

DRAFT
SUBJECT TO LEGAL REVIEW FOR ACCURACY, CLARITY, AND CONSISTENCY
MARCH 1, 2004

Exchange of Letters on the PBS

[letter from Australia to the United States]

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

Dear Ambassador Zoellick:

I have the honour to confirm the following understanding reached between Australia and the United States of America in the course of negotiations regarding Annex 2-C (Pharmaceuticals) of the Free Trade Agreement between our two governments signed this day:

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 its determination on an application, on an expeditious basis, to facilitate any application to the Pharmaceutical Benefits Pricing Authority.
2. Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list.

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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 a reimbursement amount.

I have the honour to propose that this letter and your letter of confirmation in reply constitute an agreement between our two Governments, to enter into force on the date that the Australia-United States Free Trade Agreement enters into force.

I have the honour to propose that this understanding also be treated as an integral part of the Free Trade Agreement.

Sincerely,

MARK VAILE

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[Letter from United States to Australia]

The Honourable Mark Vaile
Minister for Trade
Parliament House
Canberra ACT 2600

Dear Minister Vaile

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

“Dear Ambassador Zoellick:

I have the honour to confirm the following understanding reached between Australia and the United States of America in the course of negotiations regarding Annex 2-C (Pharmaceuticals) of the Free Trade Agreement between our two governments signed this day:

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 its 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 a reimbursement amount.

I have the honour to propose that this letter and your letter of confirmation in reply constitute an agreement between our two Governments, to enter into force on the date that the Australia-United States Free Trade Agreement enters into force.

I have the honour to propose that this understanding also be treated as an integral part of the Free Trade Agreement.

Sincerely,

MARK VAILE”

I have the further honour to confirm that my government shares this understanding and that these letters constitute an agreement between our two Governments, to enter into force on the date that the United States-Australia Free Trade Agreement enters into force and that this understanding is an integral part of the Free Trade Agreement.

Sincerely,

Robert B. Zoellick