

## CHAPTER 26

### TRANSPARENCY AND ANTI-CORRUPTION

\*This Chapter is similar to that of TPP, together with note of freeze clause under CPTPP (according to WTO Center-VCCI)

#### Section A: Definitions

##### Article 26.1: Definitions

For the purposes of this Chapter:

**act or refrain from acting in relation to the performance of official duties** includes any use of the public official's position, whether or not within the official's authorised competence;

**administrative ruling of general application** means an administrative ruling or interpretation that applies to all persons and fact situations that fall generally within the ambit of that administrative ruling or interpretation and that establishes a norm of conduct, but does not include:

- (a) a determination or ruling made in an administrative or quasi-judicial proceeding that applies to a particular person, good or service of another Party in a specific case; or
- (b) a ruling that adjudicates with respect to a particular act or practice;

**foreign public official** means any person holding a legislative, executive, administrative or judicial office of a foreign country, at any level of government, whether appointed or elected, whether permanent or temporary, whether paid or unpaid, irrespective of that person's seniority; and any person exercising a public function for a foreign country, at any level of government, including for a public agency or public enterprise;

**official of a public international organisation** means an international civil servant or any person who is authorised by a public international organisation to act on its behalf; and

**public official** means:

- (a) any person holding a legislative, executive, administrative or judicial office of a Party, whether appointed or elected, whether permanent or temporary, whether paid or unpaid, irrespective of that person's seniority;
- (b) any other person who performs a public function for a Party, including for a public agency or public enterprise, or provides a

public service, as defined under the Party's law and as applied in the pertinent area of that Party's law; or

- (c) any other person defined as a public official under a Party's law.<sup>1</sup>

## **Section B: Transparency**

### **Article 26.2: Publication**

1. Each Party shall ensure that its laws, regulations, procedures and administrative rulings of general application with respect to any matter covered by this Agreement are promptly published or otherwise made available in a manner that enables interested persons and Parties to become acquainted with them.
2. To the extent possible, each Party shall:
  - (a) publish in advance any measure referred to in paragraph 1 that it proposes to adopt; and
  - (b) provide interested persons and other Parties with a reasonable opportunity to comment on those proposed measures.
3. To the extent possible, when introducing or changing the laws, regulations or procedures referred to in paragraph 1, each Party shall endeavour to provide a reasonable period between the date when those laws, regulations or procedures, proposed or final in accordance with its legal system, are made publicly available and the date when they enter into force.
4. With respect to a proposed regulation<sup>2</sup> of general application of a Party's central level of government respecting any matter covered by this Agreement that is likely to affect trade or investment between the Parties and that is published in accordance with paragraph 2(a), each Party shall:
  - (a) publish the proposed regulation in an official journal, or on an official website, preferably online and consolidated into a single portal;

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<sup>1</sup> For the United States, the obligations in Section C shall not apply to conduct outside the jurisdiction of federal criminal law and, to the extent they involve preventive measures, shall apply only to those measures covered by federal law governing federal, state and local officials.

<sup>2</sup> A Party may, consistent with its legal system, comply with its obligations that relate to a proposed regulation in this Article by publishing a policy proposal, discussion document, summary of the regulation or other document that contains sufficient detail to adequately inform interested persons and other Parties about whether and how their trade or investment interests may be affected.

- (b) endeavour to publish the proposed regulation:
  - (i) no less than 60 days in advance of the date on which comments are due; or
  - (ii) within another period in advance of the date on which comments are due that provides sufficient time for an interested person to evaluate the proposed regulation, and formulate and submit comments;
- (c) to the extent possible, include in the publication under subparagraph (a) an explanation of the purpose of, and rationale for, the proposed regulation; and
- (d) consider comments received during the comment period, and is encouraged to explain any significant modifications made to the proposed regulation, preferably on an official website or in an online journal.

5. Each Party shall, with respect to a regulation of general application adopted by its central level of government respecting any matter covered by this Agreement that is published in accordance with paragraph 1:

- (a) promptly publish the regulation on a single official website or in an official journal of national circulation; and
- (b) if appropriate, include with the publication an explanation of the purpose of and rationale for the regulation.

### **Article 26.3: Administrative Proceedings**

With a view to administering in a consistent, impartial and reasonable manner all measures of general application with respect to any matter covered by this Agreement, each Party shall ensure in its administrative proceedings applying measures referred to in Article 26.2.1 (Publication) to a particular person, good or service of another Party in specific cases that:

- (a) whenever possible, a person of another Party that is directly affected by a proceeding is provided with reasonable notice, in accordance with domestic procedures, of when a proceeding is initiated, including a description of the nature of the proceeding, a statement of the legal authority under which the proceeding is initiated and a general description of any issue in question;
- (b) a person of another Party that is directly affected by a proceeding is afforded a reasonable opportunity to present facts and arguments in support of that person's position prior to any final administrative

action, when time, the nature of the proceeding and the public interest permit; and

- (c) the procedures are in accordance with its law.

#### **Article 26.4: Review and Appeal<sup>3</sup>**

1. Each Party shall establish or maintain judicial, quasi-judicial or administrative tribunals or procedures for the purpose of the prompt review and, if warranted, correction of a final administrative action with respect to any matter covered by this Agreement. Those tribunals shall be impartial and independent of the office or authority entrusted with administrative enforcement and shall not have any substantial interest in the outcome of the matter.

2. Each Party shall ensure that, with respect to the tribunals or procedures referred to in paragraph 1, the parties to a proceeding are provided with the right to:

- (a) a reasonable opportunity to support or defend their respective positions; and
- (b) a decision based on the evidence and submissions of record or, where required by its law, the record compiled by the relevant authority.

3. Each Party shall ensure, subject to appeal or further review as provided for in its domestic law, that the decision referred to in paragraph 2(b) shall be implemented by, and shall govern the practice of, the office or authority with respect to the administrative action at issue.

#### **Article 26.5: Provision of Information**

1. If a Party considers that any proposed or actual measure may materially affect the operation of this Agreement or otherwise substantially affect another Party's interests under this Agreement, it shall, to the extent possible, inform that other Party of the proposed or actual measure.

2. On request of another Party, a Party shall promptly provide information and respond to questions pertaining to any proposed or actual measure that the requesting Party considers may affect the operation of this Agreement, whether or not the requesting Party has been previously informed of that measure.

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<sup>3</sup> For greater certainty, review need not include merits (*de novo*) review, and may take the form of common law judicial review. The correction of final administrative actions may include a referral back to the body that took that action.

3. A Party may convey any request or provide information under this Article to the other Parties through their contact points.
4. Any information provided under this Article shall be without prejudice as to whether the measure in question is consistent with this Agreement.

## **Section C: Anti-Corruption**

### **Article 26.6: Scope**

1. The Parties affirm their resolve to eliminate bribery and corruption in international trade and investment. Recognising the need to build integrity within both the public and private sectors and that each sector has complementary responsibilities in this regard, the Parties affirm their adherence to the *APEC Conduct Principles for Public Officials*, July 2007, and encourage observance of the *APEC Code of Conduct for Business: Business Integrity and Transparency Principles for the Private Sector*, September 2007.
2. The scope of this Section is limited to measures to eliminate bribery and corruption with respect to any matter covered by this Agreement.
3. The Parties recognise that the description of offences adopted or maintained in accordance with this Section, and of the applicable legal defences or legal principles controlling the lawfulness of conduct, is reserved to each Party's law, and that those offences shall be prosecuted and punished in accordance with each Party's law.
4. Each Party shall ratify or accede to the *United Nations Convention against Corruption*, done at New York on October 31, 2003 (UNCAC).

### **Article 26.7: Measures to Combat Corruption**

1. Each Party shall adopt or maintain legislative and other measures as may be necessary to establish as criminal offences under its law, in matters that affect international trade or investment, when committed intentionally, by any person subject to its jurisdiction:<sup>4</sup>
  - (a) the promise, offering or giving to a public official, directly or indirectly, of an undue advantage, for the official or another person or entity, in order that the official act or refrain from acting in

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<sup>4</sup> A Party that is not a party to the *Convention on Combating Bribery of Foreign Public Officials in International Business Transactions*, including its Annex, done at Paris on November 21, 1997, may satisfy the obligations in subparagraphs (a), (b) and (c) by establishing the criminal offences described in those subparagraphs in respect of "in the exercise of his or her official duties" rather than "in relation to the performance of his or her official duties".

relation to the performance of or the exercise of his or her official duties;

- (b) the solicitation or acceptance by a public official, directly or indirectly, of an undue advantage, for the official or another person or entity, in order that the official act or refrain from acting in relation to the performance of or the exercise of his or her official duties;
- (c) the promise, offering or giving to a foreign public official or an official of a public international organisation, directly or indirectly, of an undue advantage,<sup>5</sup> for the official or another person or entity, in order that the official act or refrain from acting in relation to the performance of or the exercise of his or her official duties, in order to obtain or retain business or other undue advantage in relation to the conduct of international business; and
- (d) the aiding or abetting, or conspiracy<sup>6</sup> in the commission of any of the offences described in subparagraphs (a) through (c).

2. Each Party shall make the commission of an offence described in paragraph 1 or 5 liable to sanctions that take into account the gravity of that offence.

3. Each Party shall adopt or maintain measures as may be necessary, consistent with its legal principles, to establish the liability of legal persons for offences described in paragraph 1 or 5. In particular, each Party shall ensure that legal persons held liable for offences described in paragraph 1 or 5 are subject to effective, proportionate and dissuasive criminal or non-criminal sanctions, which include monetary sanctions.

4. No Party shall allow a person subject to its jurisdiction to deduct from taxes expenses incurred in connection with the commission of an offence described in paragraph 1.

5. In order to prevent corruption, each Party shall adopt or maintain measures as may be necessary, in accordance with its laws and regulations, regarding the maintenance of books and records, financial statement disclosures, and accounting and auditing standards, to prohibit the following acts carried out for the purpose of committing any of the offences described in paragraph 1:

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<sup>5</sup> For greater certainty, a Party may provide in its law that it is not an offence if the advantage was permitted or required by the written laws or regulations of a foreign public official's country, including case law. The Parties confirm that they are not endorsing those written laws or regulations.

<sup>6</sup> Parties may satisfy the commitment regarding conspiracy through applicable concepts within their legal systems, including *asociación ilícita*.

- (a) the establishment of off-the-books accounts;
- (b) the making of off-the-books or inadequately identified transactions;
- (c) the recording of non-existent expenditure;
- (d) the entry of liabilities with incorrect identification of their objects;
- (e) the use of false documents; and
- (f) the intentional destruction of bookkeeping documents earlier than foreseen by the law.<sup>7</sup>

6. Each Party shall consider adopting or maintaining measures to protect, against any unjustified treatment, any person who, in good faith and on reasonable grounds, reports to the competent authorities any facts concerning offences described in paragraph 1 or 5.

#### **Article 26.8: Promoting Integrity among Public Officials**

1. To fight corruption in matters that affect trade and investment, each Party should promote, among other things, integrity, honesty and responsibility among its public officials. To this end, each Party shall endeavour, in accordance with the fundamental principles of its legal system, to adopt or maintain:

- (a) measures to provide adequate procedures for the selection and training of individuals for public positions considered especially vulnerable to corruption, and the rotation, if appropriate, of those individuals to other positions;
- (b) measures to promote transparency in the behaviour of public officials in the exercise of public functions;
- (c) appropriate policies and procedures to identify and manage actual or potential conflicts of interest of public officials;
- (d) measures that require senior and other appropriate public officials to make declarations to appropriate authorities regarding, among other things, their outside activities, employment, investments, assets and substantial gifts or benefits from which a conflict of interest may result with respect to their functions as public officials; and

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<sup>7</sup> For the United States, this commitment applies only to issuers that have a class of securities registered pursuant to 15 U.S.C 781 or that are otherwise required to file reports pursuant to 15 U.S.C 78o (d).

- (e) measures to facilitate reporting by public officials of acts of corruption to appropriate authorities, if those acts come to their notice in the performance of their functions.

2. Each Party shall endeavour to adopt or maintain codes or standards of conduct for the correct, honourable and proper performance of public functions, and measures providing for disciplinary or other measures, if warranted, against public officials who violate the codes or standards established in accordance with this paragraph.

3. Each Party, to the extent consistent with the fundamental principles of its legal system, shall consider establishing procedures through which a public official accused of an offence described in Article 26.7.1 (Measures to Combat Corruption) may, where appropriate, be removed, suspended or reassigned by the appropriate authority, bearing in mind respect for the principle of the presumption of innocence.

4. Each Party shall, in accordance with the fundamental principles of its legal system and without prejudice to judicial independence, adopt or maintain measures to strengthen integrity, and to prevent opportunities for corruption, among members of the judiciary in matters that affect international trade or investment. These measures may include rules with respect to the conduct of members of the judiciary.

#### **Article 26.9: Application and Enforcement of Anti-Corruption Laws**

1. In accordance with the fundamental principles of its legal system, no Party shall fail to effectively enforce its laws or other measures adopted or maintained to comply with Article 26.7.1 (Measures to Combat Corruption) through a sustained or recurring course of action or inaction, after the date of entry into force of this Agreement for that Party, as an encouragement for trade and investment.<sup>8</sup>

2. In accordance with the fundamental principles of its legal system, each Party retains the right for its law enforcement, prosecutorial and judicial authorities to exercise their discretion with respect to the enforcement of its anti-corruption laws. Each Party retains the right to take *bona fide* decisions with regard to the allocation of its resources.

3. The Parties affirm their commitments under applicable international agreements or arrangements to cooperate with each other, consistent with their respective legal and administrative systems, to enhance the effectiveness of law

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<sup>8</sup> For greater certainty, the Parties recognise that individual cases or specific discretionary decisions related to the enforcement of anti-corruption laws are subject to each Party's own domestic laws and legal procedures.

enforcement actions to combat the offences described in Article 26.7.1 (Measures to Combat Corruption).

### **Article 26.10: Participation of Private Sector and Society**

1. Each Party shall take appropriate measures, within its means and in accordance with fundamental principles of its legal system, to promote the active participation of individuals and groups outside the public sector, such as enterprises, civil society, non-governmental organisations and community-based organisations, in the prevention of and the fight against corruption in matters affecting international trade or investment, and to raise public awareness regarding the existence, causes and gravity of, and the threat posed by, corruption. To this end, a Party may:

- (a) undertake public information activities and public education programmes that contribute to non-tolerance of corruption;
- (b) adopt or maintain measures to encourage professional associations and other non-governmental organisations, if appropriate, in their efforts to encourage and assist enterprises, in particular SMEs, in developing internal controls, ethics and compliance programmes or measures for preventing and detecting bribery and corruption in international trade and investment;
- (c) adopt or maintain measures to encourage company management to make statements in their annual reports or otherwise publicly disclose their internal controls, ethics and compliance programmes or measures, including those that contribute to preventing and detecting bribery and corruption in international trade and investment; and
- (d) adopt or maintain measures that respect, promote and protect the freedom to seek, receive, publish and disseminate information concerning corruption.

2. Each Party shall endeavour to encourage private enterprises, taking into account their structure and size, to:

- (a) develop and adopt sufficient internal auditing controls to assist in preventing and detecting acts of corruption in matters affecting international trade or investment; and
- (b) ensure that their accounts and required financial statements are subject to appropriate auditing and certification procedures.

3. Each Party shall take appropriate measures to ensure that its relevant anti-corruption bodies are known to the public and shall provide access to those bodies, if appropriate, for the reporting, including anonymously, of any incident

that may be considered to constitute an offence described in Article 26.7.1 (Measures to Combat Corruption).

### **Article 26.11: Relation to Other Agreements**

Subject to Article 26.6.4 (Scope), nothing in this Agreement shall affect the rights and obligations of the Parties under UNCAC, the *United Nations Convention against Transnational Organized Crime*, done at New York on November 15, 2000, the *Convention on Combating Bribery of Foreign Public Officials in International Business Transactions*, with its Annex, done at Paris on November 21, 1997, or the *Inter-American Convention Against Corruption*, done at Caracas on March 29, 1996.

### **Article 26.12: Dispute Settlement**

1. Chapter 28 (Dispute Settlement), as modified by this Article, shall apply to this Section.

2. A Party may only have recourse to the procedures set out in this Article and Chapter 28 (Dispute Settlement) if it considers that a measure of another Party is inconsistent with an obligation under this Section, or that another Party has otherwise failed to carry out an obligation under this Section, in a manner affecting trade or investment between Parties.

3. No Party shall have recourse to dispute settlement under this Article or Chapter 28 (Dispute Settlement) for any matter arising under Article 26.9 (Application and Enforcement of Anti-Corruption Laws).

4. Article 28.5 (Consultations) shall apply to consultations under this Section, with the following modifications:

- (a) a Party other than a consulting Party may make a request in writing to the consulting Parties to participate in the consultations, no later than seven days after the date of circulation of the request for consultations, if it considers that its trade or investment is affected by the matter at issue. That Party shall include in its request an explanation of how its trade or investment is affected by the matter at issue. That Party may participate in consultations if the consulting Parties agree; and
- (b) the consulting Parties shall involve officials of their relevant anti-corruption authorities in the consultations.

5. The consulting Parties shall make every effort to find a mutually satisfactory solution to the matter, which may include appropriate cooperative activities or a work plan.

## ANNEX 26-A

### TRANSPARENCY AND PROCEDURAL FAIRNESS FOR PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES<sup>9</sup>

#### Article 1: Definitions

For the purposes of this Annex:

**national health care authority** means, with respect to a Party listed in the Appendix 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 programme; and

**national health care programme** means a health care programme in which a national health care authority makes the determinations or recommendations regarding the listing of pharmaceutical products or medical devices for reimbursement, or regarding the setting of the amount of such reimbursement.

#### Article 2: Principles

The Parties are committed to facilitating high-quality health care 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>10</sup> in delivering high-quality health care;
- (b) the importance of research and development, including innovation associated with research and development, related to pharmaceutical products and medical devices;

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<sup>9</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' applicable systems relating to pharmaceutical products and medical devices, without prejudice to the obligations in Chapter 26 (Transparency and Anti-corruption), 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.

<sup>10</sup> For the purposes of this Annex, each Party shall define the scope of the products subject to its laws and regulations for pharmaceutical products and medical devices in its territory, and make that information publicly available.

- (c) the need to promote timely and affordable access to pharmaceutical products and medical devices, through transparent, 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 recognise 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.

### **~~Article 3: 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 programmes operated by the national health care authorities,<sup>11,12</sup> the Party shall:~~

- ~~(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>13</sup>;~~
- ~~(b) disclose procedural rules, methodologies, principles and guidelines used to assess such proposals;~~

~~\*(This clause is freeze under CPTPP)~~

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<sup>11</sup> ~~This Annex shall not apply to government procurement of pharmaceutical products and medical devices. If a public entity providing health care services engages in government procurement for pharmaceutical products or medical devices, formulary development and management with respect to that activity by the national health care authority shall be considered an aspect of such government procurement.~~

<sup>12</sup> ~~This Annex shall not apply to procedures undertaken for the purpose of post-market subsidisation of pharmaceutical products or medical devices procured by public health care entities if the pharmaceutical products or medical devices eligible for consideration are based on the products or devices that are procured by public health care entities.~~

<sup>13</sup> ~~In those cases in which a Party's national health care authority is unable to complete consideration of a proposal within 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.~~

- ~~(e) afford applicants<sup>14</sup> and, if appropriate, the public, timely opportunities to provide comments at relevant points in the decision-making process;~~
- ~~(d) provide applicants with written information sufficient to comprehend the basis for recommendations or determinations regarding the listing of new pharmaceutical products or medical devices for reimbursement by national health care authorities;~~
- ~~(e) make available:~~
  - ~~(i) an independent review process; or~~
  - ~~(ii) an internal review process, such as by the same expert or group of experts that made the recommendation or determination, provided that the review process includes, at a minimum, a substantive reconsideration of the application,<sup>15</sup> and~~

~~that may be invoked at the request of an applicant directly affected by a recommendation or determination by a Party's national health care authorities not to list a pharmaceutical product or a medical device for reimbursement,<sup>16</sup> and~~
- ~~(f) provide written information to the public regarding recommendations or determinations, while protecting information considered to be confidential under the Party's law.~~

~~\*(This clause is freeze under CPTPP)~~

#### **Article 4: Dissemination of Information to Health Professionals and Consumers**

As is permitted to be disseminated under the Party's laws, regulations and procedures, each Party shall permit a pharmaceutical product manufacturer to disseminate to health professionals and consumers through the manufacturer's website registered in the territory of the Party, and on other websites 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

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<sup>14</sup> ~~For greater certainty, each Party may define the persons or entities that qualify as an "applicant" under its laws, regulations and procedures.~~

<sup>15</sup> ~~For greater certainty, the review process described in subparagraph (e)(i) may include a review process as described in subparagraph (e)(ii) other than one by the same expert or group of experts.~~

<sup>16</sup> ~~For greater certainty, subparagraph (e) does not require a Party to provide more than a single review for a request regarding a specific proposal or to review, in conjunction with the request, other proposals or the assessment related to those other proposals. Further, a Party may elect to provide the review specified in subparagraph (e) either with respect to a draft final recommendation or determination, or with respect to a final recommendation or determination.~~

~~\*(This clause is freeze under CPTPP)~~

in the Party's territory. A Party may require 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.

#### **Article 5: Consultation**

1. To facilitate dialogue and mutual understanding of issues relating to this Annex, each Party shall give sympathetic consideration to and shall afford adequate opportunity for consultation regarding a written request by another Party to consult on any matter related to this Annex. The consultations shall take place within three months of the delivery of the request, except in exceptional circumstances or unless the consulting Parties agree otherwise.<sup>17</sup>

2. Consultations shall involve officials responsible for the oversight of the national health care authority or officials from each Party responsible for national health care programmes and other appropriate government officials.

#### **Article 6: Non-Application of Dispute Settlement**

No Party shall have recourse to dispute settlement under Chapter 28 (Dispute Settlement) for any matter arising under this Annex.

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<sup>17</sup> Nothing in this paragraph shall be construed as requiring a Party to review or change decisions regarding specific applications.

## APPENDIX TO ANNEX 26-A

### PARTY-SPECIFIC DEFINITIONS

Further to the definition of national healthcare authorities in Article 1, **national health care authorities** means:

- (a) For Australia, the Pharmaceutical Benefits Advisory Committee (PBAC), with respect to PBAC's role in making determinations in relation to the listing of pharmaceutical products for reimbursement under the Pharmaceutical Benefits Scheme.
- (b) For Brunei Darussalam, the Ministry of Health. For greater certainty, Brunei Darussalam does not currently operate a national health care programme within the scope of this Annex.
- (c) For Canada, the Federal Drug Benefits Committee. For greater certainty, Canada does not currently operate a national health care programme within the scope of this Annex.
- (d) For Chile, the Undersecretary of Public Health. For greater certainty, Chile does not currently operate a national health care programme within the scope of this Annex.
- (e) For Japan, the Central Social Insurance Medical Council with respect to its role in making recommendations in relation to the listing or setting of the amount of reimbursement for new pharmaceutical products.
- (f) For Malaysia, the Ministry of Health. For greater certainty, Malaysia does not currently operate a national health care programme within the scope of this Annex.
- (g) For New Zealand, the Pharmaceutical Management Agency (PHARMAC), with respect to PHARMAC's role in the listing of a new pharmaceutical<sup>18</sup> for reimbursement on the *Pharmaceutical Schedule*, in relation to formal and duly formulated applications by suppliers in accordance with the *Guidelines for Funding Applications to PHARMAC*.

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<sup>18</sup> For the purposes of New Zealand, "pharmaceutical" means a "medicine" as defined in the *Medicines Act 1981* as at the date of signature of this Agreement on behalf of New Zealand.

- (h) For Peru, the Viceministry of Public Health. For greater certainty, Peru does not currently operate a national health care programme within the scope of this Annex.
- (i) For Singapore, the Drug Advisory Committee (DAC) of the Ministry of Health with respect to the DAC's role in the listing of pharmaceutical products. For greater certainty, Singapore does not currently operate a national health care programme within the scope of this Annex.
- (j) For the United States, the Centers for Medicare & Medicaid Services (CMS), with respect to CMS's role in making Medicare national coverage determinations.
- (k) For Viet Nam, the Ministry of Health. For greater certainty, Viet Nam does not currently operate a national health care programme within the scope of this Annex.