Supplementary Submission

Senate Community Affairs References Committee Inquiry

Consumer Access to Pharmaceutical Benefits

Prepared by Pfizer Australia

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Pfizer

Australia

Disclosure

Pfizer Australia provided a submission to the Senate Community Affairs References Committee Inquiry, Consumer Access to Pharmaceutical Benefits in April 2010. The submission was prepared by Pfizer Australia – a wholly owned subsidiary of Pfizer Inc., based in New York. Wyeth is now a part of Pfizer Inc. The merger of local Wyeth and Pfizer entities is pending in Australia and is subject to completion of various local legal and regulatory obligations.

On 7 May 2010 Pfizer Australia representatives appeared at the public hearing for this inquiry.

Pfizer is directly impacted by the Therapeutic Groups announced in 2009. In May 2009, the Government announced it would create a new Therapeutic Group (TG) for 'higher potency' HMG Co-A reductase inhibitors, i.e. Lipitor® – atorvastatin (manufactured by Pfizer) and Crestor ®– rosuvastatin (manufactured by AstraZeneca). In the Mid Year Economic and Fiscal Outlook (MYEFO) on Monday 2 November three new TGs were announced by the Minister; one of which is the Venlafaxine group which will include venlafaxine (Efexor®-XR) and desvenlafaxine (Pristiq®). Both Efexor®-XR and Pristiq® are registered to Wyeth Australia.

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Supplementary material for the inquiry

Following the public hearings into the Community Affairs Committee inquiry into Consumer Access to Pharmaceutical Benefits (7 May 2010) we maintain that, on balance, the potential consumer harm and confusion related to the introduction of therapeutic groups (TGs) is not outweighed by the savings that will be achieved. The implementation of PBS reforms in 2007 instituted systematic measures which allow the Government to achieve significant savings from the PBS in a clear, transparent and predictable manner with no harm to consumers or confusion to prescribers.

We remain concerned there appears to be uncertainty around the implications of the new TGs amongst the consumer and clinician groups who appeared before the committee. This lack of clarity has not been acknowledged by the Department of Health & Ageing and in fact appears to have largely discounted as not relevant [CA92: "*From our perspective there are significant errors and misunderstandings in the majority of submissions provided to the committee…"].* Whilst there has been clear confirmation TGs are a savings measure there does not seem to have been adequate consideration of the fact that TGs are based on a clinical assessment of interchangeability at an individual patient level.

"*Significant errors and misunderstandings*" should be avoided at all costs when they relate to medicines being prescribed, dispensed and taken in the wider community. If eminent doctors, peak bodies representing patients, the medical profession and manufacturers do not understand, it is further evidence that the policy should not be pursued in its current form.

The recently signed Memorandum of Understanding (MOU) between the Commonwealth and Medicines Australia demonstrates the willingness and benefits of industry and Government collaborating on the ongoing systematic reforms of the PBS. The next wave of PBS reform is built on constructive policy reform measures which will deliver savings to the Government and the consumer, plus greater access, whilst allowing industry greater certainty.

Our submission highlights three key areas of ongoing concern, namely the:

1. Lack of transparency in establishing TGs
2. Lack of consultation in establishing TGs
3. Lack of consideration of the risk/benefit profile of the TGP policy

Lack of transparency

The Pharmaceutical Benefits Advisory Committee (PBAC) was clearly directed by the Minister of Health to identify areas of savings and constrained by the Minister in terms of its preference for communication with both sponsor companies and the public. [1,2]

Sponsor companies were not involved in the consideration of the medicines for inclusion in the new TGs. As the TGs are considered purely a savings (or pricing) measure the lack of transparency on the PBAC agenda would be argued as appropriate by the Department of Health & Ageing. However, the TGs are based on clinical determination of interchangeability therefore sponsor companies should be afforded due and transparent process.

It is our understanding new evidence was considered in the recommendation of the new TGs.[3] If new evidence was considered for the TGs it would be our expectation as a manufacturer to have an opportunity to review the new information. This would be the normal process for when the PBAC considers new evidence (as detailed in our Appendix D of our original submission).

For the HP statin TG, Crestor was listed on the PBS on 1 December 2006. At the time of the PBAC recommendation in July 2006 as far as we were made aware there was no discussion of the possibility of a TG. If there is new evidence that has been considered for the comparison of atorvastatin and rosuvastatin we maintain it is essential we are provided with this evidence and given an opportunity to review any analyses.

In the case of the selected anti-depressant TG it is not clear why the recommendation that the two medicines were considered interchangeable was made at the March 2009 PBAC meeting and not at the time of initial recommendation for the listing of desvenlafaxine at the November 2008 PBAC meeting, only 4 months earlier.

Given the PBAC is now required to make an assessment as to whether a newly listed medicine is to be included in a therapeutic group at the time of its initial assessment, we can only conclude that desvenlafaxine was assessed in November 2008 as NOT being interchangeable at an individual patient level with venlafaxine.

Finally, we believe the recently signed MOU provides greater guidance on the formation of a TG. But there remains the issue of appropriate evidentiary requirements for assessing interchangeability. If the assessment of cost-minimisation is considered by

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[1] CA78 *The PBAC received a request from the Minister for us to consider therapeutic groups in the following areas*.
[2] CA78 *You would have to ask the minister whether or not it would be on the agenda. My personal view would be that, yes, there should be no reason why not*.
[3] CA81 *Senator FIERRAVANTI-WELLS: When a drug is listed, you become aware of a whole series of information that is available about a particular drug. When the PBAC goes to make the decision that medicines are interchangeable as a part of the process, do you conduct a new evaluation for the formation of the therapeutic groups? Professor Sansom: Absolutely. In November and December we undertook a literature review of what was new and what had come out. It is just part of the normal process. PBAC does inform itself.*

the PBAC the first step in determining interchangeability it would be reasonable to expect that the subsequent steps and associated evidentiary requirements to support this should be provided to the sponsors.

We maintain as per Term of Reference b) (page 17) and Appendix D that **the true test of interchangeability is the experience of the individual patient.** Given the population based evidence appraisals that are conducted by the PBAC we do not believe that these data are appropriate for determining interchangeability at the individual patient level. Within the PBAC context for example, the test for comparison is often whether a sample mean is comparable to another sample mean on the basis of their respective population means. No conclusion is made regarding individuals in either the sample or the population of samples or even less, the population of funding interest.

The only question that can be answered regarding the interchangeability of two products is limited to a representative patient (in terms of the samples studied) and is the a priori probability of an outcome before their initial administration of one of the compounds and only whether there will be non inferiority of one of those compounds compared to the other i.e. there is no two way non inferiority test or test for equivalence.

As was proposed in our submission the necessary steps required in order to make inferences or conclusions on an individual patient basis are:

- the assessment of the individual patient for representativeness (this is done in a general sense in submissions)
- the exclusion of non superiority (or the performance of two way non inferiority) and
- the assessment of evidence that patients can be switched and that the outcomes assessed previously will be unaffected.

Lack of consultation

Interpretations of what constitutes consultation may differ, however, the practice of consultation in relation to the listing and maintenance of medicines on the PBS is well established and it was not followed in this case. There was no clear explanation given as to why past practice was not followed and why the information was kept from patient groups and companies until the very last moment.

There has been no acknowledgement of the concerns around the lack of consultation raised by a number of stakeholder groups with the implementation of TGs in 1997-98. Nor is there acknowledgement that the SSRI TG was not implemented as a direct result of concerns raised by stakeholders during consultation. Stakeholders are again expressing the same concerns.

The lack of consultation, whether perceived or actual, is not acknowledged by DoHA.[4]

We are unable to comment if the consultation process may have been different if the TGs were not considered as part of a Budget process. However, our expectation and recent experience, for example with the bDMARD review, is that there will be a consultative process that is satisfactory to all affected parties.

The DOHA submission states "*The department then undertook a lengthy consultation process from May to August 2009 with the most affected company*." (Section 4(d), p.16).

The department does not state which company was 'most affected' and what criteria it used to determine which company was most affected. There are many criteria that could determine the extent of impact depending on whether 'affect' is considered from a consumer or cost perspective. This statement by the department would seem to suggest that if you are only marginally affected, as opposed to being the most affected company, you are not entitled to be consulted.

Given the extent of the impact of one of the proposed TGs has not yet been determined we are yet to see how extensive any consultations may be regarding this group.

We do agree correspondence was entered into however this does not constitute consultation. The DoHA submission to this Senate inquiry lists the correspondence on p.17 but this does not demonstrate the unsuccessful requests for information we put forward.

The advice provided to date is inadequate. The Government has refused to provide any information regarding the methodologies used to make its determination. Pfizer has repeatedly requested information from both the PBAC and the Minister regarding the justification and evidence utilised to reach the recommendation that the medicines in the new TGs are 'interchangeable at the patient level.'

As per Appendix E in our original submission our expectations around consultation are based on experience with the PBAC for the listing of new medicines, expansion of indication or cost-effectiveness reviews.

Within the context of consultation we would like to provide additional information on two other points raised during the hearing.

From our perspective there are five key misunderstandings in the submissions. … They are: firstly, that therapeutic groups require doctors to substitute one medicine for

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[4] *CA 92: From our perspective there are five key misunderstandings...and finally, that there was no consultation in the forming of the recent therapeutic groups. CA93… "the suggestion that there was no consultation in forming the groups is simply wrong."*

another; …. thirdly, that patients will have to switch from a drug in a therapeutic group they need because of cost;[5]

The two points above are inter-linked. TGs may require a doctor to substitute one medicine for another if a TGP is introduced. Although DoHA are of the view there will never be a TGP for any medicines in the new TGs ["*As I said, these recently formed groups would not have resulted in any change. None of the drugs in the four recent therapeutic groups had price premiums applied at the time the groups were disallowed by the Senate*.", Hansard, CA93] it is important to understand the true potential for the application of a TGP.

In the case of Lipitor® and Crestor®, the HP statin TG, it is important to note that the first assessment of prices, the WAMTC or benchmarking process, was conducted in December 2009. There will be an annual review of prices until the TG no longer exists. Therefore the assertion that a patient premium is not an issue does not cover the life of the TG. There will be an assessment of prices within the TG annually, at which point the option for a TGP will be re-evaluated by the affected company.

Secondly, and perhaps most importantly, in the case of Pristiq® and Efexor-XR® the pricing review had not been undertaken when submission to this inquiry closed or when the disallowance motion was tabled.[6]

Pristiq® (desvenlafaxine) was listed on the PBS from 1 February 2009. In the pricing related correspondence received 3 December 2009 it was indicated that the WAMTC of prices for the TG would occur in August 2010 (for application of any PBS price reductions on 1 December 2010). On the 25 March 2010 correspondence from the Pricing Section indicated that following the disallowance motion the new TGs ceased to exist. Accordingly, the performance of the August 2010 WAMTC price review for venlafaxine and desvenlafaxine is dependent on their inclusion as part of a TG. It is important to note that no price calculations by DOHA should have been conducted prior to the disallowance of the select anti-depressant TG. As the disallowance was passed on 11 March 2010 there was not 12 months of data[7] available, as is required by the PBPA. As the selected anti-depressant TG ceased to exist at the disallowance a TGP could not be applied; a TGP can only be applied to medicines within a TG.

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[5] Hansards, CA92, Mr David Learmonth.

[6] Hansards, CA103. *Mr Learmonth—I am sorry: there were none requested at their creation; it is a matter of fact. Mr Stuart—No increase in price was requested at the time the instruments were made. The department, at the time that the instruments were disallowed, had completed its price negotiations with the companies. No therapeutic group premium had been asked for. In that case, there would have been no therapeutic group premium applied to these products and not even any need to invoke the government's special provisions that save any potential effect on patients.*

[7] Medicare Australia PBS statistics are not live data and therefore there is an acknowledged lag period between dispensing and uploading of information into the MA database.

Lack of consideration of the risk/benefit profile of the TGP measure

It was consistently communicated that the TGP policy is a pricing policy. However, it cannot be ignored that the fundamental assessment of which medicines may be included in a TG is made on a clinical effectiveness and safety basis.[8] There is undeniably a patient health component to this savings measure.

We maintain there are two elements to the consideration of this policy in terms of consumer wellbeing. There is the consideration of the impact of additional cost through the application of a TGP, a measure that cannot be excluded as an option. This was shown to have impacted on consumer access, and by logical conclusion health, following the introduction of TGs in 1998. (p.18, Pfizer submission)

Secondly, the need for education following the introduction of TGs was demonstrated in 1998 and 2010 but is still being ignored with the formation of the new TGs. There are no provisions for an education campaign and the need for any education remains unrecognised. [9]

In conclusion a number of recommendations from our original submission were addressed primarily through the May 2010 MOU. However, we believe that the remaining issues can be addressed through the following recommendations still outstanding from our original submission.

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[8] CA102: *This is a good way of doing it insofar as it does not affect patient access, it does not affect a clinician's ability to use which medicine they choose and think is appropriate and it does not affect the price to consumers; nonetheless, it improves sustainability.*

[9] *CA112 Senator MOORE…. What is the process for advising practitioners, particularly general practitioners, about how these systems work? Is that coming through the PBAC? Is it coming through the department? Is it coming through Medicare? Where do people go to understand the process to know what drugs are listed, what costing process is used and how a therapeutic group operates, particularly, as I said, while already operating in the system?*
Mr Learmonth—The full answer will come, but mostly pricing the PBS is invisible, and that is fine because it does not impact on anything a doctor is prescribing or what patients pay. In the context of this, the therapeutic group premiums would be the circumstance.
Senator MOORE—But a number of doctors did not seem to understand. All the information on the proposed therapeutic group was out March last year. It was all there about how it was going to work. They did not know. Their evidence actually showed that they thought there was going to be an impact on patients at quite a serious level. Some quite serious statements were given in evidence today about the proposed impact on patients in this process. I am just wondering about how the information is shared with general practitioners about how a therapeutic group operates.

Questions on notice

1. **What do you suggest is a sound definition of interchangeability?**

The true test of interchangeability is the experience of the individual patient.

2. **What do you consider would be a fuller, more independent analysis of all clinical evidence that should be taken into consideration when medicines have to be determined as interchangeable?**

We believe that the PBAC has the expertise to perform this assessment once it has been defined. We maintain that there are two steps necessary to determining if two or more medicines are interchangeable at a patient level; 1) a definition of interchangeable at the individual patient level and 2) definition of the evidentiary requirements necessary to determine that two or more medicines are suitable for inclusion in a TG.

As stated on page 4 we believe there are clear minimal requirements for evidentiary requirements to underpin the formation of a TG. We support the Medicines Australia proposal put forward on the criteria and evidentiary requirements necessary to determine that two or medicines may be interchangeable.

3. **I would like to get some information from you on notice as to the exact cost difference of the changes in terms of the drugs in your examples?**

The PBS subsidised cost of Lipitor® has not changed following the first annual WAMTC for the HP statin TG. Page 7 contains further details on Pristiq® and Efexor-XR®.

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