

DRAFT
Subject to Legal Review for Accuracy, Clarity, and Consistency

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

Dear Ambassador Schwab:

I have the honor to confirm the following understanding of the delegations of the United States of America and the Republic of Korea reached during the course of negotiations regarding the Free Trade Agreement (“the Agreement”) between our two Governments signed this day.

In implementing Article 5.3.5(e) of the Pharmaceutical Products/Medical Devices Chapter (the “Chapter”), Korea shall:

- (a) establish and maintain a review body that reviews, at the request of a directly affected applicant, recommendations or determinations regarding the pricing and reimbursement of pharmaceutical products or medical devices (as defined in Article 5.8 of the Chapter);
- (b) ensure that the review body is independent of the health care authorities at its central level of government (as defined in Article 5.8 of the Chapter) that operates or maintains procedures for the listing of 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 and detailed written information required in Article 5.3.5(d) of the Chapter, inform those applicants of their right to seek independent review and the required procedures for seeking that review; and
- (d) ensure that the review is completed within a reasonable and specified time.

Members of such independent review body 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 operates or maintains procedures for the listing of 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
- (d) be appointed for a set period of time and may not be removed by the health care authorities at Korea’s central level of government that operates or maintains procedures

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for the listing of 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 of confirmation in reply shall constitute an agreement between our Governments.

Sincerely,

Kim Hyun-chong
Minister for Trade

[Reply Letter Forthcoming]