

Sent: Friday, 15 June 2007

Subject: Response to question on notice on interchangeability

Today at the hearing I took a question from Senator Moore about the definition of the term 'interchangeability'. I noted at that time that I had defined the term interchangeability in my opening statement to the Committee and that the Pharmaceutical Benefits Advisory Committee (PBAC) currently used this approach in determining whether or not to advise the Minister that a drug was interchangeable. The definition in my opening statement was as follows:

"Interchangeability means that these drugs are pharmaceutically related, have the same mechanism of action and provide similar therapeutic outcomes at equivalent doses at the individual patient level"

I noted that I would check whether there were specific guidelines in this regard. I have done so, and determined that this term is not addressed in the Guidelines for Lodgement of PBAC Submissions. On reflection that is not unexpected as these are guidelines for companies that focus on appropriate levels of evidence for PBAC submissions.

I have ascertained however that the Pharmaceutical Benefits Pricing Authority Annual Report 2005-06 (page 10) contains the following information on interchangeability:

The Therapeutic Group Premium Policy was introduced by the Government in 1998. The policy applies within specifically defined groups of drugs which have similar safety and health outcomes. Within these groups, the drugs can be interchanged at the patient level.

The PBPA Annual Report can be found at:

[http://www.health.gov.au/internet/wcms/publishing.nsf/Content/D54934A7E75638F6CA2572170082946F/\\$File/pbpa%20annual%20report%202006.pdf](http://www.health.gov.au/internet/wcms/publishing.nsf/Content/D54934A7E75638F6CA2572170082946F/$File/pbpa%20annual%20report%202006.pdf)

In addition confidential minutes from the PBAC when they have considered the formation of therapeutic group premium (TGP) groups confirms that the definition in my opening statement is highly consistent with the view of the PBAC.

I hope this suffices as an answer to the Committee in what is an unusually short timeframe. Please let me know if there is a more formal requirement to lodge this response. Regards,

Rosemary Huxtable
First Assistant Secretary
Pharmaceutical Benefits Division
Department of Health and Ageing