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Inquiry into Draft National Health (Pharmaceutical Benefits - Charges) Regulations 2008

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Executive Summary

This submission argues:

1. That the original justification for partial cost-recovery – ensuring the continued viability and sustainability of the PBAC and its capacity to enhance access to cost-effective medicines for all Australian citizens and their families who need them– has not altered since the August report from the Senate Committee on Community Affairs into the *National Health Amendment (Pharmaceutical and Other Benefits—Cost Recovery) Bill 2008*;
2. That adequate allowance is made in the draft regulations for exceptions involving full or partial fee waiver to ensure that important low-volume medicines are still listed on the PBS;
3. That the regulations are in-line with the Government's Cost-Recovery policy and any impact upon industry is outweighed by the potential gains to the PBAC process which is presently faced with a enormous, and increasing, workload;
4. That it is in the interests of Australia's working families, pensioners and low-income earners to have access to quality medicines at affordable prices and that the PBS is an important institution which embodies Australia's 'fair-go' attitude;
5. That the draft regulations accommodate the Government's *National Medicines Policy* in that they ensure the sustainability of the PBS which depends, in turn, upon a viable and independent PBAC, although reference could be made to the National Medicines policy in clause 4 of the Regulations.

Introduction

This submission relies upon extracts of an earlier submission made to the Senate Committee for Community Affairs' inquire into the enabling legislation for the current draft regulations.[1] While the views of the authors on the appropriateness and desirability of partial cost-recovery mechanisms have not changed, we thank the Committee for the opportunity to again comment on the proposed draft regulations and to address the concerns of Government, Opposition and cross-bench Senators contained in the Committee's previous report.[2] This submission is set out to address specific concerns which were raised by Members and Senators during the second reading speech phase of the Parliamentary debate.

Part 1 – An Independent PBAC?

As one of the 'three pillars'[3] of Australia's public healthcare system the Pharmaceutical Benefits Scheme has enjoyed bipartisan support since its inception 60 years ago. That all Australian federal governments have remained committed to the PBS highlights its importance as an instrument of equality – representing the Australian notion of a 'fair go'. As a system for ensuring timely and affordable access to medicines to all Australian citizens and their families it is arguably 'one of the best systems of pharmaceutical delivery in the world.'[4] Central to its continuing success has been the independent role played by the Pharmaceutical Benefits Advisory Committee in determining the cost-effectiveness of new medicines.

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1 Thomas Faunce, Timothy Vines, 'Submission to Senate Committee on Community Affairs (*National Health Amendment (Pharmaceutical and Other Benefits Cost-Recovery) Bill 2008*' (Senate), submission number 11 http://www.aph.gov.au/Senate/committee/clac_ctte/nat_hth_pharm_cost_recover_08/submissions/sub11.pdf accessed 10 September 2008.

2 http://www.aph.gov.au/senate/committee/clac_ctte/nat_hth_pharm_cost_recover_08/report/report.pdf accessed on 8 September 2008.

3 Senator Siewert, Senate Debates, 28 August 2008, 14 (proof copy).

4 Joe Hockey, House of Representatives Debates, 5 June 2008, 4660.

The PBAC performs its functions in accordance with the procedure set out in section 101 (3A&B) of the *National Health Act 1953* (Cth), which, 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).'[5] Both industry and the members of the PBAC share a common goal of ensuring that recommendations made by the PBAC to the responsible minister (who, with Cabinet, ultimately decide to list a drug on the PBS)[6] remain independent of private, industry influence.[7] A concern raised by Members and Senators during the Committee and 2nd-reading stage of the bill was whether cost-recovery (even partial) would result in 'corporate-capture' and weaken the independence of the PBAC and the confidence Ministers could place on the Committee's recommendations.

Concern:

That the proposed regulations will impact upon the independence of the PBAC or create a perception of corporate-capture.

Rebuttal:

The proposed measures in the regulations amount only to partial cost recovery.[8] Further, as any revenue raised is paid into the General Consolidated Revenue Fund (CRF), rather than to the PBAC

5 Thomas Faunce, Timothy Vines, 'Submission to Senate Committee on Community Affairs (*National Health Amendment (Pharmaceutical and Other Benefits Cost-Recovery) Bill 2008*' (Senate), submision number 11 http://www.aph.gov.au/Senate/committee/clac_ctte/nat_hth_pharm_cost_recover_08/submissions/sub11.pdf accessed 10 September 2008.

6 s101(4)(b) *National Health Act 1953* (Cth).

7 Comments made at *A Practical Update On The PBAC Submission Guidelines Workshop* (Galaxy Room, Royal Randwick) (Thursday, September 4, 2008) (ARCS Australia).

8 As compared with the PBS cost-recovery measures considered by the previous government in 2005-06: Joe Hockey, House of Representatives Debates, 5 June 2008, 4660; Rebecca de Boer, *Bills Digest 6 June 2008, no. 125, 2007–08* at 3. At this time it was opposed by the then Labor Opposition.

itself,[9] the body remains at arms-length from the industry who helps to support it. The PBAC will neither set the fees to be levied nor handle the monies raise, with the Department of Health and Ageing continuing to fund the Committee and the Scheme.[10] PBAC decisions will still remain reviewable, either through a resubmission or to the PBS Review panel (for American therapeutic manufacturers) under the *AUSFTA*. It should be noted that a growing risk to the independence of the PBAC comes, not so much from industry, as from public campaigns driven by a general ignorance of the PBAC listing process. For example the initial decision of the PBAC to not list the HPV-vaccine Gardasil resulted in a media driven campaign where cost-effectiveness arguments were drowned out by calls for Government intervention.[11]

Part 2 – A Sustainable PBAC:

An issue of concern, which these regulations may help address, is the ability for the PBAC members to continue to provide a high-level of analytical and specialised skills in assessing the cost-effectiveness of proposed drugs. With the new Guidelines, both industry and the PBAC will be required to deal with more complex meta-analyses of clinical trials; economic modelling and pre-modelling.[12] While industry has been able to recruit private consultancy companies to assist it in preparing submissions to the PBAC, with the number of experts and agencies growing immensely

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9 Proposed section 99YBA(4) of the *National Health Amendment (Pharmaceutical and Other Benefits Cost-Recovery) Bill 2008* indicates that fees set under the regulations would be 'payable to the Commonwealth'. See the Department of Health and Ageing, 'Submission to Senate Committee on Community Affairs (*National Health Amendment (Pharmaceutical and Other Benefits Cost-Recovery) Bill 2008*' (Senate), submission number 10, 12.

10 Monies and debts to be managed by the Department of Finance and Administration: Department of Health and Ageing, 'Submission to Senate Committee on Community Affairs (*National Health Amendment (Pharmaceutical and Other Benefits Cost-Recovery) Bill 2008*' (Senate), submission number 10, 12.

11 Elizabeth E. Roughead, Andrew L. Gilbert & Agnes I. Vitry, 'The Australian funding debate on quadrivalent HPV vaccine: A case study for the national pharmaceutical policy.' [2008] *Health Policy* doi:10.1016/j.healthpol.2008.03.012 ; Sally Crossings, 'Breast Cancer Media Frenzy Anything but Helpful', *Crikey Online Article* (Tuesday, 15 July 2008) <http://www.crikey.com.au/Politics/20080715-Breast-cancer-wonder-drug-media-frenzy.html> accessed 10 September 2008; Agnes Vitry, 'How Gardasil Hype Undermined the PBAC', *Crikey Online Article* (Tuesday, 22 July 2008) <http://www.crikey.com.au/Politics/20080722-How-Gardasil-hype-undermined-the-PBAC.html> accessed 10 September 2008.

12 Comments made at *A Practical Update On The PBAC Submission Guidelines Workshop* (Galaxy Room, Royal Randwick) (Thursday, September 4, 2008) (ARCS Australia).

in the previous 6 years,[13] the PBAC has had to manage with the money provided to it by the Government. Consequently, with an increasing workload – and an increase in the complexity of the submissions – the resources available to the PBAC will need to grow in order for it to remain viable and sustainable into the future.[14] Additional funding, coming from partial cost-recovery could enhance the ability of the PBAC to attract 'greater numbers of high-level experts' to assist with its work.[15]

Currently 85% of the funding for PBS prescriptions comes from the Government, while the remaining 15% (~ $1.15 billion in 06-07) comes from patient copayments. Government expenditure on the PBS is estimated to total some $7 billion for FY 2007-08.[16] The predicated[17] (but by no means certain)[18] revenue expect to be raised through the cost-recovery measure is $9.4 million for FY 2008-09, rising to $14 million in 2009-10[19] This pales in comparison to the total cost (to Government and Australians) of the PBS. Moreover, with Australian Pharmaceutical industry estimated to have an annual turnover of $18 billion[20] (although this figure may also include transportation, storage and other product supply-chain outputs)[21] the fees proposed in the regulations are reasonable and appropriate. Even though industry disputes the $18 billion figure, a listing on the PBS provides a private financial advantage to companies, especially where the

13 Ibid.

14 Nick Lush, 'PBAC Workload up 40% since 04', *PharmaInFocus Online* Article. Posted 1 September 2008 <http://www.pharmainfocus.com.au/news.asp?newsid=2451> accessed 10 September 2008.

15 Thomas Faunce, Timothy Vines, 'Submission to Senate Committee on Community Affairs (*National Health Amendment (Pharmaceutical and Other Benefits Cost-Recovery) Bill 2008*' (Senate), submission number 11 http://www.aph.gov.au/Senate/committee/clac_ctte/nat_hth_pharm_cost_recover_08/submissions/sub11.pdf accessed 10 September 2008.

16 Monies and debts to be managed by the Department of Finance and Administration: Department of Health and Ageing, 'Submission to Senate Committee on Community Affairs (*National Health Amendment (Pharmaceutical and Other Benefits Cost-Recovery) Bill 2008*' (Senate), submission number 10, 8; Belinda Neal, House of Representatives Debates, 5 June 2008, 4663.

17 *Explanatory Memorandum* to the *National Health Amendment (Pharmaceutical and Other Benefits Cost-Recovery) Bill 2008*, 1.

18 Rebecca de Boer, *Bills Digest 6 June 2008, no. 125, 2007–08* at 10.

19 *Explanatory Memorandum* to the *National Health Amendment (Pharmaceutical and Other Benefits Cost-Recovery) Bill 2008*, 1.

20 Department of Health and Ageing, 'Submission to Senate Committee on Community Affairs (*National Health Amendment (Pharmaceutical and Other Benefits Cost-Recovery) Bill 2008*' (Senate), submission number 10, 11.

21 Nick Lush, 'Special Feature: Is Aussie pharma facing a perfect storm?', *PharmaInFocus Online Article*, 1 September 2008 <http://www.pharmainfocus.com.au/feature.asp?featureid=273> accessed 10 September 2008.

therapeutic is a single-brand medicines listed in the new F1 category. Pharmaceutical companies 'shared a total of of $4.46 billion from the Commonwealth via the PBS subsidy' in 2006-07,[22] further emphasising the commercial advantage gained from a PBS listing. If the revenue raised through the proposed cost-recovery levies was directed as additional revenue to the PBAC the agency could potentially engage in more post-listing pharmacovigilance in tandem with the Therapeutic Goods Administration.

Recommendation:

That the money raised through the proposed regulations should be provided to the PBAC as *additional funding* as it represents an important, if symbolic,[23] contribution from industry to a Scheme which provides significant private profits – notwithstanding the PBS's ultimate public purpose.

Part 3 – Orphan Drugs and Low-volume drugs:

[Re: Senators Colbeck and Fielding]

Concern:

Members of the Committee and the Senate voiced concerns that the proposed regulations could prove to be a disincentive to companies seeking to list a new product.[24] While all 'blockbuster' or high-volume drugs provide a good return on investment for pharmaceutical companies, small populations (such as children, indigenous Australians, palliative care patients etc...) could suffer if new drugs were not listed.

Senator Colbeck stated that he '...do[es] express some concern that fees for the additional indications may provide a significant disincentive for companies to put some of these products up for additional approvals' while Senator Fielding expressed his own concern that '...there [may] be some drugs in the future that will not be available for vulnerable Australians because making applications to get those drugs on the PBS could be cost prohibitive to the company applying? That

22 Mark Dreyfus QC, House of Representatives Debate, 5 June 2008, 4667.
23 Rebecca de Boer, *Bills Digest 6 June 2008, no. 125, 2007–08* at 10.
24 Senator Colbeck, Senate Debates, 28 August 2008, 13 (proof).

would be of concern especially in Australia where we have a sense of a fair go.'[25]

Rebuttal:

Proposed clause 14 of the regulations exempts various classes of medicines from any fee. First amongst these are those drugs designated 'Orphan Drugs' under regulation 16J of the *Therapeutic Goods Regulations 1990*.[26] This, hopefully, addresses the reasonable and valid concerns of honourable Senators and Members that the proposed reforms to the PBS could harm vulnerable Australians. Moreover, medicines required in times of a 'national emergency' (such as an Influenza epidemic) are also exempted under proposed clause 14(b)(ii).

Submitters may apply for an exemption under proposed clause 14 when filing their submission, or can apply for a waiver (full or partial) of the fees under proposed clause 15. Waivers can be considered (and granted) for any class of drug – not just those listed in clause 14.

Indeed, the regulations appear to take into *direct* consideration the need to ensure that a submission does not become financially 'unviable' because of any anticipated charges. Subclause 15(2) reads:

> 15 ...
> (2) The Department may waive a fee, or part of a fee, payable under these Regulations if the application involves the public interest and payment of the fee *would make the application financially unviable.* [emphasis added].

Where an applicant is unsuccessful in obtaining a waiver, an appeal can first be made to the Department and, if no satisfactory result is reached, the decision can be further appealed to the AAT under the *Administrative Decisions (Judicial Review) Act 1975.* The regulations provide the necessary flexibility to accommodate low-volume medicines or medicines utilised by a small population (such palliative care patients, indigenous health or paediatrics) and allow for a low-cost appeal mechanism to ensure that due consideration is made of the policy underlying the *National Health Act* and the *Regulations*.

Off-label prescribing was raised by the Committee as an on-going concern. However, this practice occurs presently (as admitted by witnesses) and it has not been demonstrated that off-label prescribing will increase should cost-recovery become part of the regulatory landscape. As it

25 Senator Fielding, Senate Debates, 28 August 2008, 14 (proof).

26 Proposed clause 14, *National Health (Pharmaceutical Benefits — Charges) Regulations 2008.*

remains for the Doctor, not the pharmaceutical company, to prescribe (and therefore prescribe off-label) it is unlikely that the behaviour of medical practitioners will be altered by the introduction of a cost-recovery fee on a third party (the pharmaceutical company).

Nonetheless, the PBAC Guidelines require a proposing company to conduct an 'applicability issues' discussion, whereby they discuss how the clinical studies relied upon in the submission could be applied in an Australian context. [27] Surveys conducted by companies asking medical practitioners about their prescribing methods (including rates of off-label prescribing) are not uncommon and could be used by the PBAC to determine whether the indication or restriction proposed by the submission is suitable for the drug.

The issues of applications for new forms or manners of administration, minor changes to use, listing new forms of administration, resubmissions without substative changes etc are dealt with in the regulations as falling into the **minor** category specified in Part 3 (3) of the regulations and so subject to the lower fees specified in Schedule 1

Finally, a review of the effect of the regulations may need to be conducted to determine if 'new indication' submissions to the PBAC have decreased substantially, although it should be born in mind that not all new indications or restrictions are cost-effective under the present system.

Recommendation:
For the purposes of clarifying any internal and external appeals of fee-waiver decisions, it is recommended that proposed clause 4 of the regulations refer to the *National Medicines Policy* to reinforce the intention of Parliament. This will benefit industry, administrative decision makers and review tribunals and provide clarity for industry over the Departmental appeal processes.

Part 4 – Timely Access to Medicines:

The process of making a Submission to the PBAC, especially since the introduction of the new

27 Comments made at *A Practical Update On The PBAC Submission Guidelines Workshop* (Galaxy Room, Royal Randwick) (Thursday, September 4, 2008) (ARCS Australia).

guidelines, has increased in complexity.[28] The requirement for companies who wish to seek fee-exemption or waiver status (under proposed clauses 14 and 15) will be require a relatively minor addition to a submissions. They will fall into the **minor** category specified in Part 3 (3) of the regulations and so the lower fees specified in Schedule 1. Futher, the proposed regulations specify time periods – 14 days – within which an appeal must be lodged, and then a further 14 day period in which the Department must review its decision. Although it is naturally desirable for medicines to be made available as early as possible the appeal process would occur *prior* to a submission's consideration by the PBAC and, therefore, Pharmaceutical companies would be advised to factor a potential the month-long appeal process into any low-value or small population medicine submission.

New Medicines

Breakthrough medicines – ie. new 'blockbuster' drugs - are likely to arise in the new fields of biologics and nanomedicines and will require in-depth review by the PBAC as there will be new effects (and possible side effects) which would make them inappropriate for fee-exemption. Given the remaining patent longevity and the 5 year data-exclusivity provisions in the *Patents Act 1991* and Therapeutic *Goods Act 1989* new 'innovator' drugs are likely to enjoy a period of high profitability which would significantly outweigh the proposed submission and listing fees.

Generics and 'Free-rider' objections

The proposed regulations are unlikely to have a detrimental effect on the introduction of Generic medicines given the definition of '*new brand'* proposed clause 3 of the regulations which reads:

> ***new brand***, for a pharmaceutical item, means a brand of the pharmaceutical item that:
>
> (a) contains the same active molecule as a listed brand of pharmaceutical item; and
> (b) is bioequivalent or biosimilar to a listed drug or listed brand of the pharmaceutical item.

The proposed price for a 'new brand' submission is $500 which should not act as a disincentive for generic manufacturers wishing to bring a new brand into the market place.

Objections were raised by Medicines Australia and members of the Committee that any fee on submissions would punish innovator firms and encourage 'free-riding', contrary to the Government's *Cost-Recovery Guidelines*. However, innovator firms enjoy, as part of their patent monopoly, 20

28 Ibid.

years – and up to 5 years more where an extension is sought under the *Patents Act* – of exclusive use and exploitation. Moreover, with the passage of amendments to the *Therapeutic Goods Act 1989* in 1999 and 2005, innovator Pharmaceutical companies can protect their clinical and scientific information for 5 years from the granting of a patent. During this time their product is the only one available on the market and will usually establish a market share which a new generic may find very difficult to erode. The dissemination of knowledge for the public benefit is the oft forgotten trade-off, which patent holders forget when seeking to extend their monopolies through evergreening tactics. The public benefit of low cost generic medicines, and the freely available knowledge which becomes available through the patent process should be kept in mind when discussing alleged 'free-rider' behaviour.

Part 5 – Review of Regulations and Discretionary Powers:

[Re: Greens Submission]

Greens Senators expressed a desire that the regulations and the '[operation] of the PBAC should be reviewed to ensure its continuing integrity under the pressures and constraints imposed by the cost recovery environment.'[29] While any review of the regulations – whether with a few to abolish, increase or decease the fees – would first be undertaken at a departmental level the Senate, through its ability to disallow a legislative instrument,[30] will have an on-going opportunity to review future regulations. Indeed, even though the regulations presently contain a clause which ensure the fees payable are indexed over time they will automatically expire ten years after their passage,[31] unless replaced earlier.

Finally, while discretionary powers to waive fees can give rise to situations whereby industry seeks to exercise political influence, the mechanism for listing pharmaceutical goods on the PBS requires, as an ultimate step, the approval of the Minister and Cabinet. This ensures that final responsibility for listing (and thus increasing the burden to tax-payers) or refusing to list (potentially resulting in the continued suffering and untimely death of Australians) rests with elected representatives. As an instrument of social-democracy, it should fall to the elected, accountable, representatives to make

29 Australian Greens, Minority Report <http://www.aph.gov.au/Senate/committee/clac_ctte/nat_hth_pharm_cost_recover_08/report/d02.htm> accessed 10 September 2008.

30 s 42 *Legislative Instruments Act 2003* (Cth). Note: Both Houses of Parliament have the ability to disallow subordinate legislation but motions to disallow regulations are more likely to occur in the Senate where there is no Government majority.

31 Part 6 *Legislative Instruments Act 2003* (Cth).

the final decision to list a drug on the PBS.

Part 6 - Concluding Remarks

Medicare and the PBS represent a true commitment to equality and a 'fair go'. While industry and private health advocates have pushed for new ways to pay for Australia's (growing) health needs, the PBS is recognised around the world as the benchmark for quality healthcare delivery. The lead author submits that universal healthcare represents the fairest 'safety net' possible and any move away from government supported healthcare should bear in mind the popular and democratic legitimacy which the PBS represents: put in place following one of the very few Constitutional amendments in Australia's history and surviving two High Court challenges. The PBAC, as a body independent of industry and government, is a critical component in ensuring the viability of the PBS. Although the revenue which will be raised from the proposed measures is likely to be more 'symbolic' than substantive – when reconciled against the $7 billion cost of the PBS – it can provide the PBAC with additional funds to expand its powers of investigation and ensure that the Committee can attract qualified individuals to serve as investigators.

The fees proposed are reasonable and appropriate for an industry which provides life-saving medicines to the Community while also making substantial profits from its products. With the data-exclusivity provisions ensuring originator companies can protect their commercial information for up to five years from registration on the Australian Register of Therapeutic Goods and the patent monopoly which provides at least 5-8 years on average of exclusive market share the fears about free-riders are misplaced.

The authors once again thank the Chair and other Committee members for devoting their time to these important regulations and commend the proposed bill to the Committee.

Sincere Regards,
Timothy Vines & Associate Professor Thomas Faunce.

Typographical Matter

As an initial, technical matter, the definition of '*PBAC Guidelines*' in clause 3 of the *Draft Regulations* appears to rely upon the old (now outdated) PBAC guidelines. Presently, the PBAC

Guidelines listed on the Pharmaceutical Benefits Scheme's website are the *'Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee* (ver. 4.2) from December 2007.[32] This submission would recommend that this definition be changed in the proposed regulations as it does not represent what appears to be the intention of the legislation and the proposed regulations.

32 See original at: http://www.health.gov.au/internet/main/publishing.nsf/Content/AECB791C29482920CA25724400188EDB/$File/PBAC4.2-3FINAL_13Mar08_.pdf accessed 10 September 2008.