CHAPTER FIVE
PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

ARTICLE 5.1: GENERAL PROVISIONS

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:

(a) adequate access to pharmaceutical products and medical devices in providing high quality health care;

(b) patented and generic pharmaceutical products and medical devices in reducing other more costly medical expenditures;

(c) sound economic incentives and competitive markets for the efficient development of and access to patented and generic pharmaceutical products and medical devices;

(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;

(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;

(f) ethical practices by pharmaceutical and medical device manufacturers and 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) 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 listing pharmaceutical products, medical devices, or indications for reimbursement, or setting the amount of reimbursement for pharmaceutical products or

第五章 药品与医疗器械

第5.1条：一般规定

缔约方认识到，尽管各方医疗保健体系存在差异，但均致力于通过促进高质量专利和仿制医药产品及医疗器械的研发与获取，持续改善国民健康水平。为实现这些目标，缔约方确认以下原则的重要性：

(a) 在提供高质量医疗保健服务时充分获取药品和医疗器械；(b) 专利和仿制医药产品及医疗器械有助于减少其他更高昂的医疗支出；(c) 健全的经济激励和竞争性市场对高效研发及获取专利和仿制医药产品与医疗器械至关重要；(d) 政府对学术和商业实验室研发活动的适当支持、知识产权保护以及其他激励措施，可促进药品和医疗器械领域的创新；(e) 通过透明和负责任的程序推动创新，并及时提供可负担的安全有效药品和医疗器械，同时不影响缔约方适用适当质量、安全和有效性标准的能力；(f) 全球范围内药品和医疗器械制造商、供应商及医疗保健提供者遵循道德实践，以实现开放、透明、负责任且合理的医疗保健决策；(g) 缔约方之间（包括各方监管机构）的合作，以提升药品和医疗器械的安全性与有效性。

ARTICLE 5.2: ACCESS 获取INNOVATION

在政党的中央政府层级卫生保健主管部门运营或维护药品、医疗器械或报销适应症清单程序，或设定药品或

medical devices, under health care programs operated by its central level of government,[1] the Party shall:

(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;

(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 the patented pharmaceutical product or medical device in the amount of reimbursement it provides;

(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

(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

(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.

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, 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.

2. To the extent possible, each Party shall:

[1] Pharmaceutical formulary development and management shall be considered to be an aspect of government procurement of pharmaceutical products for health care agencies that engage in government procurement. Chapter Seventeen (Government Procurement), rather than this Chapter, shall apply to government procurement of pharmaceutical products.

医疗器械在其中央政府层面运营的医疗保健计划下的报销金额时[1]，该政党应：

(a) 确保适用于药品、医疗器械或报销适应症列入清单的程序、规则、标准及指南，或为药品或医疗器械设定报销金额的程序、规则、标准及指南公平、合理且非歧视；(b) 确保缔约方在药品或医疗器械经相关监管机构批准为安全有效后，若对其实施报销金额的确定，则该确定应基于竞争性市场价格；若其确定未基于竞争性市场价格，则该缔约方应：(i) 在其提供的报销金额中适当认可专利药品或医疗器械的价值；(ii) 允许药品或医疗器械制造商基于安全性或有效性证据，申请高于用于确定报销金额的对照产品（如有）所获报销金额的增量报销；(iii) 允许药品或医疗器械制造商在报销金额决定作出后，基于其提供的产品安全性或有效性证据申请提高该产品的报销金额；(c) 允许药品或医疗器械制造商基于其提供的产品安全性或有效性证据，申请该产品额外医疗适应症的报销。

第5.3条：透明度

1. 每一方应确保其普遍适用的关于药品或医疗器械定价、报销或监管事项的法律、法规和程序迅速公布或以其他方式提供，以便利害关系人和另一方能够了解这些法律、法规和程序。

2. 在可能范围内，每一方应：

[1] 药品目录开发和管理应被视为从事政府采购的医疗保健机构对药品进行政府采购的一个方面。第十七章（政府采购）而非本章应适用于药品的政府采购。

(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, or regulation of pharmaceutical products or medical devices that are published in accordance with paragraph 2(a), each Party:

(a) shall publish the proposed regulations, including an explanation of the purpose of those regulations, in a single official journal of national circulation,[2] 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.

(a) 提前公布其拟采纳的任何此类措施；以及 (b) 为利害关系人和另一方提供对此类拟议措施发表意见的合理机会。

3. 对于其中央政府层面发布的、与药品或医疗器械的定价、报销或监管相关的任何事项的拟议法规（根据第2款(a)项公布），每一缔约方：

(a) 应在全国发行的官方期刊上公布拟议法规（包括对该法规目的的解释）[2]，并鼓励通过其他渠道分发；(b) 在大多数情况下，应在公众意见截止日期前至少60天公布拟议法规；(c) 在通过最终法规时，应以书面形式回应利害关系人在意见征询期内提出的重大实质性意见，并说明对拟议法规作出的任何实质性修订。

4. 在可能的情况下，每一缔约方应在其中央政府层面发布的、与药品或医疗器械的定价、报销或监管相关的任何事项的最终法规公布日期与生效日期之间留出合理时间。

5. 若缔约方中央政府层面的卫生保健主管部门在其运营的医疗保健计划中，实施或维持用于列出药品、医疗器械或报销适应症的程序，或设定药品或医疗器械报销金额的程序，则该缔约方应：

(a) 确保在合理、明确的期限内完成对所有关于药品或医疗器械定价或报销审批的正式请求的审议；

(b) 在合理、明确的期限内向申请人披露所有程序性
用于确定药品或医疗器械定价和报销的规则、方法学、原则、标准（包括用于确定对照产品的标准，如有）以及指南；

[2] 尽管有(a)项的规定，若一政党的中央政府层级的卫生保健主管部门根据该政党法律无权在官方期刊上发布其法规，则应在官方网站的显著位置公布其拟议法规，包括对拟议法规目的的解释。

(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 medical devices.

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, objective, and impartial manner.

(c) 为申请人提供及时且有实质意义的机会，使其能够在药品或医疗器械定价和报销决策过程的相关环节提出意见；(d) 在合理规定的期限内，向申请人提供有关药品或医疗器械定价和报销建议或决定依据的详细书面说明，包括引用在作出此类建议或决定时所依据的任何专家意见或学术研究；(e) 设立可由直接受建议或决定影响的申请人请求启动的独立审查程序；(f) 使所有报销决策机构对所有利益相关者开放，包括创新和仿制药公司；以及(g) 公开所有与药品或医疗器械定价或报销相关的委员会成员名单。

6. 每一缔约方应确保所有普遍适用的措施，涉及药品或医疗器械的定价、报销或监管的任何事项，均以合理、客观和公正的方式实施。

ARTICLE 5.4: DISSEMINATION OF INFORMATION

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.

第5.4条：信息传播

每一缔约方应允许药品制造商通过在该缔约方领土内注册的制造商官方网站以及在该缔约方领土内注册的医学期刊网站（包含直接链接至制造商官方网站）传播有关其药品的真实且不误导的信息，前提是该产品已获得该缔约方'领土内的市场批准，且信息包含风险和收益平衡，并仅限于该缔约方主管监管机构已批准该产品上市的适应症。

ARTICLE 5.5: ETHICAL BUSINESS PRACTICES

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.

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

ARTICLE 5.5: 道德商业实践

1. 每一缔约方应采取或维持适当措施，禁止药品或医疗器械制造商和供应商向医疗专业人员或机构提供不当诱导，以列入、购买或开具符合其中央政府层面运营的医疗保健计划报销资格的药品或医疗器械产品。

2. 各方应制定或维持适当的处罚和程序，以执行其根据第1款制定或维持的措施。

第5.6条：监管合作

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.

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.

ARTICLE 5.7: MEDICINES AND MEDICAL DEVICES COMMITTEE

1. The Parties hereby establish a Medicines and Medical Devices Committee.

2. The functions of the Committee shall be to:

(a) monitor and support the implementation of this Chapter;

(b) promote discussion and mutual understanding of issues related to this Chapter; and

(c) explore opportunities for collaboration on issues related to this Chapter.

3. The Committee shall:

(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;

(b) meet at least once a year unless the Parties otherwise agree; and

(c) report the results of each meeting to the Joint Committee.

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.

Article 5.8: DEFINITIONS

For purposes of this Chapter:

health care authorities at a Party's central level of government means 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 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

1. 根据第9.8条（技术性贸易壁垒委员会），一方应便利考虑关于承认另一方境内机构实施的合格评定程序结果的请求，包括关于良好生产规范、良好实验室规范和仿制药上市许可协议谈判的请求。

2. 缔约方应向药品和医疗器械委员会及根据第9.8条设立的技术性贸易壁垒委员会报告批准此类请求的可行性和适当性。

第5.7条：药品和医疗器械委员会

1. 缔约方特此设立药品和医疗器械委员会。

2. 委员会的职能应包括：(a) 监督并支持本章的实施；

(b) 促进与本章相关问题的讨论和相互理解；以及(c) 探索本章相关问题上的合作机会。

3. 委员会应：(a) 由负责中央级政府机构的官员组成

al级别医疗保健计划及其他相关中央政府层面官员，并应由各缔约方卫生与贸易官员共同主持；(b) 除非缔约方另有约定，每年至少召开一次会议；且 (c) 向联合委员会汇报每次会议成果。

4. 委员会可设立工作组以处理本章所涉问题的技术层面，包括与监管合作相关的问题，并确定其职权范围。

第5.8条：DEFINITIONS

就本章而言：

政党的中央政府层级的卫生保健主管部门指属于或由政党中央政府层面设立、用于运营或管理其医疗保健计划的实体；

由政党的中央政府层级运营的医疗保健计划，是指政党的中央政府层级的卫生保健主管部门

make the decisions regarding matters to which this Chapter applies;[3] and

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

对本章适用的事项做出决定；[3] 且

药品或医疗器械指药物、生物制品、医疗器械或诊断产品。

[3] For greater certainty, Medicaid is a regional level of government health care program in the United States, not a central level of government program.

[3] 为更明确起见，医疗补助计划是美国地区层面的政府医疗保健计划，而非中央政府层面的计划。

[*TRANSLATION*]

June 30, 2007

The Honorable Susan C. Schwab
United States Trade Representative
Washington, D.C.

Dear Ambassador Schwab:

I have the honor to confirm the following understanding reached between the delegations of the Republic of Korea and the United States of America during the course of negotiations regarding Chapter Five (Pharmaceutical Products and Medical Devices) of the Free Trade Agreement between our two Governments signed this day:

1. In implementing Article 5.3.5(e) (Transparency), Korea shall:

   (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;[1]

   (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;

   (c) when providing applicants for reimbursement with the 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

[1] The definitions set out in Article 5.8 (Definitions) apply to this letter.

[翻译]

2007年6月30日

尊敬的苏珊·C·施瓦布 美国贸易
代表 华盛顿特区

尊敬的施瓦布大使：

我荣幸地确认，大韩民国与美利坚合众国代表团在关于两国政府今日签署的自由贸易协定第五章（药品和医疗器械）的谈判过程中达成以下谅解：

1. 在实施第5.3.5(e)条（透明度）时，韩国应：

   (a) 设立并维持一个机构，应直接受影响的申请人请求，审查关于药品或医疗器械定价及报销的建议或决定；[1](b) 确保(a)项所述机构独立于其中央政府层面运营或维持药品、医疗器械或报销适应症列名程序、或设定药品或医疗器械报销金额的卫生保健主管部门；(c) 在向报销申请人提供第5.3.5(d)条要求的有意义、详细的书面信息时，告知这些申请人其有权寻求独立审查及申请该审查的程序；以及(d) 确保审查在合理的规定期限内完成。

2. 第1款(a)项所指审查机构的成员应：

   (a) 由具有相关专业知识和经验的专业人士组成；(b) 不得是韩国中央政府层面运营或维护药品、医疗器械或报销适应症清单程序，或设定药品或医疗器械报销金额的卫生保健主管部门的雇员或成员；(c) 在审查结果中不拥有可能影响其审查行为或决定的金钱、职业或个人利益；且

[1] 第5.8条（定义）中列出的定义适用于本函。

(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.

I have the honor to propose that this letter and your letter in reply confirming that your Government shares this understanding shall constitute an integral part of the Free Trade Agreement.

Sincerely,

[*SGN/*]
Hyun Chong Kim

(d) 被任命固定任期，且不得由韩国中央政府层面运营或维护药品、医疗器械或报销适应症清单程序，或设定药品或医疗器械报销金额的卫生保健主管部门予以免职。

我荣幸地提议，本函及贵方确认贵国政府认同此理解的复函，将构成《自由贸易协定》不可分割的一部分。

此致，

[SGN/]金玄忠

June 30, 2007

The Honorable Hyun Chong Kim
Minister for Trade
Seoul, Republic of Korea

Dear Minister Kim:

I have the honor to acknowledge receipt of your letter of this date, which reads as follows:

> I have the honor to confirm the following understanding reached between the delegations of the Republic of Korea and the United States of America during the course of negotiations regarding Chapter Five (Pharmaceutical Products and Medical Devices) of the Free Trade Agreement between our two Governments signed this day:
>
> 1. In implementing Article 5.3.5(e) (Transparency), Korea shall:
>
> (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;[1]
>
> (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;
>
> (c) when providing applicants for reimbursement with the 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

[1] The definitions set out in Article 5.8 (Definitions) apply to this letter.

2007年6月30日

尊敬的金玄忠阁下 贸易部长
首尔, 大韩民国

尊敬的金部长:

我荣幸地确认收到您今日的来信，内容如下:

> 我荣幸地确认大韩民国与美利坚合众国代表团在关于两国政府今日签署的《自由贸易协定》第五章（药品和医疗器械）的谈判过程中达成的以下谅解:
>
> 1. 在实施第5.3.5(e)条（透明度）时，韩国应:
>
> (a) 设立并维持一个机构，以应直接受影响的申请人请求，审查关于药品或医疗器械定价及报销的建议或决定；[1](b) 确保(a)项所述机构独立于其中央政府层面运营或维持药品、医疗器械或报销适应症列名程序，或设定药品或医疗器械报销金额的卫生保健主管部门；(c) 在向报销申请人提供第5.3.5(d)条要求的有意义、详细的书面信息时，告知这些申请人其有权寻求独立审查及申请该审查的程序；以及(d) 确保审查在合理的规定期限内完成。
>
> 2. 第1款(a)项所指审查机构的成员应:
>
> (a) 由具有相关专业知识和经验的专业人士组成；(b) 非韩国中央政府层面运营或维护药品、医疗器械或报销适应症清单程序，或设定药品或医疗器械报销金额的卫生保健主管部门的雇员或成员;

[1] 第5.8条（定义）中列出的定义适用于本函。

(c) pharmaceutical products, medical devices, or indications for reimbursement, or for setting the amount of reimbursement for pharmaceutical products or medical devices;

(d) 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

(e) 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.

I have the honor to propose that this letter and your letter in reply confirming that your Government shares this understanding shall constitute an integral part of the Free Trade Agreement.

I have the further honor to confirm that my Government shares this understanding and that your letter and this letter in reply shall constitute an integral part of the Free Trade Agreement.

Sincerely,

Susan C. Schwab

(c) 药品、医疗器械或报销适应症，或设定药品或医疗器械报销金额；(d) 在审查结果中无可能影响其行为或决策的金钱、职业或个人利益；且(e) 任期固定，不得由韩国中央政府层面运营或维护药品、医疗器械或报销适应症清单程序，或设定药品或医疗器械报销金额的卫生保健主管部门免职。

我荣幸地提议，本函及贵方回函确认贵国政府认同此理解，将构成《自由贸易协定》的组成部分。

我进一步荣幸地确认，我国政府认同此理解，且贵方来函与本回函将构成《自由贸易协定》的组成部分。

此致，

苏珊·C·施瓦布