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

February 4, 2016

The Honorable Shuichi Takatori
State Minister of Cabinet Office of Japan
Tokyo, Japan

Dear State Minister Shuichi Takatori:

I have the honor to confirm the following understanding with regard to Annex 26-A (Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices) to Chapter 26 (Transparency and Anti-corruption) of the Trans-Pacific Partnership Agreement signed on this day:

The Government of Japan (Japan) and the Government of the United States of America (United States) recognize the valuable contribution of the medical device industry to the health of our societies and of our economies. Access to medical devices is essential to every country's health care system and provides benefits to patients worldwide. Both countries are among the world's largest markets for and exporters of medical devices.

In this connection, while Japan emphasized the need to maintain its universal health care system, Japan and the United States also recognize the importance of transparency and procedural fairness in the operation of national health care programs by national health care authorities, including with respect to medical devices. Japan and the United States confirm that each government will maintain at least the current level of consistency with Article 3 (Procedural Fairness) of Annex 26-A (Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices) with respect to the treatment of medical devices by: (1) the Central Social Insurance Medical Council, with respect to its role in making recommendations in relation to the listing or setting amount of reimbursement; and (2) the Centers for Medicare & Medicaid Services (CMS), with respect to CMS's role in making Medicare national coverage determinations, respectively.

Furthermore, under the framework of consultation mechanism provided for in Article 5 (Consultation) of Annex 26-A (Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices), Japan and the United States affirm our readiness to consult on any matter related to the Annex, including relevant future health care programs.

I would be grateful if you would confirm that this understanding is shared by your Government.

Sincerely,

Ambassador Michael B. G. Froman

Auckland, February 4, 2016

His Excellency
Mr. Michael B.G. Froman
United States Trade Representative

Dear Ambassador Froman,

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 with regard to Annex 26-A (Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices) to Chapter 26 (Transparency and Anti-corruption) of the Trans-Pacific Partnership Agreement signed on this day:
>
> The Government of Japan (Japan) and the Government of the United States of America (United States) recognize the valuable contribution of the medical device industry to the health of our societies and of our economies. Access to medical devices is essential to every country's health care system and provides benefits to patients worldwide. Both countries are among the world's largest markets for and exporters of medical devices.
>
> In this connection, while Japan emphasized the need to maintain its universal health care system, Japan and the United States also recognize the importance of transparency and procedural fairness in the operation of national health care programs by national health care authorities, including with respect to medical devices. Japan and the United States confirm that each government will maintain at least the current level of consistency with Article 3 (Procedural Fairness) of Annex 26-A (Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices) with respect to the treatment of medical devices by: (1) the Central Social Insurance Medical Council, with respect to its role in making recommendations in relation to the listing or setting amount of reimbursement; and (2) the Centers for Medicare & Medicaid Services (CMS), with respect to CMS's role in making Medicare national coverage determinations, respectively.
>
> Furthermore, under the framework of consultation mechanism provided for in Article 5 (Consultation) of Annex 26-A (Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices), Japan and the United States affirm our readiness to consult on any matter related to the Annex, including relevant future health care programs.
>
> I would be grateful if you would confirm that this understanding is shared by your Government."

I have further the honor to confirm that my Government shares this understanding.

Sincerely,

高鳥修一

Shuichi Takatori
State Minister of Cabinet Office of Japan