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**Subject to Legal Review for Accuracy, Clarity, and Consistency**

**CHAPTER FIVE**  
**PHARMACEUTICALS AND MEDICAL DEVICES**

ARTICLE 5.1: GENERAL PROVISIONS

The Parties recognize that while differences exist in each Party's health care system, 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 means of continuing to improve the health of their nationals. In pursuing these objectives, the Parties are committed to the following principles:

- (a) the importance of adequate access to pharmaceutical products and medical devices in providing high quality health care;
- (b) the importance of patented and generic pharmaceutical products and medical devices in reducing other more costly medical expenditures;
- (c) the importance of sound economic incentives and competitive markets for the efficient development of and access to patented and generic pharmaceutical products and medical devices;
- (d) the importance of appropriate government support of research and development in academic and commercial laboratories, intellectual property protections, and other incentives for innovation in the research and development of pharmaceutical products and medical devices;
- (e) the need to promote innovation and timely and affordable access to safe and effective pharmaceutical products and medical devices through transparent and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety, and efficacy;
- (f) the importance of ethical practices by pharmaceutical and medical devices manufacturers or suppliers and by health care providers on a global basis in order to achieve open, transparent, accountable, and reasonable health care decision-making; and
- (g) the importance of cooperation between the Parties, including each Party's regulatory authorities, to improve the safety and efficacy of pharmaceutical products and medical devices.

ARTICLE 5.2: ACCESS TO INNOVATION

To the extent that health care authorities at a Party's central level of government operate or maintain procedures for the listing of pharmaceutical products, medical devices, or indications for reimbursement or setting the amount of reimbursement for pharmaceutical

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products or medical devices, under health care programs operated by its central level of government,<sup>1</sup> a Party shall:

- (a) ensure that the procedures, rules, criteria, and guidelines that apply to the listing of pharmaceutical products and medical devices, indications for reimbursement, or setting the amount of reimbursement, for pharmaceutical products or medical devices are fair, reasonable, and non-discriminatory;
- (b) ensure that the Party's determination, if any, of the reimbursement amount for a pharmaceutical product or medical device, once approved by the appropriate regulatory authority as safe and effective, is based on competitive market-derived prices; or if its determination is not based on competitive market-derived prices, then that Party shall:
  - (i) appropriately recognize the value of patented pharmaceutical products and medical devices in the amount of reimbursement it provides;
  - (ii) permit pharmaceutical or medical device manufacturers to apply, based on evidence of safety or efficacy, for an increased amount of reimbursement over that provided for comparator products, if any, used to determine the amount of reimbursement;
  - (iii) permit manufacturers of a pharmaceutical product or medical device, after a decision on a reimbursement amount is made, to apply for an increased amount of reimbursement for that product based on the provision of evidence of its safety or efficacy; and
- (c) permit manufacturers of a pharmaceutical product or medical device to apply for reimbursement of additional medical indications for that product, based on the provision of evidence of the product's safety or efficacy.

**ARTICLE 5.3: TRANSPARENCY**

1. Each Party shall ensure that its laws, regulations, and procedures of general application respecting any matter related to the pricing, reimbursement, and regulation of pharmaceutical products and medical devices are promptly published or otherwise made available in such a manner as to enable interested persons and the other Party to become

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<sup>1</sup> Pharmaceutical formulary development and management shall be considered to be an aspect of government procurement of pharmaceutical products for healthcare agencies that engage in government procurement. Chapter Seventeen (Government Procurement) and not the provisions of this Chapter shall govern government procurement of pharmaceutical products.

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acquainted with them.

2. To the extent possible, each Party shall:
  - (a) publish in advance any such measures that it proposes to adopt; and
  - (b) provide interested persons and the other Party a reasonable opportunity to comment on such proposed measures.
  
3. With respect to proposed regulations of general application of its central level of government, respecting any matter related to the pricing, reimbursement, and regulation of pharmaceutical products and medical devices, which are published in accordance with paragraph (2) (a), each Party:
  - (a) shall publish the proposed regulations, including an explanation of the purpose of such measures, in a single official journal of national circulation,<sup>2</sup> and encourage publication through additional outlets;
  - (b) should in most cases, publish the proposed regulations not less than 60 days before the comment due date; and
  - (c) shall address in writing significant, substantive comments received from interested persons during the comment period and explain any substantive revision made with respect to the proposed regulations published in accordance with paragraph (2) (a) at the time it adopts final regulations.
  
4. To the extent possible, each Party should allow reasonable time between publication of final regulations of general application of its central level of government respecting any matter related to the pricing, reimbursement, and regulation of pharmaceutical products and medical devices and their effective date.
  
5. To the extent that health care authorities at a Party's central level of government operate or maintain procedures for the listing of pharmaceutical products, medical devices, or indications for reimbursement or setting the amount of reimbursement for pharmaceutical products or medical devices, under health care programs operated by its central level of government, a Party shall:
  - (a) ensure that consideration of all formal requests for the pricing or approval of pharmaceutical products and medical devices for reimbursement is completed within a reasonable and specified time;

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<sup>2</sup> Notwithstanding this subparagraph, health care authorities at a Party's central level of government that are not authorized under the Party's domestic law to publish their regulations in the official journal of national circulation shall publish their proposed regulations, including explanations of the purpose of such measures, on prominent locations on their official Internet sites.

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- (b) disclose to applicants within a reasonable and specified time all procedural rules, methodologies, principles, criteria, including those used, if any, to determine comparative products, and guidelines used to determine pricing and reimbursement for pharmaceutical products or medical devices;
- (c) afford applicants timely and meaningful opportunities to provide comments at relevant points in the pricing and reimbursement decision-making processes for pharmaceutical products and medical devices;
- (d) within a reasonable and specified time, provide applicants with meaningful and detailed written information regarding the basis for recommendations or determinations of the pricing and reimbursement of pharmaceutical products or medical devices, including citations to any expert opinions or academic studies relied upon in making such recommendations or determinations;
- (e) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination;
- (f) make all reimbursement decision-making bodies open to all stakeholders, including innovative and generic companies; and
- (g) make publicly available the membership list of all committees related to the reimbursement and pricing of pharmaceutical products and medical devices.

6. Each Party shall ensure that all measures of general application respecting any matter related to the pricing, reimbursement, and regulation of pharmaceutical products and medical devices are administered in a reasonable, objective, and impartial manner.

**ARTICLE 5.4: DISSEMINATION OF INFORMATION**

Each Party shall permit a pharmaceutical manufacturer to disseminate through the official Internet site registered by the manufacturer in the territory of the Party, and medical journal Internet sites registered in the territory of that Party that include direct links to that manufacturer's official Internet site, truthful and not misleading information regarding its 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 all indications for which the Party's competent regulatory authorities have approved the marketing of that pharmaceutical product.

**ARTICLE 5.5: ETHICAL BUSINESS PRACTICES**

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1. Each Party shall adopt or maintain the appropriate measures to prohibit improper inducements by pharmaceutical or medical device manufacturers or suppliers to health care professionals or institutions for the listing, purchasing, or prescribing of pharmaceutical or medical device products eligible for reimbursement under health care programs operated by its central level of government.
2. Each Party shall adopt or maintain appropriate penalties and procedures to enforce the measures that it adopts or maintains in conformity with paragraph 1.

ARTICLE 5.6: REGULATORY COOPERATION

1. Consistent with Article 9.8 (TBT: Committee on Technical Barriers to Trade), a Party will facilitate consideration of a request to recognize the results of conformity assessment procedures conducted by bodies in the other Party's territory, including a request for the negotiation of an agreement with respect to Good Manufacturing Practices, Good Laboratory Practices, and marketing approval of generic drugs.
2. The Parties shall report on the feasibility and appropriateness of granting any such request to the Medicines and Medical Devices Committee and the Committee on Technical Barriers to Trade.

Article 5.7: MEDICINES AND MEDICAL DEVICES COMMITTEE

1. The Parties hereby establish a Medicines and Medical Devices Committee ("Committee").
2. The function of the Committee shall be to:
  - (a) monitor and support the implementation of the pharmaceutical product and medical device-related obligations in this Chapter;
  - (b) promote discussion and mutual understanding of issues related to this Chapter; and
  - (c) discuss possible opportunities for collaborative efforts on issues related to this Chapter.
3. The Committee shall be co-chaired by health and trade officials of each Party and be comprised of officials of central level government agencies responsible for central level health care programs and other appropriate central level government officials.
4. The Committee shall meet at least once a year unless the Parties agree otherwise.
5. The Committee shall report the results of each meeting to the Joint Committee.

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6. The Committee may, as agreed by both Parties, establish and determine the scope and mandate of working groups to address technical aspects of issues related to this Chapter, including those related to regulatory cooperation.

Article 5.8: DEFINITIONS

For the purposes of this Chapter:

**health care authorities at a Party's central level of government** means, unless otherwise specified, 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 program operated by a Party's central level of government** means a health care program in which the health care authorities of a Party's central level of government make the decisions regarding matters to which this Chapter applies;<sup>3</sup> and

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

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<sup>3</sup> For greater certainty, Medicaid is a regional level of government health care program in the United States, not a central level of government program.