

AUSFTA Annex 2-C	KORUS FTA Ch. 5
<p data-bbox="71 233 344 272">1. Agreed Principles</p> <p data-bbox="71 310 1052 423">The Parties are committed to facilitating high quality health care and continued improvements in public health for their nationals. In pursuing these objectives, the Parties are committed to the following principles:</p> <p data-bbox="71 467 1052 542">(a) the important role played by innovative pharmaceutical products in delivering high quality health care;</p> <p data-bbox="71 581 1052 695">(b) the importance of research and development in the pharmaceutical industry and of appropriate government support, including through intellectual property protection and other policies;</p> <p data-bbox="71 734 1052 889">(c) the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious, and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety, and efficacy; and</p> <p data-bbox="71 928 1052 1084">(d) the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.</p>	<p data-bbox="1058 233 1318 272">General Provisions</p> <p data-bbox="1058 277 2011 500">The Parties recognize that while there are differences between 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 a means of continuing to improve the health of their nationals. In pursuing these objectives, the Parties affirm the importance of:</p> <p data-bbox="1058 539 2011 613">(a) adequate access to pharmaceutical products and medical devices in providing high quality health care;</p> <p data-bbox="1058 652 2011 727">(b) patented and generic pharmaceutical products and medical devices in reducing other more costly medical expenditures;</p> <p data-bbox="1058 766 2011 889">(c) sound economic incentives and competitive markets for the efficient development of and access to patented and generic pharmaceutical products and medical devices;</p> <p data-bbox="1058 928 2011 1084">(d) 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;</p> <p data-bbox="1058 1123 2011 1279">(e) promoting 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;</p> <p data-bbox="1058 1318 2011 1393">(f) ethical practices by pharmaceutical and medical device manufacturers and suppliers and by health care providers on a global</p>

	<p>basis in order to achieve open, transparent, accountable, and reasonable health care decision-making; and</p> <p>(g) cooperation between the Parties, including each Party's regulatory authorities, to improve the safety and efficacy of pharmaceutical products and medical devices.</p>
<p>2. Transparency2c-1</p> <p>To the extent that a Party's federal healthcare authorities operate or maintain procedures for listing new pharmaceuticals or indications for reimbursement purposes, or for setting the amount of reimbursement for pharmaceuticals, under its federal healthcare programs, it shall:</p> <p>(a) ensure that consideration of all formal proposals for listing are completed within a specified time;</p> <p>(b) disclose procedural rules, methodologies, principles, and guidelines used to assess a proposal;</p> <p>(c) afford applicants timely opportunities to provide comments at relevant points in the process;</p> <p>(d) provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities;</p> <p>(e) provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law; and</p>	<p>ARTICLE 5.3: TRANSPARENCY</p> <p>1. Each Party shall ensure that its laws, regulations, and procedures of general application respecting any matter related to the pricing, reimbursement, or regulation of pharmaceutical products or medical devices are promptly published or otherwise made available in such a manner as to enable interested persons and the other Party to become acquainted with them.</p> <p>2. To the extent possible, each Party shall:</p> <p>(a) publish in advance any such measures that it proposes to adopt; and</p> <p>(b) provide interested persons and the other Party a reasonable opportunity to comment on such proposed measures.</p> <p>3. With respect to proposed regulations of general application of its central level of government respecting any matter related to the pricing, reimbursement, or regulation of pharmaceutical products or medical devices that are published in accordance with paragraph 2(a), each Party:</p> <p>(a) shall publish the proposed regulations, including an explanation of the purpose of those regulations, in a single official journal of</p>

(f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.

national circulation, and encourage their distribution through additional outlets;

(b) should in most cases publish the proposed regulations not less than 60 days before the date public comments are due; and

(c) shall, at the time it adopts final regulations, address in writing significant, substantive comments received from interested persons during the comment period and explain any substantive revision it made to the proposed 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, or regulation of pharmaceutical products or 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 listing 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 or medical devices for reimbursement 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 pricing and reimbursement of pharmaceutical products or medical devices;

2 Notwithstanding subparagraph (a), health care authorities at a Party's central level of government that are not authorized under the Party's law to publish their regulations in the official journal shall publish their proposed regulations, including explanations of the purpose of the proposed regulations, on prominent locations on their official Internet sites.

(c) afford applicants timely and meaningful opportunities to provide comments at relevant points in the pricing and reimbursement decision-making processes for pharmaceutical products or medical devices;

(d) within a reasonable, specified period, provide applicants with meaningful, 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 pricing or reimbursement of pharmaceutical products or

	<p>medical devices.</p> <p>6. Each Party shall ensure that all measures of general application respecting any matter related to the pricing, reimbursement, or regulation of pharmaceutical products or medical devices are administered in a reasonable, <b>objective</b>, and impartial manner.</p>
	<p>ARTICLE 5.2: ACCESS TO INNOVATION</p> <p>To the extent that health care authorities at a Party's central level of government operate or maintain procedures for listing 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, the Party shall:</p> <p>(a) ensure that the procedures, rules, criteria, and guidelines that apply to the listing of pharmaceutical products, medical devices, or indications for reimbursement, or setting the amount of reimbursement for pharmaceutical products or medical devices are fair, reasonable, and non-discriminatory;</p> <p>(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, <b>is based on competitive market- derived prices</b>; or if its determination is not based on competitive market- derived prices, then that Party shall:</p> <p>(i) <b>appropriately recognize the value of the patented pharmaceutical product or medical device in the amount of reimbursement it provides;</b></p>

	<p>(ii) permit a manufacturer of the pharmaceutical product or medical device 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; and</p> <p>(iii) permit a manufacturer of the pharmaceutical product or medical device, after a decision on a reimbursement amount is made, to apply for an increased amount of reimbursement for the product based on evidence the manufacturer provides on the product's safety or efficacy; and</p> <p>(c) permit a manufacturer of the pharmaceutical product or medical device to apply for reimbursement of additional medical indications for the product, based on evidence the manufacturer provides on the product's safety or efficacy.</p>
<p>5. Dissemination of Information</p> <p>Each Party shall permit a pharmaceutical 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 pharmaceuticals that are approved for sale 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 pharmaceuticals.</p>	<p>ARTICLE 5.4: DISSEMINATION OF INFORMATION</p> <p>Each Party shall permit a pharmaceutical manufacturer to disseminate through the manufacturer's official Internet site registered in the Party's territory and through medical journal Internet sites registered in the Party's territory, that include direct links to the manufacturer's official Internet site, truthful and not misleading information regarding the manufacturer's pharmaceutical product, provided that the product has marketing approval in the Party's territory and the information includes a balance of risks and benefits and is limited to indications for which the Party's competent regulatory authorities have granted market approval for that product.</p>
	<p>ARTICLE 5.5: ETHICAL BUSINESS PRACTICES</p>

	<ol style="list-style-type: none"> <li>1. Each Party shall adopt or maintain appropriate measures to prohibit pharmaceutical product or medical device manufacturers and suppliers from providing improper inducements 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.</li> <li>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.</li> </ol>
<p>4. Regulatory Cooperation</p> <p>The Parties shall seek to advance the existing dialogue between the Australian Therapeutic Goods Administration and the U.S. Food and Drug Administration with a view to making innovative medical products more quickly available to their nationals.</p>	<p>ARTICLE 5.6: REGULATORY COOPERATION</p> <ol style="list-style-type: none"> <li>1. Consistent with Article 9.8 (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.</li> <li>2. The Parties shall report on the feasibility and appropriateness of granting any such request to the Medicines and Medical Devices Committee and to the Committee on Technical Barriers to Trade established under Article 9.8.</li> </ol>
<p>3. Medicines Working Group</p> <p>(a) The Parties hereby establish a Medicines Working Group.</p> <p>(b) The objective of the Working Group shall be to promote discussion and mutual understanding of issues relating to this Annex (except those</p>	<p>ARTICLE 5.7: MEDICINES AND MEDICAL DEVICES COMMITTEE</p> <ol style="list-style-type: none"> <li>1. The Parties hereby establish a Medicines and Medical Devices Committee.</li> <li>2. The functions of the Committee shall be to:</li> </ol>

<p>issues covered in paragraph 4), including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes.2C-2</p> <p>(c) The Working Group shall comprise officials of federal government agencies responsible for federal healthcare programs and other appropriate federal government officials.</p>	<ul style="list-style-type: none"> <li>(a) monitor and support the implementation of this Chapter;</li> <li>(b) promote discussion and mutual understanding of issues related to this Chapter; and</li> <li>(c) explore opportunities for collaboration on issues related to this Chapter.</li> </ul> <p>3. The Committee shall:</p> <ul style="list-style-type: none"> <li>(a) comprise officials of central level government agencies responsible for central level health care programs and other appropriate central level government officials, and shall be co-chaired by health and trade officials of each Party;</li> <li>(b) meet at least once a year unless the Parties otherwise agree; and</li> <li>(c) report the results of each meeting to the Joint Committee.</li> </ul> <p>4. The Committee may 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.</p>
	<p>Article 5.8: DEFINITIONS</p> <p>For purposes of this Chapter:</p> <p>health care authorities at a Party's central level of government means</p>

	<p>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;</p> <p>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;<sup>3</sup> and</p> <p>pharmaceutical product or medical device means a pharmaceutical, biologic, medical device, or diagnostic product.</p>
<p>For the purposes of this Annex:</p> <p>federal healthcare program means a health care program in which the Party's federal health authorities make the decisions regarding matters to which this Annex applies.</p>	<p>Fn: For greater certainty, Medicaid is a regional level of government health care program in the United States, not a central level of government program.</p>
<p><b>SIDE LETTERS</b></p>	
<p>In order to enhance transparency, meaningful consultation, and accountability in the process of selecting, listing, and pricing of pharmaceuticals under its Pharmaceutical Benefits Scheme (PBS), Australia shall provide an applicant seeking to have a pharmaceutical listed on the PBS formulary:</p> <p>(a) an opportunity to consult relevant officials prior to submission of an application for listing, including on the selection of a comparator pharmaceutical;</p> <p>(b) an opportunity to respond fully to reports or evaluations relating to the applications that are prepared for the technical subcommittees of the Pharmaceutical Benefits Advisory Committee (PBAC);</p> <p>(c) an opportunity for a hearing before PBAC while it is considering</p>	<p>In implementing Article 5.3.5(e) (Transparency), Korea shall:</p> <p>(a) establish and maintain a body to review, at the request of an applicant that is directly affected, recommendations or determinations regarding the pricing and reimbursement of pharmaceutical products or medical devices;</p> <p>(b) ensure that the body referred to in subparagraph (a) is independent of the health care authorities at its central level of government that operate or 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;</p> <p>(c) when providing applicants for reimbursement with the</p>

reports or advice from the technical subcommittees to the PBAC regarding applications; and

(d) sufficient information on the reasons for PBAC's determination on an application, on an expeditious basis, to facilitate any application to the Pharmaceutical Benefits Pricing Authority.

2. Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list.

3. In order to make its process of selection, listing, and pricing of pharmaceuticals and indications under its PBS more expeditious, Australia shall:

(a) reduce the time required to implement recommendations of the PBAC, where possible;

(b) introduce procedures for more frequent revisions and dissemination of the Schedule of Pharmaceutical Benefits, where possible; and

(c) make available expedited procedures for processing of applications not requiring an economic evaluation.

4. Australia shall provide opportunities to apply for an adjustment to the price of a pharmaceutical under the PBS.

meaningful, detailed written information required in Article 5.3.5(d), inform those applicants of their right to seek independent review and the procedures for seeking that review; and

(d) ensure that the review is completed within a reasonable, specified period.

2. Members of the review body referred to in paragraph 1(a) shall:

(a) be comprised of professionals with relevant expertise and experience;

(b) not be employees or members of the health care authorities at Korea's central level of government that operate or 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;

(c) have no pecuniary, professional, or personal interest in the outcome of the review that might affect their conduct or decisions with respect to the review; and

(d) be appointed for a fixed period and may not be subject to removal by the health care authorities at Korea's central level of government that operate or maintain procedures for listing pharmaceutical products, medical devices, or indications for the reimbursement, or for setting the amount of reimbursement for pharmaceutical products or for medical devices.