

Subject to Legal Review for Accuracy, Clarity and Consistency

[date of signature of the TPP Agreement]

Dear:

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 the Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices of Chapter 26 (Transparency and Anticorruption) of the Trans-Pacific Partnership Agreement (“the Annex”) signed on this day:

The Government of Japan (“Japan”) and the Government of the United States of America (“the 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 Paragraph X.2 of the Annex with respect to the treatment of medical devices by: (1) 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 Paragraph X.4 of the Annex, 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.

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