Working together for a healthier world™

Response to the Productivity Commission's Draft Report on

Regulatory Burdens on Business

Prepared by Pfizer Australia

38-42 Wharf Road, West Ryde NSW 2114

30 July 2008

Response to the Productivity Commission's Draft Report on Regulatory Burdens on Business

We would like to thank the Productivity Commission for considering Pfizer Australia's submission to its Review of Regulatory Burdens on Business. We feel that Commission's Draft Report accurately reflects our position. We also appreciate the opportunity to participate in the Commission's Roundtable on 16 July 2008 with other stakeholders in the Australian medicines sector.

We fully support all three recommendations that the Commission makes in the Therapeutic Goods Area (Draft Responses 4.1-3).

In this paper, we want to clarify a number of statements in our submission that we feel may have been misunderstood by the Commission and some stakeholders. We also want to make several suggestions in response to issues in the Commission's draft report.

The Therapeutic Goods Administration (TGA)

When we met with other stakeholders at the Commission's Roundtable, we were concerned that the TGA misunderstood our intentions and that we were questioning its capability as a regulator. So we wish to stress again that we firmly believe the TGA's assessment of the medicines' quality, safety and efficacy is of the highest standard. The advice that our Australian manufacturing staff receive from the TGA following audits is also excellent. The TGA's policy work has been very good.

Our contribution to the Productivity Commission was never intended to question TGA's commitment to public health and safety. Nor was it aimed in any way at its scientific and technical competency. Rather, we wanted to suggest improvements to way that TGA engages with the industry, in particular by being:

- more *transparent* – so that we understand its decision-making
- more *consultative* – so that we, and all other stakeholders, are fully engaged when the TGA develops policies and guidelines.

Good Manufacturing Practice (GMP)

One issue that has emerged since we lodged our submission is a change to the way that the TGA is prepared to issue formal GMP Certificates. The Office of Manufacturing Quality (OMQ) will no longer issue a GMP Certificate following a successful initial audit of a manufacturing site. Our understanding is that OMQ will only issue a GMP Certificate following successful second and subsequent GMP audit. Although TGA will, of course, still allow the importation of products into Australia from a manufacturing site with GMP clearance, we are concerned there may be an impact on Pfizer's business internationally, caused by non-availability of a GMP Certificate for GMP compliant sites that supply jurisdictions in addition to Australia.

Pfizer Australia would like to propose a monitoring period, during which the full impact of the changes in GMP guidelines can be assessed and form the basis for further discussion with TGA.

We have also had the experience of the OMQ requiring re-inspection of overseas manufacturing plants which hold current and valid GMP clearance from TGA. We were recently contacted by the OMQ, which wished to schedule an inspection for a site in Korea for which we held valid GMP clearance until 2010. OMQ allowed Pfizer only five days to reach a decision on participation in the site audit. Whilst we understand the logic behind TGA's position – and of course accept the need to routinely re-examine the GMP compliance of manufacturing facilities – a five-day notice period does not allow us sufficient time to investigate the feasibility of a desk top audit and potentially avoid the need for a site audit. Consequently, we had to accept the site audit. As we discussed during the Roundtable meeting, we seek transparency from the OMQ regarding scheduled TGA audits, so that we can investigate whether the appropriate documentation can be collated in a timely manner for a desk-top audit. Pfizer does recognise the need for site audits – indeed these play an important role in ensuring the quality of medicinal products – however, we believe that site inspections should be reserved for those cases where there is no reasonable prospect of being able to pass a desk-top audit.

The Pharmaceutical Benefits Advisory Committee (PBAC)

We are aware that there will always be different views between those who submit evidence for consideration by the Committee and those who evaluate the evidence, but we feel that the Department's response to the Draft Report did not fully appreciate our concerns about the PBAC evaluation process, particularly with regard to role of external evaluators contracted to assess PBAC submissions. Errors in the evaluation process will always occur and we appreciate the work done within the Evaluation Section to quality control these errors. However it is evident that the Committee places a higher reliance on the evaluation report and less on the submission, so that where matters are in dispute it will be the evaluation that will largely determine the view of PBAC. As the consequences of many of these disputes are either rejection or deferral, these errors result in significant administrative burden as well as delays in access to often-life-saving medications. Thus while quality control is likely to identify and remove or correct many errors, it is not possible in such a complex technical field to achieve even 80% perfection.. Consequently, we feel there are a number of real opportunities for making improvements for both sponsors and the PBAC.

In our submission, we said that:

> we feel that an increasing number of elements in evaluations are either simply wrong or contain major omissions, and consequently the PBAC is being given guidance that may lead to them incorrectly reject our medicines … While there is a review process, this can only assess the PBAC's own processes, not the evaluation itself. (p9-10)

Examples of significant errors we have encountered include:

- incorrect statistical analysis
- errors of omission (evaluators overlooking detailed justifications for the use of figures upon which calculations are based – and then stating in their commentary that no justification was provided)
- unsubstantiated hypotheses or counter-arguments

The two issues we want to address are:

- how to minimise the number of errors in the first place; and
- how to correct errors that do occur.

In all that follows, we need to stress that we are referring to errors of *method* and *fact* – that is, where there is an objective error. We see this as distinct from subjective judgements, such as different interpretations of data. We do not regard the latter as an 'error'.

Minimising errors

At the basic level, evaluations must, of course, be conducted at a standard that minimises avoidable errors which unfairly hinder the success of a reimbursement application or delay the reimbursement of a medicine. We have some difficulty, however, in making firm suggestions for reducing errors in the first place, as there are important parts of the evaluation system that are unclear to us: how many evaluators there are; what their workload is; how many submissions they typically evaluate for each sitting of the PBAC; how often they are replaced or rotated (if at all); what sort of feedback they receive from the PBAC and Pharmaceutical Benefits Branch; and how feedback is institutionalised amongst the body of evaluators. We also do not know how the responses we provide to the PBAC and its subcommittees are actually handled by those groups and, most importantly, have no opportunity to interact with the evaluators during the evaluation process. It would certainly help us to know how the PBAC views those responses which point out errors in evaluations, and what formal processes it has for dealing with them. (That is, greater transparency would be of value to us and it would ultimately reduce administrative burden.)

We are mindful that any changes have to work within the resources available to evaluate submissions. For example, having two or more evaluations in parallel for each submission (as occurs in grant applications and peer reviewed publications) rather than just one as currently occurs would, in principle, reduce the chance of errors. However, we recognise that such an option is almost certainly impractical. Health Technology Assessment has become a highly technical skill in the last decade, and the number of individuals in Australia with the necessary skills is very limited. Also, we do not believe that it would be possible involve experts from other countries as methods used internationally are very different to those used in Australia.

We are, as we noted above, hampered by our lack of knowledge of the 'infrastructure' of PBAC evaluations. Improvements are probably best explored through a review within DoHA, with input from sponsors and contracted evaluators.

Correcting errors

The second issue we want to address is how to correct errors that are made in evaluations. In its submission to the Review, the Department wrote:

> If the sponsor has correctly identified in its pre-sub-committee response that errors of fact or omissions exist in the evaluation report, the errors are documented and tabled at the sub-committee meeting. The errors are then formally acknowledged and specifically brought to the attention of the PBAC, and the sponsor, as part of the minutes of the meetings. The evaluators receive the comments from the sponsors to the evaluation reports. The groups also receive general feedback on their performance as part of usual contract management between the Pharmaceutical Evaluation Branch and the academic evaluation groups. (p73, draft report)

As we stated earlier, we believe that the Evaluation Section plays an important role in the quality control of submissions, and it may be that it is under-resourced given the nature of the task assigned to it. We agree that the brief outline provided in the Department's response will lead to continuous improvement. However we welcome more detail to be made available to the industry of the nature of the feedback and statistics on performance. Further, it appears that the existing process described might not adequately address the correction of the errors identified at the time of review by PBAC.

Given that decisions involving hundreds of millions of dollars rest on evaluators' reports, and the PBAC already has enough complex material to assess in a very limited time, we feel that objective errors of fact and method must be corrected *before* the evaluator's commentary is presented to the PBAC. This may well require a process of direct interaction between evaluators and sponsors..

The Department is correct in saying we have the opportunity to respond when we identify errors – but the opportunity is limited. As we noted in our submission, we have at most four days to provide a response, and the response is limited to four pages of text (in at least 11 point font), with a further two pages of figures or tables. If the submission is also reviewed by the Drug Utilisation Subcommittee (DUSC), the sponsor is given only one additional page to respond. The final opportunity we have to respond to the evaluation is when we address the PBAC, for which we are allocated only 10 minutes and have only one week to prepare.

Lastly, as we noted above, we do not know how the PBAC regards responses which point out errors, or what formal processes it has for handling them or even the detailed nature of discussion around matters of dispute. This raises an important potential failing in the system with regard to procedural fairness that we feel the Commonwealth should consider: the minutes of the PBAC cannot fully reflect the nature of the discussion by the Committee nor the role of the evaluation. Therefore any subsequent 'appeal' through resubmission cannot adequately address all the issues considered by PBAC.

Pre-submission advice by the Pharmaceutical Benefits Branch

In our submission, we had said that:

> There have been times when advice given to us by the Branch [in the] initial stage is not reflected *at all* in the independent evaluation (upon which the listing decision is based), or in the PBAC's final recommendations to the Minister (page 9).

Because of this, we had asked that, "advice given by the Branch to be binding on the evaluators."

The Commission's position is that advice by the Branch cannot be binding on the independent evaluator, as this would make the Department itself the de facto decision-maker. We agree with this: the evaluation *must* be independent. We want to make another suggestion which, we feel, will maintain the independence of the evaluation, but deliver greater certainty and transparency:

1. pre-submission meetings should continue as they current do (Pfizer Australia values these greatly and understand they are useful to the Branch as well)
2. The sponsor should then minute all of the advice given by the Branch, and check this with the Branch for accuracy
3. The sponsor should include this advice in their submission, so that the evaluator is aware of the advice
4. Where the evaluator decides to conduct the evaluation using a *different* approach to that discussed between the Branch and the sponsor, the evaluator should be required to provide an explanation for this change in their commentary.

This approach would:

- keep the evaluation fully independent
- discourage evaluators from lightly selecting a different evaluation method to the one advised by the Branch (by introducing a degree of accountability and transparency without binding the evaluator)
- provide both the Branch and the sponsor with feedback on why the evaluator selected a different method – which would help in the preparation of future submissions.

The Department's comments on PBAC processes

We see in the draft report that the Department responded to our concern that the PBAC lacked sufficient time to complete its assessments. The Department is correct in saying that "the length of the scheduled PBAC meetings has increased to three days, three times per year". What is missing from this statement, however, is that before the change, the PBAC met *four* times a year for 1-3 days – so the new arrangements involved only a minor change to the number of sitting days. Also, the Department states that "the PBAC holds separate one-day extraordinary meetings to deal with other Matters." This is quite true, but the PBAC minutes show that the Committee usually only deals with one or two assessments in these extraordinary meetings.

The following is a list of extraordinary meetings since 2005 and the number of positive recommendations made[1] (the minutes record no deferrals or negative recommendations – if there were any at all).

- April 2008 2 positive recommendations
- December 2007 1 positive recommendation
- November 2006 1 positive recommendation
- May 2006 1 positive recommendation
- March 2006 1 positive recommendation

[1] Source: http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-outcomes-by-meeting

In short, our concern remains that the PBAC lacks sufficient time to assess the growing number of submissions being put to it.

Aligning TGA and PBAC processes

We appreciate the Commission's Draft Recommendation 4.3:

> The Pharmaceutical Benefits Advisory Committee should be allowed, when requested by applicants, to conduct its assessment of a medicine for PBS listing in parallel with the TGA's assessment of the application to register the medicine.

This would be a substantial advance for us, particularly when listing new medicines.

At the Commission's roundtable on 16 July, the suggestion was made that aligning TGA and PBAC processes may involve higher costs for manufacturers. We can see no justification for this. Alignment would involve no additional work or different types of work or shorter timeframes – just a different scheduling.

Weighted Average Monthly Treatment Cost (WAMTC)

We agree with Medicines Australia's comments on WAMTC: the process is complex and costly for companies. There are technical problems with WAMTC – such as its insensitivity to differences between GP and specialist prescribing, or higher initiation rates for newly-listed medicines, or restrictions on the use of certain medicines, or differences between on-patent versus off-patent medicines. These however are essentially policy issues and we appreciate that they are outside the Commission's remit. There is, however, a point about WAMTC that does not appear to have been made which would help reduce the costs of compliance.

The purpose of WAMTC is to keep medicine prices low for taxpayers and medicine users. It has a broad public benefit – it is not a narrow, private benefit to the supplying manufacturers (indeed, the purpose of WAMTC is reduce prices – manufacturers never get price increases as a result of WAMTC reviews.)

In order to set prices under WAMTC, manufacturers have to purchase:

1. data on prescription volumes from either:
   - Medicare Australia (for medicines where the price is above the PBS co-payment level), or
   - the Pharmacy Guild (where the price is below the PBS co-payment, and hence is not captured by Medicare)
2. price information from the private firm, IMS.

Medicare Australia's cost-recovery fees form a large component of the WAMTC costs[2].

The point we wish to make is that manufacturers are being charged a cost-recovery fee for government data in order to help the government to make a decision whose beneficiaries

[2] It may be possible to source the data from alternative sources such as the University of Sydney's Australian General Practice Statistics and Classification Centre: BEACH or 'Bettering the Evaluation And Care of Health'. However accessing these data also involves costs.

are the government and the Australian public. This is not consistent with the Australian Government's Cost Recovery Guidelines[3] (p30-34). We feel, therefore, that manufacturers who have to participate in WAMTC reviews should be exempted from charges imposed by Medicare Australia for the use of its data.

Hospital medicines

There is one final point we wanted to correct in the Commission's draft report. The report focuses on medicines supplied in the community – in which case it is certainly true that most prescription medicines are supplied through the PBS (p58) and roughly 80-90% of medicines are supplied this way (p54). There is, however, also a large supply of medicines via hospitals.

In 2005-06—the year for which the most recent figures are available—Australian public hospitals dispensed $1.2 billion worth of medicines[4] and private hospitals $1.7 billion[5]. (By contrast, the PBS reimbursed $6.1 billion for prescription medicines in the same period[6], although roughly $600 million of this would have covered medicines used in private hospitals.)

We appreciate that public hospitals – and hence their medicines – are a State Government responsibility, and hence outside the remit of the Productivity Commission. Nonetheless, our experience is that these medicines are routinely overlooked. Because of the investment involved, we feel that it is important that they are noted in the Commission's final report – even though they are outside the Commission's scope.

For further information…

Dr Rob Wiseman
Manager, Strategic Policy
Public Affairs and Policy
Pfizer Australia

38-42 Wharf Road, West Ryde NSW 2114
t: 02 9850 3716
f: 02 9850 3111
e: rob.wiseman@pfizer.com

[3] Commonwealth of Australia (2005) *Australian Government Cost Recovery Guidelines* (Financial Management Guidance No. 4) Canberra: DoFA

[4] Australian Institute of Health and Welfare (2007) *Australian hospital statistics 2005–06*. Health services series no. 30. Cat. no. HSE 50.Canberra: AIHW.

[5] ABS (2007) *Private Hospitals 2005-06*. ABS Cat. No. 4390.0. Canberra: ABS

[6] Pharmaceutical Benefits Pricing Authority (2006) *Annual Report for the year ending 30 June 2006*. Canberra: Department of Health and Ageing.