

[TRANSLATION]

June 30, 2007

The Honorable Susan C. Schwab  
United States Trade Representative  
Washington, D.C.

Dear Ambassador Schwab:

I have the honor to confirm the following understanding reached between the delegations of the Republic of Korea and the United States of America during the course of negotiations regarding Chapter Five (Pharmaceutical Products and Medical Devices) of the Free Trade Agreement between our two Governments signed this day:

1. In implementing Article 5.3.5(e) (Transparency), Korea shall:
  - (a) establish and maintain a body to review, at the request of an applicant that is directly affected, recommendations or determinations regarding the pricing and reimbursement of pharmaceutical products or medical devices;<sup>1</sup>
  - (b) ensure that the body referred to in subparagraph (a) is independent of the health care authorities at its central level of government that operate or maintain procedures for listing pharmaceutical products, medical devices, or indications for reimbursement, or for setting the amount of reimbursement for pharmaceutical products or medical devices;
  - (c) when providing applicants for reimbursement with the meaningful, detailed written information required in Article 5.3.5(d), inform those applicants of their right to seek independent review and the procedures for seeking that review; and
  - (d) ensure that the review is completed within a reasonable, specified period.
2. Members of the review body referred to in paragraph 1(a) shall:
  - (a) be comprised of professionals with relevant expertise and experience;
  - (b) not be employees or members of the health care authorities at Korea's central level of government that operate or maintain procedures for listing pharmaceutical products, medical devices, or indications for reimbursement, or for setting the amount of reimbursement for pharmaceutical products or medical devices;
  - (c) have no pecuniary, professional, or personal interest in the outcome of the review that might affect their conduct or decisions with respect to the review; and

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<sup>1</sup> The definitions set out in Article 5.8 (Definitions) apply to this letter.

- (d) be appointed for a fixed period and may not be subject to removal by the health care authorities at Korea's central level of government that operate or maintain procedures for listing pharmaceutical products, medical devices, or indications for the reimbursement, or for setting the amount of reimbursement for pharmaceutical products or for medical devices.

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

Sincerely,

[SGM]  
Hyun Chong Kim

June 30, 2007

The Honorable Hyun Chong Kim  
Minister for Trade  
Seoul, Republic of Korea

Dear Minister Kim:

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

I have the honor to confirm the following understanding reached between the delegations of the Republic of Korea and the United States of America during the course of negotiations regarding Chapter Five (Pharmaceutical Products and Medical Devices) of the Free Trade Agreement between our two Governments signed this day:

1. In implementing Article 5.3.5(e) (Transparency), Korea shall:
  - (a) establish and maintain a body to review, at the request of an applicant that is directly affected, recommendations or determinations regarding the pricing and reimbursement of pharmaceutical products or medical devices;<sup>1</sup>
  - (b) ensure that the body referred to in subparagraph (a) is independent of the health care authorities at its central level of government that operate or maintain procedures for listing pharmaceutical products, medical devices, or indications for reimbursement, or for setting the amount of reimbursement for pharmaceutical products or medical devices;
  - (c) when providing applicants for reimbursement with the meaningful, detailed written information required in Article 5.3.5(d), inform those applicants of their right to seek independent review and the procedures for seeking that review; and
  - (d) ensure that the review is completed within a reasonable, specified period.
2. Members of the review body referred to in paragraph 1(a) shall:
  - (a) be comprised of professionals with relevant expertise and experience;
  - (b) not be employees or members of the health care authorities at Korea's central level of government that operate or maintain procedures for listing

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<sup>1</sup> The definitions set out in Article 5.8 (Definitions) apply to this letter.

The Honorable Hyun Chong Kim  
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- (c) pharmaceutical products, medical devices, or indications for reimbursement, or for setting the amount of reimbursement for pharmaceutical products or medical devices;
- (d) have no pecuniary, professional, or personal interest in the outcome of the review that might affect their conduct or decisions with respect to the review; and
- (e) be appointed for a fixed period and may not be subject to removal by the health care authorities at Korea's central level of government that operate or maintain procedures for listing pharmaceutical products, medical devices, or indications for the reimbursement, or for setting the amount of reimbursement for pharmaceutical products or for medical devices.

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

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

Sincerely,

Susan C. Schwab