Wyeth

Leading the Way to
a Healthier World

Submission to the Senate Community Affairs Committee

Inquiry into the National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008

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EXECUTIVE SUMMARY

Wyeth Australia strongly believes that cost recovery fees for listing medicines and vaccines on the Pharmaceutical Benefits Scheme (PBS) and on the National Immunisation Program (NIP) are inappropriate.

The introduction of cost recovery fees is likely to limit patients' access to innovative and improved medicines, thereby undermining the PBS and its policy objective of providing affordable, timely and equitable access.

Cost recovery for PBAC submissions and pricing negotiations with the Department of Health and Ageing will add to the already substantial costs of bringing an innovative medicine to market and having it reimbursed. It may also result in a disincentive for sponsors to seek additional reimbursement for products that are already listed. Efforts to widen patient access where clinical benefit is evident may require a number of major PBAC submissions. Products for small patient populations and from small companies will be disproportionately affected.

Furthermore, cost recovery arrangements are not compliant with the Government's own Cost Recovery Guidelines because cost recovery:

- will counteract Government medicines policy as well as innovation and industry policy objectives;
- will not increase efficiency; and
- appears to be a measure to raise revenue.

Cost recovery is not likely to directly affect the operation or independence of the PBAC. However, the introduction of cost recovery has the potential to delay and complicate any efforts to improve PBAC and pricing processes due to requirements to manage stakeholder concerns and perceptions around PBAC's independence.

On this basis, Wyeth Australia affirms that cost recovery will be detrimental to patient access in the short and long term and should not proceed.

1 INTRODUCTION

Wyeth Australia appreciates this opportunity to comment on the National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008. We note and broadly support Medicines Australia's submission.

Wyeth develops and manufactures innovative small molecule medicines, biopharmaceuticals as well as vaccines. We are currently exploring more than 60 new therapies in areas such as cardiovascular and metabolic disease, inflammation, neuroscience, oncology and women's health. In 2007, Wyeth invested US$3.3 billion in R&D.

At Wyeth, our vision is to lead the way to a healthier world. We act on this at all levels of our organisation and in our interactions with the broader community including patients, carers, health professionals and employees. In order to live up to being an active health partner we constantly consider the bigger picture, engaging in the wider health policy debate and minimising our carbon foot print to ensure environmental sustainability for future generations.

2 IMPACT ON ACCESS

The introduction of cost recovery fees for PBAC and pursuant pricing negotiations can have a negative impact on the listing of medicines on the PBS and hence patients' access.

There are several scenarios where companies might decide not to list a medicine on the PBS or where substantial delays in PBS listing can occur:

- Australia is a small market. Companies might give priority to pursuing registration and reimbursement in other, bigger markets where no fees for reimbursement applications exist. Interestingly, Wyeth is not aware of any other country where applications for public reimbursement incur fees. This will apply particularly to smaller or start-up companies that are more likely to face financial restraints.
- Companies will be less inclined to submit an application to list a new product that has an indication for only a small patient population or to seek reimbursement for a new indication for an already listed product.
- Medicines for rare or orphan diseases, in particular, will be affected. The Bill includes provisions for waiving cost recovery fees but no details are available. Consequently, there is a risk of medicines for orphan diseases being subject to evaluation fees.

  Furthermore, submissions for medicines for orphan indications are already subject to great uncertainty for the sponsor. The PBAC does not have a specific process for the evaluation of orphan indications. As such, it is very difficult for the sponsor to anticipate whether a submission might be successful or not. The imposition of evaluation fees, or the uncertainty whether evaluation fees will be waived or not, might contribute to a decision not to seek listing.

- PBAC cost recovery fees will be a disincentive to seek minor extensions to currently reimbursed indications, to seek listing for new formulations or delivery mechanisms, or any other incremental improvements.

As a result of any of the above scenarios, patients' access to more efficacious treatments would be denied as companies find it unviable to list on the PBS and thus only make the product available through private prescriptions or decide not to market the product at all.

Introduction of cost recovery arrangements for the PBAC might also result in higher prices of medicines as it is unrealistic to assume that all companies can or are willing to absorb the additional costs of PBAC and pricing cost recovery fees. This is particularly true where PBAC approval takes a number of submissions to achieve.

It is obvious that this would undermine the PBS and its policy objective of providing affordable, timely and equitable access.

Relistor example
Methylnaltrexone (Relistor) is a medicine currently under evaluation by the Therapeutic Goods Administration (TGA) for the treatment of opioid-induced constipation in patients receiving palliative care. Relistor provides an important treatment option for a very sick patient population but is unlikely to be a significant addition to Wyeth's portfolio in terms of financial return. Wyeth will be submitting for reimbursement in November of this year. With the introduction of PBAC fees, if this first submission is unsuccessful, future submissions will need to weigh the likelihood of success against the potential for financial return. This is not a decision Wyeth will make lightly; however, the introduction of PBAC cost recovery fees may significantly influence the decision.

3 IMPACT ON INNOVATION AND INDUSTRY

Cost recovery contradictory to innovation policy objectives
As we will outline in more detail in the subsequent paragraphs, the introduction of cost recovery for PBS and NIP listing activities contradicts innovation policy objectives. The new Government has repeatedly emphasised its aim to provide a favourable environment for innovation and R&D. This also includes encouraging the appropriate uptake of innovative products in the market.

The pharmaceutical industry in particular has been identified by the Minister for Innovation, Industry, Science and Research as an industry that the Australian Government wants to expand and support. The Minister has established the Pharmaceuticals Industry Strategy Group, which will 'develop a plan to attract investment in R&D, clinical trials and manufacturing activity in Australia.'[1] PBAC cost recovery will counteract these, and other, efforts targeted at creating a more conducive environment for investment in pharmaceutical R&D.

[1] Minister for Innovation, Industry, Science and Research 2008. The Roadmap to Pharmaceuticals Research and Manufacturing. Media Release, 26 May 2008.

Issues related to equity and fairness

Cost recovery fees will disproportionately affect products with smaller target populations. The decisions to list these products might depend on such fees.

Smaller companies and start-up companies will also be more exposed. Smaller and newer pharmaceutical companies might decide to launch a new product in other markets first where they do not have significant listing costs, especially if they do not have funds at hand. This might delay the listing of some medicines in Australia.

Australia is at risk of being relegated to a second phase of applications when products become better established internationally. The result will be a considerable delay in being able to provide significant improvements to best medical practice in Australia.

Additional barrier to entry

In its submission to the Productivity Commission's Inquiry into Cost Recovery by Government Agencies, the Department of Industry, Science and Resources observed that cost recovery charges may deter the development of whole industries, by contributing to barriers to entry:[2]

> … *the long-term viability of a new and emerging industry may be inhibited by unduly heavy regulation and cost recovery, especially if these burdens are of an up-front kind.*
> (sub. 62, p. 6)

This is of particular relevance for the biotech industry, which is still a very young industry. The great majority of biotech companies are not profitable, with the global biotech industry still operating at a loss.[3] Cost recovery fees will certainly be a major decision factor whether to launch a product in Australia or not.

Substantial costs of bringing a medicine to market

The proposed cost recovery fees add to the already substantial costs of bringing a medicine to market. The industry already incurs high costs in relation to PBAC and listing processes, such as the preparation of PBAC submissions and other activities that are included in clinical development to ensure cost-effectiveness data are available.

The introduction of the new PBAC Guidelines has also led to increased costs, with a significantly higher workload and number of hours needed to prepare a submission that fulfils the amended Guideline requirements.

In addition, innovator companies are already taking substantial price cuts and losses in profits due to PBS reforms. The R&D-based industry is contributing two thirds of total savings in the first four years of PBS reform.[4] Cost recovery will add additional financial

[2] Department of Industry, Science and Resources 2000. Submission to the Productivity Commission Inquiry into Cost Recovery by Commonwealth Regulatory, Administrative and Information Agencies.
[3] Ernst & Young 2008. Beyond Borders: Global Biotechnology Report 2008.
[4] Medicines Australia 2007. Opening Statement by Medicines Australia to the Senate Community Affairs Legislation Committee Inquiry on the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007.

pressure on these innovative companies that are already carrying most of the financial impact of PBS reform.

Price levels for innovative medicines are also lower in Australia than in many of the comparable OECD countries, thus rendering products currently provided on the PBS less profitable than in other countries. Cost recovery measures will further erode the viability of these and new products.

Disadvantage for first-in-class medicines

The introduction of PBAC fees will also lead to a major disadvantage for first-in-class medicines. Currently, it is not uncommon for an innovative first-in-class medicine to require up to three or four submissions to obtain PBS listing. A subsequent medicine listing on the basis of cost-minimisation can secure reimbursement in a much quicker timeframe. With the introduction of PBAC fees, not only does the first-in-class medicine lose any first-to-market benefit, it will also shoulder a greater financial burden for PBAC consideration.

High fee levels

The level of proposed fees is significant. Total fees are effectively doubled for new medicines while generic companies 'free-ride' on innovators' fees (see Table below).

Furthermore, major submissions usually do not achieve a positive PBAC recommendation on their first consideration.

Table: TGA and proposed PBAC fees

	New medicine	Generic
TGA	$170,000	$65,000
PBAC	$119,500	$500
Pricing	$25,000	
Total if succesful at first submission	**$314,500**	**$65,500**
PBAC - major submission / resubmission	$119,500	$500
Total if succesful at re-submission	**$434,000**	**$66,000**

4 EFFECT ON OPERATION AND INDEPENDENCE OF THE PBAC

A variety of stakeholders, including academics, clinicians and politicians, have voiced concerns that cost recovery will affect the independence of the PBAC. Wyeth believes that this will not be the case. Cost recovery arrangements for the PBAC will not directly affect its operation – positively or negatively.

However, if cost recovery is introduced, the PBAC and the Government will have to fight the perception by other stakeholders that the independence of the PBAC will be affected.

In addition, it is very unlikely that cost recovery will lead to improvements in the operation of the PBAC. Ongoing efforts to improve PBAC and PBS listing processes are already underway – cost recovery will not advance these. In actual fact, cost recovery might negatively impact these efforts as the stakeholders will have to be conscious of how certain changes and improvements in processes could be perceived. As a consequence, certain initiatives to enhance these processes might be delayed or not introduced at all. Ultimately, patients will suffer as possible improvements in timely access will not be realised.

Efforts by the Government to convince other stakeholders of the ongoing independence of the PBAC despite cost recovery will also remain tainted by previous claims of current Government members that cost recovery will jeopardise PBAC's independence.

Wyeth is committed to working with Government and other stakeholders to improve PBAC and PBS processes. We believe that the introduction of cost recovery would complicate and potentially delay future efforts.

5 PBAC COST RECOVERY AND COST RECOVERY GUIDELINES

The imposition of cost recovery fees for PBAC and pricing activities will not conform with the Government's own Cost Recovery Guidelines.

The Guidelines state that cost recovery should not just be undertaken to earn revenue. On this basis, Government should outline clearly what cost recovery of PBAC and pricing activities is meant to achieve. However, no realistic objectives have been set or communicated by Government. There is no evidence of a review of the operation of the PBAC that is related to the introduction of cost recovery and that could serve as a basis for improving PBAC efficiencies.

It is unclear how cost recovery will deliver a significant contribution to the objective of 'maintaining the capacity for listing drugs,' which was given as the objective for this measure in the 2008-09 Budget Papers. Firstly, all fees paid will go into consolidated revenue. Secondly, the expected annual revenue of $14 million (from the second year onwards) seems negligible when compared to the estimated Government expenditure for pharmaceutical services and benefits, including vaccines, of $8,908 million for 2008-09.

In addition, the measure appeared in the 2008-09 Budget without any prior consultation by the current Government. The planned implementation date was 1 July 2008, seven weeks after the measure was announced in the Budget and in the middle of the current financial year of many companies. All these factors support the perception that this measure indeed is a revenue raising exercise to balance the 2008-09 Budget.

The Cost Recovery Guidelines also outline that a common goal of introducing cost recovery is to increase efficiency. However, efficiency gains cannot be expected in relation to PBAC cost recovery. This is mainly due to four reasons:

- Since fees will go to consolidated revenue, neither the Department of Health and Ageing nor the PBAC will obtain any additional funds through cost recovery. As such, cost recovery will not provide any incentives to change or improve their operation.

- Companies are already incentivised to deliver high-quality submissions and engage in efficient pricing negotiations in order to achieve quick market access through the PBS.
- Charging fees will not improve the expertise and ability of companies to produce high-quality submissions.
- Fees will not improve the expertise or ability of the members of the PBAC or its support agencies to evaluate the submissions it receives.

Furthermore, the purpose of the PBS is to provide universal and affordable access to medicines for all Australians. As such, the 'beneficiary pays' principle of cost recovery cannot simply be translated into companies (and others who are making submissions) paying for the listing process as being the main beneficiaries of PBS listing.

This becomes particularly evident when looking at vaccines. Apart from being a central element of prevention, the benefits of vaccines go beyond immunised individuals and are also accrued by unimmunised individuals and society as a whole through herd protection. As such, vaccines have a significant positive public health and economic impact:[5]

> *'Immunization does appear to be an important tool for improving survival and strengthening economies. (…) And it does so in an extremely cost-beneficial way.'*

Companies do benefit financially from having medicines listed on the PBS. However, the need for PBAC review and pricing negotiations originates from Government policy and as such is imposed on the industry if it wants to provide universal access to its medicines.

And last, but certainly not least, the Government's Guidelines state that cost recovery should not be introduced where the effects of introduction are inconsistent with policy objectives. As outlined previously, cost recovery will negatively affect the PBS policy objective of providing affordable, timely and equitable access to medicines as well as the Government's industry and innovation policy objectives.

Cost recovery principles

…

2. Cost recovery should not be applied where it is not cost effective, where it is inconsistent with government policy objectives or where it would unduly stifle competition or industry innovation

…

Source: Department of Finance and Administration 2005, Australian Government Cost Recovery Guidelines July 2005

[5] Bloom, DE; Canning, D and Weston, M. 2005. The Value of Vaccination. *World Economics* 6(3):15-39.

6 CONCLUSION

Wyeth Australia strongly believes that cost recovery fees for listing medicines and vaccines on the PBS and on the National Immunisation Program are inappropriate. The introduction of cost recovery fees:

- Is likely to limit patients' access to new and improved medicines;
- Will add to the already substantial costs of bringing an innovative medicine to market and having it reimbursed for wider patient access;
- Will not improve companies' or the PBAC's expertise and ability to produce and evaluate submissions;
- Is not compliant with the Government's own Cost Recovery Guidelines; and
- Is likely to delay and complicate any efforts to improve PBAC and pricing processes due to stakeholder concerns and perceptions around PBAC's independence.

On this basis, Wyeth Australia affirms that cost recovery will be detrimental to medicines as well as innovation policy objectives and principles and should not proceed.

We would be delighted to discuss any aspect of this submission with the Senate Committee or provide further details and clarification.