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TRANS-PACIFIC PARTNERSHIP

TRANSPARENCY CHAPTER-ANNEX ON TRANSPARENCY AND PROCEDURAL

FAIRNESS FOR HEALTHCARE TECHNOLOGIES

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**ANNEX:
TRANSPARENCY AND PROCEDURAL FAIRNESS FOR HEALTHCARE
TECHNOLOGIES**

PARAGRAPH X.1: AGREED PRINCIPLES

The Parties share a commitment to promoting the development of and facilitating access to high-quality patented and generic pharmaceutical products and medical devices, as a means of continuing to improve the health of their nationals. In pursuing these objectives, the Parties affirm the importance of:

- (a) adequate access to high-quality pharmaceutical products and medical devices in providing high-quality health care;
- (b) high-quality patented and generic pharmaceutical products and medical devices in reducing other more costly medical expenditures;
- (c) sound economic incentives and the operation of competitive markets, or the adoption or maintenance by a Party of procedures that appropriately value objectively demonstrated therapeutic significance of high quality patented and generic pharmaceutical products and medical devices, for the efficient development of and access to such products and devices;
- (d) promoting innovation and timely and affordable access to safe and effective pharmaceutical products and medical devices through transparent, expeditious and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety, and efficacy;
- (e) ethical practices by manufacturers and suppliers of pharmaceutical products and medical devices and by health care providers on a global basis in order to achieve open, transparent, accountable, and reasonable health care decision-making; and
- (f) cooperation among the Parties to improve the availability of safe, effective, high-quality pharmaceutical products and medical devices through transparent, expeditious and accountable procedures, without regard to the origin of the products or devices.

PARAGRAPH X.2: TRANSPARENCY RELATED TO HEALTHCARE TECHNOLOGIES

1. Each Party shall comply with Articles [XX.2.] (Transparency-Publication) with respect to any matter related to the reimbursement for pharmaceutical products or medical devices.

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2. To the extent possible, each Party shall allow reasonable time between publication of final regulations of general application at the central level of government respecting any matter related to the reimbursement for pharmaceutical products or medical devices and the effective date of such regulations.
3. Each Party shall ensure that all measures of general application at the central level of government respecting any matter related to reimbursement for pharmaceutical products or medical devices are administered in a reasonable, objective, consistent, non-discriminatory, and impartial manner.

PARAGRAPH X.3: PROCEDURAL FAIRNESS RELATED TO HEALTHCARE TECHNOLOGIES

To the extent that health care authorities of a Party's central level of government 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, under health care programs operated by its central level of government¹, a Party shall:

- (a) ensure that consideration of all formal applications for the approval of pharmaceutical products or medical devices for reimbursement or for setting the amount of reimbursement for such products is completed within a reasonable, specified period;
- (b) disclose to applicants within a reasonable, specified period all procedural rules, methodologies, principles, criteria (including those used, if any, to determine comparator products), and guidelines used to determine the eligibility for, and amount of, reimbursement for pharmaceutical products or medical devices;
- (c) afford applicants timely and meaningful opportunities to provide comments at relevant points in the decision-making process related to reimbursement for pharmaceutical products or medical devices;
- (d) ensure that the Party's determination of the reimbursement amount for a pharmaceutical product or medical device has a transparent and verifiable basis consisting of competitive market-derived prices in the Party's territory, or an alternative transparent and verifiable basis consisting of other benchmarks that appropriately recognize the value of the patented or generic pharmaceutical products or medical devices at issue;

¹ Pharmaceutical formulary development and management shall be considered to be an aspect of government procurement of pharmaceutical products for health care agencies that engage in government procurement. Chapter X (Government Procurement), rather than this Chapter, shall apply to government procurement of pharmaceutical products.

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- (e) where a Party provides for a determination of the reimbursement amount on a basis other than competitive market-derived prices in that territory, that Party shall permit a manufacturer of the pharmaceutical product or medical device in question, before or after a decision on a reimbursement amount is made, to apply for an increased amount of reimbursement for the product or device based on evidence the manufacturer provides on the product's superior safety, efficacy or quality as compared with comparator products;
- (f) establish procedures that allow a manufacturer of a pharmaceutical product or medical device to apply for reimbursement for additional medical indications for the product, based on evidence the manufacturer provides on the product's safety or efficacy;
- (g) within a reasonable, specified period, provide detailed written information to applicants regarding the basis for recommendation or determination relating to their applications for reimbursement of pharmaceutical products or medical devices, including citations to any expert opinions or academic studies upon which the Party has relied;
- (h) make available to the public written information regarding its recommendations and determinations relating to the reimbursement of pharmaceutical products or medical devices, subject to any requirements under the Party's law to protect information considered to be confidential;
- (i) make available an opportunity for independent appeal or review of recommendations or determinations relating to reimbursement for pharmaceutical products or medical devices; and
- (k) make publicly available the membership list of all committees involved in determinations related to the reimbursement of pharmaceutical products or medical devices.

PARAGRAPH X.4: DISSEMINATION OF INFORMATION TO HEALTH PROFESSIONALS AND CONSUMERS

Each Party shall permit a pharmaceutical product manufacturer to disseminate to health professionals and consumers through the manufacturer's Internet site registered in the territory of the Party, and on other Internet sites registered in the territory of the Party linked to that site, information that is truthful and not misleading regarding its pharmaceutical products that are approved for sale in the Party's territory, provided that the information includes a balance of risks and benefits and is limited to indications for which the Party's competent regulatory authorities have approved the marketing of the pharmaceutical products.

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PARAGRAPH X.5: ETHICAL BUSINESS PRACTICES

[Placeholder for provisions on ethical business practices]

PARAGRAPH X.6: COOPERATION

1. The Parties recognize that international cooperation is important to increasing the availability of pharmaceutical products and medical devices through transparent, expeditious and accountable procedures at the central level of government, and that such cooperation should be encouraged regardless of the origin of such products or devices.

2. *[Placeholder for possible cooperative mechanisms]*

PARAGRAPH X.7: DEFINITIONS

For purpose of this Chapter:

health care authorities of a Party's central level of government means entities that are part of or have been established by a Party's central level of government to operate or administer its health care programs;

health care programs operated by a Party's central level of government means health care programs in which the health care authorities of a Party's central level of government make the decisions regarding matters to which this Chapter applies;² and

pharmaceutical product or medical device means a pharmaceutical, biologic, medical device, or diagnostic product.

[Placeholder for additional definitions]

² [Negotiator's Note: Clarifying footnote regarding scope of application, such as with respect to central versus regional level of government healthcare programs.]