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Senator Scott Ryan
Chair
Senate Finance and Public Administration Committees
PO Box 6100
Parliament House
Canberra ACT 2600
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Dear Senator Ryan,

Thank you for the opportunity to appear before the Committee inquiring into the Government's administration of the PBS.

This letter contains additional information from matters arising during the hearing.

Supply of medicines

Evidence from the Department of Health and Ageing suggested that it was an individual company's choice to commence the manufacture and supply of medicines prior to notification of listing. However, as part of the post PBAC process, companies are required to submit documentation to the PBS listings section which includes a notification from the manufacturer's responsible person which includes the guarantee to supply (see NHA Section 99AEB) the medicine from the date of PBS listing.

The guarantee of supply requirement formed part of the 2006 PBS reform package and was designed to *protect supply by requiring the suppliers of new brands of medicines listing on the PBS to guarantee to supply for a minimum period and imposing penalties if they fail to meet this commitment. Interruptions to supply are also disruptive for patients, prescribers and pharmacists.*[1] As reported in The Impact of PBS Reform: *The provisions try to give the Government as much notice as possible about supply failures in order to minimise the impact on patients, prescribers and pharmacists.*[2]

[1] Item 3.1.6. Guarantee of Supply http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs_reform_02feb07.htm.
[2] Department of Health and Ageing. The Impact of PBS Reform. http://www.pbs.gov.au/info/industry/useful-resources/impact-of-pbs-eform

In the case of the deferred Pfizer medicines, we were required to provide this information prior to 15 February 2011 for a 1 April 2011 PBS listing. Pfizer was not informed of the deferral until 25 February 2011. Once the company has committed to supply from a certain date, it must commence the necessary procedures to meet this government-required commitment. This includes manufacturing and/or importing stock, which generally requires 2-3 months.

In the case of Fragmin, we have around $300,000 worth of stock in temperature-controlled storage. This stock shelf-life expires in approximately 18 months. In addition, our company policy and the standard is for stock to have a minimum shelf-life of at least 6 months at time of sale.

Clearly, there are ongoing employment and logistics costs to support Fragmin and to maintain readiness should Cabinet decide to accept the PBAC's recommendation and end the deferral. Companies also have to retain highly qualified personnel to maintain and support the medicine's regulatory requirements, including post-marketing safety surveillance and medical queries from healthcare professionals and patients.

Patient numbers

We would like to clarify that the proposed Fragmin PBS listing impacts approximately 24,000 patients over five years, as stated in our submission.

It is our understanding there are no additional regulatory costs associated with the deferred medicines, based on the understanding that all the PBS listings requirements have been met.

Patents and listing applications

Companies whose multi-billion dollar research and development investments result in the discovery of a medical application for new molecules generally apply for patent protection. The rigorous and crucially important testing regime usually consumes half of that patent life.

It is important to recognise that the patent clock continues to tick while regulatory processes drag on. When Cabinet defers medicines which have demonstrated their safety, efficacy and cost effectiveness, the patent life of these medicines is effectively shortened. This further reduces the appeal of investing in research and development for new medicines.

When a small market like Australia becomes more uncertain, it will have longer-term impacts on the access to innovative medicines for Australian patients. The decision to bring a medicine to market in Australia requires significant planning. Typically several years are required for the development and implementation of the regulatory processes required to bring a medicine to patients.

Therefore, it is too early to see an impact on the number of applications to register and gain reimbursement for new medicines. The current submissions were commenced a very long time before Cabinet's surprise decision to defer new medicines.

Companies are currently in the 2012-2013 planning period and the unpredictability of the Australian PBS as a result of the Cabinet deferrals decision is part of the decision-making process for every new medicine, particularly those medicines with niche or orphan indications.

Breach of the MOU

The decision by Cabinet to defer the listing of a small number of medicines is contrary to the intent of the Memorandum of Understanding signed by both parties just a few months earlier.

> *Both parties intend that the MOU will promote efficiency and sustainability of the PBS and support, by the provision of a stable pricing policy environment, a viable and responsible medicines industry in Australia, consistent with the objectives of the National Medicines Policy.*[3]

Stability was almost the sole benefit for industry – and government explained that publicly:

> *The Government appreciates the role which… Medicines Australia… played in constructively negotiating reforms that will result in better services for consumers, certainty for… the pharmaceutical industry, and a more sustainable PBS for the future.*
>
> Nicola Roxon MP, News release 17 November 2010

The industry was assured that the very substantial savings it had offered in negotiations would fund new medicines for Australians.

> *It means that we will save nearly $2 billion worth of expenditure and that means we will be able to invest in new drugs when they become available and need to be listed on the PBS.*
>
> Nicola Roxon MP, Hansard, 23 November 2010

Industry is of the view that the unprecedented deferral of recommended medicines is a breach of a four year agreement which was only a few months old.

Further savings

The MOU was designed to save a large and growing amount of money for government, while maintaining Australians' access to new, innovative medicines. The deferral policy doesn't achieve either of these aims: it reduces Australians' access to medicines, destabilises industry and does not save much money, if any.

The price disclosure arrangements in both tranches of PBS reform will pay enormous dividends for government and have only just begun to flow. Industry warranted that price disclosure would result in medicines reducing in price by 23 per cent. However, reductions so far have been up to 71 per cent (see p.29, Pfizer submission).

Over $2 billion in blockbuster medicine comes off patent in the next two years. The savings for the PBS, driven by price closure and other elements of the MOU, will reap enormous savings.

[3] http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm

The first round of PBS reform was originally calculated to save $3 billion and is now widely acknowledged to have saved double that figure. The second round of PBS reform will be equally successful, without any need for short-term measures which deny Australians access to medicine and save very little in comparison.

Pfizer is more than willing to provide any further clarification that committee members may require on this matter.

Yours sincerely

Alissa Brown
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