CHAPTER 29

PUBLICATION AND ADMINISTRATION

Section A: Publication and Administration

Article 29.1: Definitions

For the purposes of this Chapter:

administrative ruling of general application means an administrative ruling or interpretation[1] 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.

Article 29.2: 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 the other Parties to become acquainted with them. To the extent possible, each Party shall make these measures available online.

2. Each Party shall, to the extent possible:

(a) publish in advance a measure referred to in paragraph 1 that it proposes to adopt; and

(b) provide interested persons and the other Parties a reasonable opportunity to comment on a proposed measure referred to in subparagraph (a).

3. Each Party shall ensure that its laws and regulations of general application at the central level of government are published on a free, publicly accessible website that is capable of performing searches for these laws and regulations by citation or through a word search, and shall ensure that this website is kept updated. Annex 29-A sets out each Party's websites.

[1] For greater certainty, an interpretation or ruling that is not binding is not an administrative ruling of general application.

Article 29.3: Administrative Proceedings

With a view to administering all measures of general application with respect to any matter covered by this Agreement in a consistent, impartial, and reasonable manner, each Party shall ensure in its administrative proceedings[2] applying measures referred to in Article 29.2.1 (Publication) to a particular person, good, or service of another Party in specific cases that:

(a) a person of another Party that is directly affected by a proceeding is provided, whenever possible and, in accordance with domestic procedures, with reasonable notice of the initiation of a proceeding, 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 the 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 29.4: Review and Appeal

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. These 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, if 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 law, that the decision referred to in paragraph 2(b) be implemented by, and govern the practice of, the office or authority with respect to the administrative action at issue.

[2] For greater certainty, administrative proceedings subject to this Article do not include proceedings that result in advisory opinions or decisions that are not legally binding.

Section B: Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices[3]

Article 29.5: Definitions

For the purposes of this Section:

national health care authority means, with respect to a Party listed in Annex 29-B (Party-Specific Definitions), 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; and

national health care program means a health care program 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 that reimbursement.

Article 29.6: 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[4] 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;

(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

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[3] For greater certainty, the Parties confirm that the purpose of this Section is to ensure transparency and procedural fairness of relevant aspects of the Parties' applicable systems relating to pharmaceutical products and medical devices, without prejudice to the obligations in this Chapter, 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.

[4] For the purposes of this Section, 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.

(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.

Article 29.7: Procedural Fairness

To the extent that a Party's national health care authority operates or maintains procedures for listing new pharmaceutical products or medical devices for reimbursement purposes, or setting the amount of that reimbursement, under a national health care program operated by the national health care authority,[5, 6] that 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;[7]

(b) disclose procedural rules, methodologies, principles, and guidelines used to assess such proposals;

(c) afford applicants[8] 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 its national health care authority;

(e) make available:

(i) an independent review process, or

[5] This Section does 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.

[6] This Section does not apply to procedures undertaken for the purpose of post-market subsidization 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.

[7] 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.

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

(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,[9] 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 authority not to list a pharmaceutical product or a medical device for reimbursement;[10] and

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

Article 29.8: 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 in the Party's territory. A Party may require that the information include a balance of risks and benefits and encompass all indications for which the Party's competent regulatory authorities have approved the marketing of the pharmaceutical product.

Article 29.9: Consultations

1. To facilitate dialogue and mutual understanding of issues relating to this Section, each Party shall give sympathetic consideration to and shall afford adequate opportunity for consultations regarding a written request by another Party to consult on any matter related to this Section. The consultations shall take place within three months of the delivery of the request, except in exceptional circumstances or unless the consulting Parties decide otherwise.[11]

[9] 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.

[10] 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.

[11] Nothing in this paragraph shall be construed as requiring a Party to review or change a decision regarding a specific application.

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 programs and other appropriate government officials.

Article 29.10: Non-Application of Dispute Settlement

No Party shall have recourse to dispute settlement under Chapter 31 (Dispute Settlement) for any matter arising under this Section.

ANNEX 29-A

PUBLICATION OF LAWS AND REGULATIONS OF GENERAL APPLICATION

For the purpose of Article 29.2.3 (Publication), laws and regulations of general application of each Party are published in the following websites:

(a) For Canada:
http://laws.justice.gc.ca/eng/
See also:
http://www.gazette.gc.ca/accueil-home-eng.html;

(b) For Mexico:
www.diputados.gob.mx/LeyesBiblio/index.htm
See also:
www.dof.gob.mx; and

(c) For the United States:
https://www.govinfo.gov/help/whats-available
See also:
http://uscode.house.gov/ (laws)
https://www.ecfr.gov/cgi-bin/text-idx?tpl=%2Findex.tpl (regulations)

ANNEX 29-B

PARTY-SPECIFIC DEFINITIONS

Further to the definition of national health care authority in Article 29.5 (Definitions), **national health care authority** means:

(a) For Canada, the Federal Drug Benefits Committee. For greater certainty, Canada does not currently operate a national health care program within the scope of this Annex.

(b) For the United States, the Centers for Medicare & Medicaid Services (CMS), with respect to CMS's role in making Medicare national coverage determinations.