



# Pharmaceutical Benefits Advisory Committee

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Telephone: (02) 6289 7099  
Facsimile: (02) 6289 4175

Address all mail to:  
THE SECRETARY  
PBAC  
GPO Box 9848  
Canberra ACT 2601

Ms Christine McDonald  
Committee Secretary  
Finance and Public Administration References Committee  
PO Box 6100  
Parliament House  
CANBERRA ACT 2612

Dear Ms McDonald

During my appearance before the Senate Finance and Public Administration References Committee Inquiry into the Government's Administration of the Pharmaceutical Benefits Scheme (PBS), Senator Fierravanti-Wells asked me to table a copy of the advice I received from the Minister for Health and Ageing in relation to the Government's decision to defer the listing of some medicines on the PBS. A copy of the letter is attached for the Committee.

In addition, Senator Fierravanti-Wells also asked me:

*"How many PBAC recommendations have not been followed by the Minister in relation to those of less than \$10 million and those over \$10 million".*

In relation to drugs estimated to cost more than \$10 million in any of the first four years of listing, there have been two prior occasions where the Pharmaceutical Benefits Advisory Committee's (PBAC) positive recommendations to list a new drug on the PBS have not been implemented: nicotine replacement therapy patches in 1994 and sildenafil citrate (Viagra®) in 2002.

In relation to drugs estimated to cost less than \$10 million in any of the first four years of listings, the Government announced on 25 February 2011 that it had deferred the listing or amendment to listing of seven medicines on the PBS, one of which will be listed on 1 August 2011.

Governments have also accepted other PBAC recommendations, such as price reductions for biological disease-modifying antirheumatic drugs listed on the PBS for the treatment of rheumatoid arthritis and recommendations that certain medicines should comprise therapeutic groups. I am aware that three recommendations by the PBAC to form therapeutic groups were subsequently disallowed by the Senate in March 2010.

Previous governments have decided not to accept other recommendations of the PBAC. For example, the recommendation of the PBAC in 2001 to maintain the price relativity between the ACE-inhibitor class of drugs and the ATRA class of drugs.

The Committee may also be interested to know that as at July 2011, 29 positive PBAC recommendations (made within the last five years) have not been implemented as sponsor companies have not proceeded with the listing process.

I trust this information is of assistance to the Committee.

Yours sincerely

Professor Lloyd Sansom AO  
9 August 2011



**THE HON NICOLA ROXON MP  
MINISTER FOR HEALTH AND AGEING**

Professor Lloyd Sansom  
Chair  
Pharmaceutical Benefits Advisory Committee  
GPO Box 9848  
MDP 952  
CANBERRA ACT 2601

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PBAC sec.

Dear Professor Sansom

*Lloyd*

I am writing to formally advise you of the Australian Government's recent decision and ongoing processes regarding new and amended listings for the Pharmaceutical Benefits Scheme (PBS), the Life Saving Drugs Program (LSDP) and the National Immunisation Program (NIP).

As you have already discussed with officers from the Department of Health and Ageing, in recently considering Pharmaceutical Benefits Advisory Committee (PBAC) and Pharmaceutical Benefits Pricing Authority (PBPA) recommended new and amended listings, Government decided to defer seven new listings to the PBS and NIP and not approve eight price increases to existing listings.

Current fiscal circumstances require the Government to closely consider all decisions with financial implications. In light of this fiscal environment the Government has determined it must consider the recommendations of the PBAC, PBPA and Australian Technical Advisory Group on Immunisation (ATAGI) in the context of whole of government priorities. The Government is therefore concentrating on listing drugs at this time for more serious conditions and where alternative treatment options are not available.

As you are aware, it has always been the case that the final decisions on the listings of medicines and vaccines have been taken by the Government, based on the expert recommendations of the PBAC and PBPA.

Those listings which have been deferred in the prevailing fiscal environment remain eligible for future consideration when fiscal circumstances permit. Deferred listings will not need to be reconsidered by PBAC, PBPA or ATAGI, unless the sponsoring company wishes to present further clinical evidence to support a price increase or cut.

The Government is committed to ensuring that all Australians have timely and affordable access to medicines, and continues to be a strong supporter of a viable medicines industry in this country and to delivering on the policy outcomes outlined in the Memorandum of Understanding with Medicines Australia.

Yours sincerely

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**NICOLA ROXON**

10 MAR 2011