited (subsequently Mayne Pharma). It was replaced from 1 July 2004 by the Pharmaceuticals Partnerships Program worth $150 million over five years.

These policies focused on subsidising research and development and not on making the types of structural and regulatory changes that would support the sustainability of the regulatory components (particularly the TGA and PBAC) critical to a pharmaceutical industry in Australia. These policies of pharmaceutical industry development, in retrospect, paid insufficient attention to supporting and developing the PBS or enhancing the PBAC.

The industry challenges that the PBAC will soon be facing are extremely challenging. It is estimated that several hundred new 'biologic' drugs are now in development pipelines. These include, for example, growth hormone, insulin, granulocyte-macrophage colony-stimulating factor (GM-CSF), or erythropoietin. Such drugs are distinctively derived from living cells and their manufacturing companies often prefer to call themselves 'discovery generics', to highlight the amount of innovative research required for successful product development of these generic products. The current worldwide market for protein-based biotech. drugs, is over $20 billion. Biotech. patents increased substantially in most nations in the period 1991-2002, including Australia (19 to 100), Canada (53-136), Sweden (24 to 93), US (1160 to 2342) and EU (650 to 2025). India (3 to 28), China (0 to 49) and Ireland (6 to 7) increased by comparatively small amounts, but achieved the strongest gains in the most recent years.[2]

In the bio/nanopharma sector, Australia retains a leading role in the Asia-Pacific region and ranks number sixth the world in terms of number of firms.[3] Without careful policy attention this positive situation may not continue. Remove Australia's three largest biotech companies (CSL, Cochlear and ResMed), for example, and the sector

as a whole suffered a 14.6% decline of share price in 2006 (the NASDAQ Biotech Index falling 14.3 per cent in the same period).

Most medical ethics guidelines preclude clinical trials on a product that is demonstrably inferior to the current standard of care. Yet the PBAC may have to evaluate with such products without the capacity to require head-to head RCTs against the best already marketed therapeutic comparitor (instead of having to do modelling placebo RCTS).

A proposed US Federal Access to *Life-Savings Drugs Act* is intended to alleviate such problems. It allows abbreviated approval of biological products that share the "principal molecular structural features" of previously approved brand-name products. Approval for pharmacy substitution is conditional on regulators approving a biologic as a clinically "interchangeable" product, rather than a "follow-on" (or "me-too'). The Bill grants the secretary of the Department of Health and Human Services (DHHS) the extraordinary discretion (and responsibility) of determining on a case-by-case basis, whether additional clinical trials are required.[4] Such developments are likely to impact on a PBAC process that as a result of the F1-F2 legislative changes must now address the vague and subjective standard of 'clinical interchangeability (rather than the more robust and objective biological equivalence).

Pharmacogenetics (the science of studying genetically-determined responses to medicinal drugs) is another area that will provide particular challenges for the PBAC. Based on recent UK and US studies, about 1 in 15 admissions to Australian hospitals are due to or involve adverse drug reactions, many of these directly leading to adverse health outcomes.[5] Such harmful side effects vary between individuals and range from failure to respond therapeutically, to minor illness and even death.[6] A few Australian companies are already starting to invest in this area. One prominent example is Genetic Technologies Ltd, which is licensed by Myriad Genetics (USA) to carrying out BRCA breast cancer genetic screening. Australia,

generally, has a strong related skills base in genetic sequencing.

Predicted developments in pharmacogenetics include (1) recording of individual patient pharmacogenetic profiles (2) establishment of prescribing guidelines, that will relate dose to genotype and highlight the possibility of adverse drug interactions (3) development of new drugs for patients with specific genotypes (drug stratification). This latter area could be of particular policy value in the context of Australian biopharma industry renewal. Pharmaceutical industry interest may extend to 'packaging' drugs along with genetic tests and takeovers or licensing of genetic test manufacturers.[7]

If pharmacogenetics is to minimize drug expenditure by reducing wastage and simplify post-marketing surveillance, then both Therapeutic Goods Administration (TGA) and the PBS officials will need to be actively involved in policy development. Under definitions of reference pricing prior to the F1-F2 categories, for example, new patented drugs seeking PBS listing in conjunction with a genetic test would still need to be evaluated for comparative cost-effectiveness against existing marketed products (without linked genetic tests). Clinical trials are becoming increasingly expensive and pharmacogenetics could provide a seemingly attractive way of reducing industry dependence on them for regulatory approvals and post-marketing surveillance. The Novartis Institutes of Biomedical Research has recently been promoting use of biomarkers to select research subjects with the idea of improving the efficiency of pharmaceutical clinical trials. Despite cautious present investor interest, linking medicines with a genetic test could facilitate valuable long term diversification in the Australian bio/nanopharma industry.

Medical nanotechnology will be another challenging area for the PBAC. It involves the development of drug/invasive therapeutic device products controllable at atomic, molecular or macromolecular levels of approximately 1-100 nanometers. Nanostructures have much greater strength, stability and surface area per unit mass than standard materials and those below 10nm possess quantum effects where size

may control, for example, the specific wavelength of emitted light.[8]

Nanotechnology is a rapidly expanding area of medical research and development globally.[9] Over 200 companies are actively involved in this area, viewing nanotechnology is having a powerful enabling function that enhances the effectiveness and market competitiveness of existing health technologies.[10] Peptide nanotubes, for example, have been investigated as the next generation of antibiotics[11] and as immune modulators[12] Nanomedical applications been investigated in neurosurgery,[13] cardiac surgery[14] and blood disorders[15] Most major pharmaceutical companies have substantial investments in nanotechnology.[16]

In Australia, nanomedicine is a rapidly growing industry sector. Starpharma, for example, (with US-based Dendritic NanoTechnologies) and Australian government and US National Institutes of Health (NIH) funding, is developing VivaGel™ as an HIV-prevention dendrimer-based microbicide gel. VivaGel™ represents bottom up nanotechnology and involves a well-defined synthetic polymer, made by adding monomers in a branching manner, binding to glycoproteins on the surface of HIV and thus preventing, in a dose-response manner, HIV binding to receptors on T-cells. VivaGel™ is the world's first dendrimer-based drug to be approved for human trials by US FDA (phase 1 study completed 2004). pSividia has developed Brachysil™ a nanostructural, porosified, biosilicon platform technology for controlled drug delivery and already have a licensing agreement for it with a US company based in China.

A recent Senate Inquiry recommended creation of a working party to consider creation of a distinct, permanent regulatory body for nanotechnology.[17] The latter approach was taken with gene technology under the *Gene Technology Act* 2000 (Cth).[18] Such a broad licensing approach, encompassing regulatory industrial, agricultural and therapeutic applications may not be the best vehicle for encouraging renewal in the uniquely complex Australian bio/nanopharma sector.

Hasty regulatory approval of nano-versions of existing drugs (as is the case with generic 'biologicals') could place expenditure burdens of public health systems and risk damage to public health. In this context, given the presumptive claims that nanomedicine manufacturers will make for reimbursement reward of their 'innovation', the maintenance of a robust system of PBS reference pricing will be critical to ensuring that the Australian public obtains value for its nanomedicine expenditure. A recent European Science Foundation report recommends that the flexible enabling functions of nanotechnology in medical applications may be lost if coordinated policies facilitating investment and efficient regulation are not developed.[19] At present, however, most regulatory concern in Australia seems to be focused generally on the safety of nanotechnology, rather than its cost-effectiveness. This will change. At that time the PBAC process will need to have capacity to deal with much more complex evaluations.

Impact on the independence of the Pharmaceutical Benefits Advisory Committee

There could be quite adverse impacts of partial cost-recovery from industry on the PBAC if this is allowed to create a client-type expectation that the PBAC will not refuse PBS registration. This concern could be alleviated if care was created in shaping the appointment and dismissal terms of PBAC members. One suggestion would be that such members are appointed for a fixed renewable term of five years and remunerated from industry fees at whatever rate proportional to that earnt in their normal professional occupation. This would leave the Federal Govt able to contribute to the general administrative costs of the PBAC secretariat...so ensuring a financial stake in PBAC independence. Shifting the proposal to maintain or increase the level of funding sought from industry, but ensuring that the Federal Government continued to make some substantial

contribution (at least existing levels and/or measured on an in-kind-basis to include working hours of DOHA staff) to PBAC operations.

Broader Concerns and Issues

Cost recovery mechanisms in other countries

It is likely that with a Democrat president US Federal legislation preventing Federal drug cost-effectiveness systems will be removed and the FDA model of cost-recovery from industry will then commence there.

Health Canada's Health Products and Foods Branch (HPFB) has established the Cost Recovery Initiative (CRI) to analyze and improve upon the current cost recovery regime that covers the regulation, licencing, and post market surveillance of health products. The current focus of the CRI is on human drugs (pharmaceutical and biological), natural health products, blood and blood products, vaccines, tissues and organs, and medical devices. There is no indication that cost-effectiveness evaluation system would not be included. The Project Objectives involve building on and consistent with Health Canada policies and direction, the CRI goal is to develop and implement a cost recovery framework to provide a long-term stable funding source for HPFB. This includes the following components:

* general cost recovery policies applicable to all product lines within HPFB;
* conduct of external consultations with stakeholders;
* the regulatory amendment and parliamentary review process; and
* the required implementation activities.[20]

Korea announced its intention to create a 'positive list' for government reimbursement of the price of pharmaceuticals in May 2006, modelled on the PBS and PBAC process. This move met by strong opposition from KORUS-FTA US negotiators who refused to attend a

Pharmaceutical and Medical Device Working Group meeting. In a public statement by a US trade representative, the US saw the decision to create the list as 'inconsistent with both the mandate of the Pharmaceutical Working Group and the market-opening spirit of the FTA.' In reality, the US negotiators had been surprised that a developed nation had adopted a similar approach to themselves and sought to use FTA negotiations to fulfil its own national interests in medicines policy, in this case by the creation of a PBS-style cost-effectiveness system.

This was not the first time that the US has used trade negotiations with Korea to impose higher drug prices. Since 1999, the US has been negotiating market access in the pharmaceutical sector with Korea. One aspect of the negotiations was to pressure Korea to adopt the "A-7 pricing system" for all new innovative medicines, that is the average ex-factory price in the A-7 countries – US, UK, Germany, France, Italy, Switzerland and Japan. This had been widely criticised, as the result required Koreans to pay much higher prices relative to their average income per person than any of the other A-7 countries. Furthermore, Korea also paid more for patented drugs than the US did in absolute terms. It is hardly unexpected that the South Koreans would want to replace such a system with the PBS-style system, using a formulary (referred to as a 'positive list') and reference pricing.

Article 5.2 of the KORUS-FTA deals with the issue of pharmaceutical innovation in a somewhat similar manner to Annex 2C of the AUS-FTA. In determining price reimbursements, the KORUS-FTA requires a Party's determination must be 'based on competitive market-derived prices' (article 5.2(b)), (which can be viewed as the US' preferred position) or if it is not, the Party must then 'appropriately recognize the value of the patented pharmaceutical product or medical device in the amount of reimbursement it provides.' The crucial focus in this context must be on the word 'value'. It is likely that the Koreans will argue, after they have set up a science-based positive list formulary like the PBS, that the term 'value'

in this alternative must mean something different than “competitive market-derived prices.” As such it would be a legitimate expectation that it referred to a process of evidence-based determination of ‘objectively demonstrated therapeutic significance’ as mentioned in AUSFTA Annex 2C.

It is likely that China will soon implement a PBS-style cost-effectiveness system linked to a central government price negotiation. On 18 April 2005, after the completion of a joint FTA Feasibility Study showing potential for significant economic benefits, Australia and China agreed to begin negotiations on an FTA.

As one of the world’s largest manufacturers of generic pharmaceuticals, China has a pharmaceuticals industry predicted to become the world’s 5th largest by 2010, and largest by 2050. Negotaions are being considered for an Australia-India FTA. I have previously suggested establishing a pharmaceuticals chapter in such FTAs including a Medicines Working Committee could be set up to facilitate dialogue about about establishing and funding, for example, regulatory mechanisms similar to Australia’s PBS, sharing expertise, data, assessments and methods of comparing effectiveness and objective therapeutic significance of existing and new medicines. The traditional of public health focus in government policy could make this an attractive proposition for Australia, India and China. The operation of the similar MWG under the AUSFTA provides a precedent.

Another approach, advocated by the first author in a variety of publications, to overcoming the problems of disjunction between the global burden of disease and the direction of health technology R&D involves aggregating and formalising at the global level existing networks of national assessors scrutinising the safety and cost-effectiveness of new health technologies. This model involves a multilateral treaty establishing basic principles and procedures for price negotiations between governments (or UN agencies) and

manufacturers of new health technologies based on expert assessment of safety and cost effectiveness

This Cost-Effectiveness Assessment Treaty model aims to enhance the global scope of fully mature regulatory processes already existent in many jurisdictions. It can provide a clear incentive system for pharmaceutical manufacturers to seek to develop innovative medicines for developing world populations, by providing a transparent pathway to a large pool of mixed charitable, United Nations and domestic government funds allocated to being spent, under a competitive tender process, upon pharmaceuticals for otherwise 'research-neglected' diseases in the developing world. Cost-recovery for assessments could become a major point of discussion for such a Treaty

Working out a road map toward such a treaty would involve, for example, discussions about principles on assessor reimbursement (possibly a tax on global financial transactions) and liability protection, rationalisation of commercial–in-confidence protections, post-marketing surveillance and performance indicators for conditional approvals and strategies to obtain information on marginal cost of production and price setting.

How cost recovery will improve the timeliness and effectiveness of the current PBS process for listing new medicines

Partial cost-recovery from industry for PBAC submissions would greatly facilitate the timeliness and effectiveness of current PBS processes if it leads for example to being able to attract greater numbers of high-level experts to do PBAC work. Money will not however be enough to lure such expert staff, they will also need to feel that the integrity of the PBS as a key element of the egalitarian social architecture of Australia is being maintained. This means they will

need protection in legislation against political or industry pressure (fixed terms with no industry say in appointment or dismissal).

The modelling and consultation underpinning the decision

Medicines Australia complains about these, but it did not complain when a much greater lack of public consultation took place with the rapid introduction of the F1-F2 changes to the PBS. It is always difficult to tell whether Medicines Australia is being merely tactical in the submissions it makes to Government Inquiries. Its bottom line is always the profits of its members' shareholders, so it hardly be expected to have a substantial commitment to ensuring the sustainability of a system that effectively operates to ensure some accountability for the non-transparent pricing of the pharmaceuticals that its members would wish to claim are innovative purely on grounds of marketing and advertising.

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