SENATE STANDING COMMITTEE ON COMMUNITY AFFAIRS

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Inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

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SUBMITTER

Pfizer Australia

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Prepared by Pfizer Australia

Pfizer

Australia

Disclosure

This submission has been prepared by Pfizer Australia – a wholly owned subsidiary of Pfizer Inc., based in New York. Pfizer Australia is this country's largest manufacturer of prescription medicines.

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.

Pfizer Australia is a member of Medicines Australia – the peak industry body for the innovative medicines industry in Australia.

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Executive Summary

The pharmaceutical industry in Australia faces significant challenges in the form of increased competition, Pharmaceutical Benefits Scheme reform and the forthcoming patent expiry on a number of medicines.

The Memorandum of Understanding (hereafter referred to as the 'MOU') between Medicines Australia and the Commonwealth of Australia provides a stable business environment for industry and further significant savings for the Scheme.

The MOU was initially signed on 6 May 2010 and was updated on 28 September 2010 to ensure Government savings would be realised.

As a member of Medicines Australia, Pfizer Australia supports the MOU.

In accordance with clause 6, Pfizer Australia supports the legislative changes required to effect policy changes arising from, or which reflect, the MOU, as represented by the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010* (hereafter referred to as "the Bill").

While recognising this Inquiry is limited to the legislative provisions relating to the MOU, it is likely the Senate Committee will examine other aspects of the MOU. It is therefore relevant to discuss in this submission some components of the MOU Pfizer believes should be highlighted to Committee members.

Commencement of MOU

It is important to recognise the majority of provisions of the MOU do not require legislative changes in order for those provisions to be implemented.

The MOU clearly states at Clause 2 "both parties agree that the MOU will be effective from the date of its execution until 30 June 2014."

In recognition of that, many of the initiatives contained within the MOU are already being actively pursued by both the Australian Government and Medicines Australia (and its member companies.)

It is worth noting that the legislation that is subject to this Inquiry represents only five clauses of the 32 clause MOU – being clauses 10, 11, 12, 13 and 14. These clauses all relate to the agreed additional savings measures negotiated by Medicines Australia and the Commonwealth.

The MOU is an agreement between the industry and the Australian Government and is not subject to approval by the Parliament. While Pfizer has clearly stated its support for

both the MOU and the Bill, the provisions of the MOU not requiring legislative change are not contingent on the legislation.

The MOU was signed by both parties without any such caveat, as shown by both the effective date being the date the MOU was signed, and the undertaking at Clause 6 for Medicines Australia to support the legislative changes.

Cabinet consideration of new medicines

The MOU provides at clause 29: *"For those submissions required to be approved by Cabinet, the Commonwealth will use its best endeavours to implement a maximum time frame of six months for consideration and decision by Cabinet. The six months will commence from the date of notification by the Department of Health and Ageing to the sponsor that pricing is agreed."*

During the Second Reading debate on the Bill in the House of Representatives on Monday 18 October 2010 on the Bill, the Member for Bowman, Mr Andrew Laming MP made the following observation:

"So it is great to see that in the MOU there is an undertaking from government that, within six months of the recommendation from the PBAC, cabinet will consider and make a decision on whether to list the drug. And it would be hoped that it would be a lot faster than six months. That is a lifetime for someone waiting for a brand new medication. So, in some ways we would like to see an even faster streamlining of the system. So often when you legislate for a minimum the minimum becomes the maximum and everything drags out to five months and 29 days. We want to see these drugs coming on straight away. What we cannot afford is a government that does not have the courage to look at the best possible system for pricing of generic pharmaceuticals, freeing up the resources and moving that around to the front end to help the innovators."

Pfizer feels it is important to clarify that in fact, the six months period does not begin from the PBAC recommendation, but *"from the date of notification by the Department of Health and Ageing to the sponsor that pricing is agreed."*

This is an important distinction. Pfizer would like to place on the record our preferred position would be that suggested by Mr Laming – six months from PBAC recommendation.

It is important to recognise that medicines are either listed on a 'cost-effective' basis or a 'cost-minimised' basis. If a medicine is listed on a 'cost-minimised' basis – it is priced comparatively to a medicine already on the PBS, which has been listed on a 'cost-effective' basis.

The MOU requires the six month period to be a maximum, but we share the concern raised by Mr Laming that a risk exists for all PBS listings requiring Cabinet approval may take the entirety of this period.

Given Pfizer's longstanding view that important medicines should be made available to Australian patients at the earliest possible opportunity, Pfizer would recommend, notwithstanding clause 29 of the MOU, the Australian Government consider a period of no more than six months from the time the PBAC provides a positive recommendation as a more appropriate maximum period. It should be noted that new medicines must already have demonstrated their cost effectiveness prior to the formal approval by Cabinet.

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