

# Trans-Pacific Partnership Agreement Transparency Chapter Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices

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**Title:** Trans-Pacific Partnership Agreement Transparency Chapter Annex on

Transparency and Procedural Fairness for Pharmaceutical Products and

**Medical Devices** 

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## Description

This is the secret December 2014 draft (with country negotiating positions) of an annex to the Trans-Pacific Partnership Agreement (TPP) "Transparency Chapter". The TPP is an attempt to create a transnational treaty regime encompassing 40 per cent of global GDP and one-third of world trade.

The draft Annex places requirements and restrictions on national healthcare access programs in how they allocate public subsidies for medicines and medical devices.



#### TRANSPARENCY CHAPTER

## ANNEX ON TRANSPARENCY AND PROCEDURAL FAIRNESS FOR PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES<sup>1</sup>,

#### **DECEMBER 17, 2014**

#### PARAGRAPH X.1: PRINCIPLES

The Parties are committed to facilitating high-quality healthcare and continued improvements in public health for their nationals including patients and the public. In pursuing these objectives, the Parties acknowledge the importance of the following principles:

- (a) the importance of protecting and promoting public health and the important role played by pharmaceutical products and medical devices<sup>2</sup> in delivering high quality health care;
- (b) the importance of research and development, including associated innovation, related to pharmaceutical products and medical devices;
- (c) the need to promote timely and affordable access to pharmaceutical products and medical devices, through transparent, [xx oppose: impartial,] expeditious, and accountable procedures, without prejudice to a Party's right to apply appropriate standards of quality, safety, and efficacy; and
- (d) the need to recognize the value of pharmaceutical products and medical devices through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical product or medical device.

#### PARAGRAPH X.2: PROCEDURAL FAIRNESS

To the extent that a Party's national health care authorities operate or maintain procedures for listing new pharmaceutical products or medical devices for reimbursement purposes, or setting the amount of such reimbursement, under national health care programs operated by the national health care authorities,<sup>34</sup> the Party shall:

<sup>1</sup> For greater certainty, the Parties confirm that the purpose of this Annex is to ensure transparency and procedural fairness of relevant aspects of Parties' [xx propose: applicable] systems relating to pharmaceutical products and medical devices as specified herein, [xx propose: if any,] without prejudice to the obligations in Chapter [ZZ (Transparency)], and not to modify a Party's system of health care in any other respects or a Party's rights to determine health expenditure priorities. [xx comment: We will drop 'if any' if other Parties accept 'applicable'.]

<sup>&</sup>lt;sup>2</sup> For purposes of this Annex, each Party shall define the scope of the products subject to its statutes and regulations for pharmaceutical products and medical devices in its territory and make such information publicly available.

<sup>&</sup>lt;sup>3</sup> This Annex shall not apply to government procurement of pharmaceutical products and medical devices. Where {a

[xx comment: On the understanding that this Annex does not apply to procedures undertaken for the purpose of post-market subsidization of pharmaceutical products or medical devices procured by public healthcare entities where the pharmaceutical products or medical devices eligible for consideration are based on the products or devices that are procured by public healthcare entities, Singapore is prepared to accept the language contained in this provision (except as specifically indicated below), provided that this understanding is shared and confirmed by Parties as set out in footnote 4 (as currently numbered in the clean version).]

- (a) ensure that consideration of all formal and duly formulated proposals for such listing of pharmaceutical products or medical devices for reimbursement is completed within a specified period of time<sup>5</sup>;
- (b) disclose procedural rules, [xx propose; xx considering: methodologies, principles, and [xx oppose; xx propose: where relevant,] guidelines used to assess such proposals<sup>6</sup>;
- (c) afford applicants<sup>7</sup>, and where appropriate, the public, timely opportunities to provide comments at relevant points in the decision-making process;
- (e) provide applicants with [xx propose: detailed] written information [xx propose: sufficient to comprehend] [xx oppose: regarding] the basis for recommendations or determinations regarding the listing of new pharmaceutical products or medical devices for reimbursement by national healthcare authorities;
- (f) make available [xx propose: xx considering: an independent] review process [xx propose; xx oppose:<sup>8</sup>] that may be invoked at the request of an applicant directly affected by such a recommendation or determination by a Party's national healthcare authorities not to list a pharmaceutical or medical device for reimbursement [xx propose: xx considering: or as an alternative, an internal review process, such as by the same expert or group of experts that made the recommendation or determination, provided that such a review process includes, at a minimum, a substantive reconsideration of the application and may

public entity providing healthcare services} a {national} healthcare authority} engages in government procurement for pharmaceutical products or medical devices, formulary development and management with respect to such activity by the {national} healthcare authority shall be considered an aspect of such government procurement.

<sup>&</sup>lt;sup>4</sup> [xx propose: This Annex shall not apply to procedures undertaken for the purpose of post-market subsidization of pharmaceutical products or medical devices procured by public healthcare entities where the pharmaceutical products or medical devices eligible for consideration are based on the products or devices that are procured by public healthcare entities.] [xx comment: xx's comment appended to the chapeau of X.2 is to be read in conjunction with this footnote.]

<sup>&</sup>lt;sup>5</sup> In those cases in which a Party's national healthcare authority is unable to complete consideration of a proposal within {the} {a} specified period of time, the Party shall disclose the reason for the delay to the applicant and shall provide for another specified period of time for completing consideration of the proposal.} {Placeholder for negotiators note.}

<sup>&</sup>lt;sup>6</sup> {Negotiators' Note: For greater certainty, it is understood that subparagraph (b) refers to procedural rules, methodologies, principles and guidelines of general application.}

For greater certainty, each Party may define the persons or entities that qualify as an "applicant" under its laws, regulations, and procedures.

<sup>&</sup>lt;sup>8</sup> [xx propose; xx oppose: For greater certainty, this does not affect the Parties' right to determine, the timing of such review.]

be invoked at the request of an applicant directly affected by such recommendation or determination]<sup>9</sup>; and

(g) provide written information to the public regarding such recommendations or determinations, while protecting information considered to be confidential under the Party's law.

# PARAGRAPH X.3: 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, truthful and not misleading information regarding its pharmaceutical products that are approved for marketing in the Party's territory as is permitted to be disseminated under the Party's laws, regulations, and procedures, provided that the information includes a balance of risks and benefits and encompasses all indications for which the Party's competent regulatory authorities have approved the marketing of the pharmaceutical product.

#### PARAGRAPH X.4: CONSULTATION

- 1. To facilitate dialogue and mutual understanding of issues relating to this Annex, each Party shall give sympathetic consideration to [xx propose: and shall afford adequate opportunity for consultation regarding] a written request by another Party [xx oppose: to consult] on any matter related to this Annex. Such consultations shall take place within {3 months} of the delivery of the request, unless the consulting Parties otherwise agree.<sup>10</sup>
- 2. Consultations shall involve officials from each Party responsible for {national} healthcare programs and other appropriate government officials.

#### PARAGRAPH X.6: DEFINITIONS

For purposes of this Annex-

<sup>&</sup>lt;sup>9</sup> {xx propose; xx considering: For greater certainty, subparagraph (f) does not require a Party to provide more than a single review process for a request regarding a specific proposal or to review, in conjunction with the request, other proposals or the {analysis} {assessment} related to such other proposals. Further, a Party may elect to provide the review process specified in subparagraph (f) either with respect to a draft final recommendation or determination, or with respect to a final recommendation or determination.}

<sup>&</sup>lt;sup>10</sup> Nothing in this paragraph shall be construed as requiring a Party to review or change decisions regarding specific applications [xx: or any aspect of national health care or healthcare subsidy programmes].

**national health care authority** means, with respect to a Party listed in the schedule to this Annex, the relevant entity or entities specified therein, and with respect to any other Party, an entity that is part of or has been established by a Party's central level of government to operate a national health care program;

**national health care program** means a health care program in which a national health care authority makes the [xx propose: determinations or recommendations] [xx oppose: decisions] regarding the listing of pharmaceutical products or medical devices for reimbursement, or regarding the setting the amount of such reimbursement.

## **PARAGRAPH X.7: Disputes**

The dispute settlement procedures provided for in Chapter BBB (Dispute Settlement) shall not apply to this Annex.

## SCHEDULE TO ANNEX

Further to the definition of national healthcare authorities in Paragraph X.6, national healthcare authorities shall mean:

(a) [xx propose: For Australia: the Pharmaceutical Benefits Advisory Committee (PBA) with respect to PBAC's role in making determinations in relation to the listing pharmaceutical products for reimbursement under the Pharmaceutical Benefits Scheme;]	of
(b) [xx propose: For Japan:;]	
[xx still considering: depending upon how Japan will define its national healthcauthority, Japan would propose a note to the effect that the review process under paragra X.3.(f) means for it the review of initial recommendation]	
(c) [xx propose: For the United States: The Centers for Medicare & Medicaid Services (CM with respect to CMS's role in making Medicare national coverage determinations;]	IS)
(d) [xx propose: For Singapore: the Drug Advisory Committee (DAC) of the Ministry Health with respect to the DAC's role in the listing of pharmaceutical products. For great certainty, Singapore does not currently operate a national healthcare programme within scope of this Annex.]	ter
{Note: xx may adjust the inscription in the Schedule pending further discussions as to apperation of the Schedule and its effect on Parties where there are no current application of the Scope of the Annex.}	