



18 May 2004

The Honourable Robert B. Zoellick  
United States Trade Representative  
600 17<sup>th</sup> Street, NW  
Washington, DC 20508

Dear Ambassador Zoellick

In connection with the signing on this date of the Australia-United States Free Trade Agreement (the "Agreement"), I have the honour to confirm the following understanding reached by the Governments of Australia and the United States in the course of negotiations regarding Annex 2-C (Pharmaceuticals):

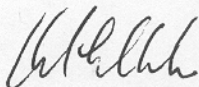
1. In order to enhance transparency, meaningful consultation, and accountability in the process of selecting, listing, and pricing of pharmaceuticals under its Pharmaceutical Benefits Scheme (PBS), Australia shall provide an applicant seeking to have a pharmaceutical listed on the PBS formulary:
  - (a) an opportunity to consult relevant officials prior to submission of an application for listing, including on the selection of a comparator pharmaceutical;
  - (b) an opportunity to respond fully to reports or evaluations relating to the applications that are prepared for the technical subcommittees of the Pharmaceutical Benefits Advisory Committee (PBAC);
  - (c) an opportunity for a hearing before PBAC while it is considering reports or advice from the technical subcommittees to the PBAC regarding applications; and
  - (d) sufficient information on the reasons for PBAC's determination on an application, on an expeditious basis, to facilitate any application to the Pharmaceutical Benefits Pricing Authority.

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2. Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list.
3. In order to make its process of selection, listing, and pricing of pharmaceuticals and indications under its PBS more expeditious, Australia shall:
  - (a) reduce the time required to implement recommendations of the PBAC, where possible;
  - (b) introduce procedures for more frequent revisions and dissemination of the Schedule of Pharmaceutical Benefits, where possible; and
  - (c) make available expedited procedures for processing of applications not requiring an economic evaluation.
4. Australia shall provide opportunities to apply for an adjustment to the price of a pharmaceutical under the PBS.

I have the honour to propose that this letter and your letter in reply confirming that your Government shares this understanding shall constitute an integral part of the Agreement.

Yours sincerely



Mark Vaile  
Minister for Trade

EXECUTIVE OFFICE OF THE PRESIDENT  
THE UNITED STATES TRADE REPRESENTATIVE  
WASHINGTON, D.C. 20508

May 18, 2004

The Honorable Mark Vaile MP  
Minister for Trade  
Parliament House  
Canberra ACT 2600

Dear Minister Vaile:

I have the honor to acknowledge receipt of your letter of this date, which reads as follows:

“In connection with the signing on this date of the Australia-United States Free Trade Agreement (the Agreement), I have the honour to confirm the following understanding reached by the Governments of Australia and the United States in the course of negotiations regarding Annex 2-C (Pharmaceuticals):

1. In order to enhance transparency, meaningful consultation, and accountability in the process of selecting, listing, and pricing of pharmaceuticals under its Pharmaceutical Benefits Scheme (PBS), Australia shall provide an applicant seeking to have a pharmaceutical listed on the PBS formulary:
  - (a) an opportunity to consult relevant officials prior to submission of an application for listing, including on the selection of a comparator pharmaceutical;
  - (b) an opportunity to respond fully to reports or evaluations relating to the applications that are prepared for the technical subcommittees of the Pharmaceutical Benefits Advisory Committee (PBAC);
  - (c) an opportunity for a hearing before PBAC while it is considering reports or advice from the technical subcommittees to the PBAC regarding applications; and
  - (d) sufficient information on the reasons for PBAC’s determination on an application, on an expeditious basis, to facilitate any application to the Pharmaceutical Benefits Pricing Authority.

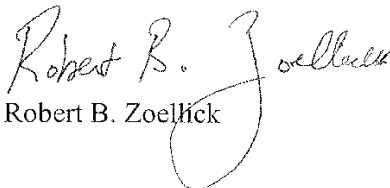
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2. Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list.
3. In order to make its process of selection, listing, and pricing of pharmaceuticals and indications under its PBS more expeditious, Australia shall:
  - (a) reduce the time required to implement recommendations of the PBAC, where possible;
  - (b) introduce procedures for more frequent revisions and dissemination of the Schedule of Pharmaceutical Benefits, where possible; and
  - (c) make available expedited procedures for processing of applications not requiring an economic evaluation.
4. Australia shall provide opportunities to apply for an adjustment to the price of a pharmaceutical under the PBS.

I have the honour to propose that this letter and your letter in reply confirming that your Government shares this understanding shall constitute an integral part of the Australia—United States Free Trade Agreement.”

I have the further honor to confirm that my Government shares this understanding and that your letter and this reply shall constitute an integral part of the United States—Australia Free Trade Agreement.

Sincerely,

  
Robert B. Zoellick