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15 October 2010

Committee Secretary
Senate Standing Committee on Community Affairs
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Ms Bleeser,

Abbott Laboratories is a global broad-based healthcare company that operates in more than 130 nations around the world. It's Australian Division, Abbott Australasia, has operated in Australia for more than 70 years and employs more then 600 people around the nation.

We thank you for the opportunity to provide a submission to this Inquiry and look forward to reviewing the final report and findings of the Committee.

With regards to the Terms of Reference Abbott Australasia would like to confine its remarks to just one aspect of the Inquiry. We would like to address the following reference:

> **(B) The criteria and clinical evidence used to qualify drugs as interchangeable at a patient level.**

The Pharmaceutical Benefits Pricing Authority (PBPA) define Therapeutic Groups as groups containing drugs that the Pharmaceutical Benefits Advisory Committee has advised are interchangeable with another drug or medical preparation at the individual patient level.

Further the PBPA defines interchangeable as brands of a pharmaceutical item with a particular strength (and brands of related pharmaceutical items) where evidence of bioequivalence or therapeutic equivalence on an individual basis (or justification for not needing such data) has been accepted by the TGA.

While these definitions provide some form of guide to the implementation of this pricing policy there are considerable information gaps still existing that, if filled, would provide industry with a much clearer understanding of both the intent and operation of the policy.

Gaps in information include definitions around both bioequivalence and therapeutic equivalence and what it means to be interchangeable at the individual patient level. In addition to definitions there is also an information gap surrounding the process and evidentiary requirements for decisions around interchangeability.

While Abbott Australasia supports the position articulated by Medicines Australia in relation to Therapeutic Goods should the Government not adopt this policy position Abbott would like to see the Department of Health and Ageing work collaboratively with industry to clearly fill the information gaps outlined above.

Should the Committee require any additional information regarding Abbott Australasia's position we would be pleased to assist.

Yours sincerely

Dean Phizacklea
General Manager
Abbott Australasia