

KOREA

TRADE SUMMARY

The U.S. goods trade deficit with Korea was \$16.1 billion in 2005, a decrease of \$3.6 billion from \$19.8 billion in 2004. U.S. goods exports in 2005 were \$27.7 billion, up 4.8 percent from the previous year. Corresponding U.S. imports from Korea were \$43.8 billion, down 5.2 percent. Korea is currently the 7th largest export market for U.S. goods.

U.S. exports of private commercial services (i.e., excluding military and government) to Korea were \$9.1 billion in 2004 (latest data available), and U.S. imports were \$4.8 billion. Sales of services in Korea by majority U.S.-owned affiliates were \$4.0 billion in 2003 (latest data available), while sales of services in the United States by majority Korea-owned firms were \$247 million.

The stock of U.S. foreign direct investment (FDI) in Korea in 2004 was \$17.3 billion, up from \$13.0 billion in 2003. U.S. FDI in Korea is concentrated largely in the manufacturing, banking, and finance sectors.

FREE TRADE AREA NEGOTIATIONS

USTR notified Congress of the President's intent to initiate negotiations on a Free Trade Agreement (FTA) with the Republic of Korea on February 2, 2006. In making this announcement, the Administration noted that Korea is our 7th largest trading partner with over \$72 billion in total trade during 2005. An FTA between the two countries promises to increase trade still further across a wide range of goods and services and, thereby, promote economic growth and the creation of better paying jobs in both countries. The announcement highlighted how an FTA with Korea would produce gains from increased agriculture and industrial goods trade, increased services trade, improvements in the protection that Korea affords to intellectual property, and the promotion of bilateral investment. Building on the close cooperation between the United States and Korea in the Asia-Pacific Economic Cooperation (APEC) forum and in the Doha Round of negotiations in the World Trade Organization (WTO), an FTA will help strengthen Korea's partnership with the United States in multilateral and regional fora. An FTA also will reinforce the shared interests of the United States and Korea and promote common values, facilitating our efforts to work together on a wide range of issues.

FOREIGN TRADE BARRIERS

IMPORT POLICIES

Tariffs and Taxes

Korea's average applied tariff rate is 11.2 percent for all products. Further, the simple average of Korea's WTO bound tariffs on all agricultural products is 52 percent, which poses a significant barrier to the export of U.S. agricultural goods. Although Korea bound 94.5 percent of its tariff lines in the WTO Uruguay Round negotiations, tariffs on most fishery products are not bound. The United States continues to press Korea to reduce its applied tariffs on agricultural and food products.

Duties remain very high on many high-value agricultural and fishery products. Korea imposes tariff rates of 30 percent or higher on most fruits and nuts, many fresh vegetables, starches, peanuts, peanut butter, various vegetable oils, juices, jams, beer, and some dairy products. Many products of interest to U.S. suppliers, including apples, beef, canned peaches, canned fruit cocktail, grape juice and grape juice concentrate, herbal teas, pears, table grapes, and a variety of citrus fruits are subject to tariff rates of 40 percent or higher.

Other products of interest to U.S. industry on which Korea imposes high tariffs include cherries, distilled spirits, frozen french fries, prepared or mashed potatoes, restaurant equipment, soups and mixed vegetable juices. In many instances Korea applies prohibitively high tariffs despite the absence of domestic production of certain agriculture products.

Korea also has established tariff-rate quotas (TRQs) that were intended to provide minimum access to previously closed markets or to maintain pre-Uruguay Round access. (*See also "Quantitative Restrictions, TRQs and Import Licensing."*) In-quota tariff rates may be very low or zero, but the over-quota tariff rates for some products are prohibitive. For example, natural and artificial honey are subject to an over-quota tariff rate of 243 percent; skim and whole milk powder, 176 percent; barley, 324 percent; malting barley, 513 percent; potatoes and potato preparations, more than 304 percent; and popcorn, 630 percent.

In order to protect domestic agricultural, fishery and plywood producers, Korea also uses "adjustment tariffs" and compounded taxes to boost applied tariff rates. Most of the adjustment tariffs are imposed on agricultural and seafood products, including frozen croaker and skate, which are products of interest to U.S. exporters. The U.S. Government has expressed concerns regarding these practices to the Korean government. In 2005, Korea renewed adjustment tariffs on 18 items, and reduced the tariff rates for five of these 18 items.

As a result of its Uruguay Round commitments, Korea also has reduced bound tariffs to zero on most or all products in the following sectors: paper, toys, steel, furniture, and farm equipment. Korea has harmonized its chemical tariffs to final rates of zero percent, 5.5 percent, or 6.5 percent, depending on the product. In addition, tariffs on scientific equipment have been reduced 65 percent from pre-Uruguay Round levels. However, on textile and apparel products, Korea's bound tariffs are relatively high: 30 percent on several man-made fibers and yarns, 30 percent on

many fabrics and most made-up and miscellaneous goods (for example, pillow cases and floor coverings), and 35 percent on most apparel items.

In September 2005, the United States, Korea, Japan, the European Union and Taiwan concluded a draft agreement under which each party would reduce the tariff rate on multi-chip integrated circuits (MCPs) to zero. All parties to this agreement are working to complete domestic procedures with a view to having the zero duty in place early in 2006. Once implemented, Korea will no longer apply a tariff of 2.6 percent on MCPs. (*For discussion of the MCP Agreement, please see Chapter 4 D, "Semiconductor Agreement"*)

Internal Supports

As part of its commitments under the 1994 WTO Agreement on Agriculture, Korea reduced its domestic support (Aggregate Measurement of Support, or AMS) of agricultural products by 13 percent by 2004.

Quantitative Restrictions - Tariff-Rate Quotas (TRQs)

Most imported non-food products no longer require prior government approval, but some products, mostly agricultural and fishery items, face import restrictions such as quotas or tariff-rate quotas (TRQs) with prohibitive out-of-quota tariffs. Korea implements quantitative restrictions through its import licensing system, which is administered by domestic producer groups or government buying agencies such as the Korea Agro-Fisheries Trade Corporation (KATC) and the Public Procurement Services (PPS). A government export-import notice lists restricted products.

Korea also continues to restrict imports of value-added soybean and corn products. By aggregating raw and value-added products under the same quota, Korea restricts market access for value-added products such as corn grits, popcorn, and soy flakes. Domestic producer groups, which administer the quotas, invariably allocate the more favorable in-quota rate to their larger members, who import raw ingredients.

Rice

In the Uruguay Round, Korea received a ten-year exception to tariffication of rice imports in return for establishing a Minimum Market Access (MMA) quota. Under the MMA quota, Korea's rice imports grew over ten years from zero percent to four percent of domestic consumption during the base period. The Korean government, through state trading enterprises, exercised full control over the purchase, distribution, and end-use of imported rice. While Korea did not purchase any U.S. rice in the early years of the MMA program, in recent years the U.S. share of Korea's total MMA rice imports increased to roughly one-fourth, and the United States became Korea's second largest supplier of imported rice, after China.

The original MMA arrangement expired at the end of 2004. However, Korea successfully negotiated a ten-year extension of the MMA arrangement. Under the extension, the MMA quota

will increase from 225,575 metric tons in 2005 to 408,698 metric tons in 2014, of which a portion will be allocated on a country-specific basis (including at least 50,076 metric tons annually from the United States). The quality of access will also improve for the first time as a portion of the MMA quota will be marketed to consumers as table rice. The table rice portion will increase from 10 percent of the quota in 2005 to 30 percent in 2010. Korea's National Assembly ratified the rice agreement on November 23, 2005. However, insufficient time remained for Korea to fulfill its rice tendering obligations under the agreement in 2005. As a result, the 2005 tendering commitments to the United States were fulfilled in February 2006, and 2006 tendering commitments will likely begin in the middle of 2006, if not sooner. The U.S. Government will continue to monitor this situation closely to ensure that Korea fulfills its commitments.

Import Clearance Procedures

Import clearance for most agricultural products in Korea typically takes three to ten days for processed products containing no unapproved food additives. Obtaining approval for unapproved additives can take six months to one year.

Customs Procedures

The Korea Customs Service (KCS) frequently classifies "blended products" under the Harmonized System (HS) heading for the major ingredient of that product, rather than under the HS heading for the blended product, which usually has a lower tariff rate. Changes in classification are often based on arbitrary standards and are at odds with practices followed by other OECD members.

(For example, in order for dehydrated potato flakes to be classified as a blended product, they must include at least 10 percent non-potato ingredients.) "Blended products" disadvantaged by this practice include potato flakes, soybean flakes, flavored popcorn, and peanut butter chips. The U.S. Government is seeking a definition of "blended products" from the World Customs Organization before proceeding on discussions about this issue.

STANDARDS, TESTING, LABELING AND CERTIFICATION

Standards and Conformity Assessment Procedures (Sampling, Inspection, Testing and Certification)

Korea maintains certain standards and conformity assessment procedures, such as sampling, inspection, testing and certification, which are burdensome and have a disproportionate impact on imports. For example, Korea has not effectively adopted the "generally recognized as safe" standard. As a result, certain Korean standards are more restrictive than internationally recognized standards; consequently, imports of "generally recognized as safe" food are frequently detained. The Korean Food and Drug Administration (KFDA) defines product categories eligible to use specific food additives narrowly; if a particular product does not fit in the defined product category, it is then classified within the "other products" category, making it

FOREIGN TRADE BARRIERS

considerably more difficult to obtain approval for microbial standards and food additives. Additionally, KFDA's determination that a product is new if formula ratios are changed, or if substitute ingredients are used, sets its procedures apart from other OECD countries.

Progress has been made in several areas, however. Korea announced its revisions to the sanitary standards for importing cod heads on August 3, 2005. Korea subsequently requested that the United States negotiate a memorandum of understanding incorporating these revisions and the U.S. Government is reviewing this request. The Korean government in July 2005 also revised its construction standards to allow houses of wood frame construction to be built to five stories rather than the previous height limit of three stories; this should expand the market for U.S. timber exports.

For non-agricultural products, Korean government agencies require prior approval to import pharmaceuticals, chemicals, computers, medical equipment, telecommunications equipment, and other products (including all food additives). While many other countries require prior approval for some products, Korea's requirements cover a much broader range of products.

Beef

Korea banned imports of U.S. beef in December 2003, after Bovine Spongiform Encephalopathy (BSE) was detected in an imported cow in the state of Washington. Before the ban, Korea was the third largest export market for U.S. beef and beef products and other ruminants, with annual exports valued at \$1.3 billion in 2003. In June 2005, Korea's Ministry of Agriculture and Forestry (MAF) indicated that it had obtained all the information it needed to issue findings concerning the safety of U.S. beef. After a second animal tested positive for BSE in Texas in June 2005, MAF requested epidemiological data on that animal before submitting its findings to the Korean Animal Health Committee (AHC). The report of the epidemiological investigation of the June 2005 case was delivered to Korea on August 31, 2005. In December 2005, the AHC recommended to the MAF Minister that trade in U.S. beef could be resumed. The Minister accepted the AHC finding and announced on December 19, 2005, that the two governments could commence talks to discuss the specific conditions for resuming imports. On January 13, 2006, the United States and Korea reached an initial agreement allowing resumption of U.S. boneless beef imports from cattle aged 30 months or less under a Beef Export Verification Program, with an anticipated reopening in April.

The U.S. Government will continue to urge Korea in the strongest terms to open its market without delay to all U.S. beef products, including bone-in beef, variety meats, and offal in accordance with international guidelines. Together these products historically accounted for approximately 50 percent by quantity of U.S. beef and beef product exports to Korea.

Throughout the ban on beef products, Korea continued to permit the imports of certain products containing ruminant ingredients, such as pharmaceuticals and cosmetics. However, U.S. exporters of those products have noted that since the ban on Korean beef was imposed, Korea's requirements for BSE-free certification have become increasingly burdensome and have begun to impede the flow of U.S. exports of these other products to Korea.

Poultry

In February 2004, Korea banned U.S. poultry meat imports (worth \$53 million in 2003) in response to detection of low pathogenic avian influenza (LPAI) in Delaware and a subsequent case of highly pathogenic avian influenza (HPAI) in Texas. The ban was substantially more disruptive to trade than necessary since Korea applied the ban on a country-wide basis rather than limiting the ban to the outbreak areas, as called for in international guidelines established by the World Organization for Animal Health (OIE). After intensive bilateral consultations, on May 2, 2005, Korea lifted the ban on U.S. poultry meat imports. The U.S. Government has requested that the Korean government accept the “regionalization” concept to ensure that U.S. poultry is not banned again should there be another outbreak of HPAI, even in remote places such as Alaska. The Korean government is awaiting the results of a study on regionalization before reengaging with the United States on this matter.

Biotechnology

Korea’s voluntary safety assessment program for biotechnology crops for human consumption was changed to a mandatory program for soybeans, corn, and potatoes on February 27, 2004 and for all other biotechnology crops on February 26, 2005. To date, 39 biotechnology crops and 11 biotechnology additives have undergone KFDA safety assessments and have received KFDA approval.

Korea has stated its intention to ratify and implement the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (the CPB) in 2006. Environmental risk assessments for biotechnology crops will become mandatory when the CPB is implemented in Korea. So far, 27 applications have been submitted for voluntary environmental assessments (13 for corn, one for soybean, six for cotton, one for alfalfa, and six for canola) and 18 of those have been completed to date. The U.S. Government continues to urge Korea to notify the appropriate WTO Committee of new requirements resulting from the implementation of the CPB in a timely manner and to implement minimally restrictive requirements, which would avoid major disruptions of trade. (*See also “Biotechnology” in “Labeling Requirements”*)

Maximum Residue Level (MRL) Testing

In 2003, a new import inspection program mandated annual maximum residue limit (MRL) testing of agricultural products on a packinghouse basis with an inspection fee of approximately \$1,960 paid for by the importer. Domestic agricultural products, however, are subject only to random tests, which are paid by the Korean government.

In 2004, in response to concerns voiced by the U.S. Government and other Korean trading partners, KFDA reduced the number of chemicals subject to testing from 196 to 47 and the fee for MRL testing from \$1,960 to approximately \$500. In August 2005, KFDA also revised its import inspection program to exempt imported food products recognized by the KFDA Commissioner as safe from mandatory laboratory inspection. These changes to Korea’s import

inspection regime have led to savings in testing fees for U.S. exporters. These changes also reduce delays and rejections of shipments.

Functional Foods

On June 28, 2003, KFDA announced its "Proposed Standards and Specifications for Health Functional Foods," with the objective of regulating health foods and nutritional supplements. Essentially, only products classified as functional foods (i.e., foods that may provide health benefits beyond basic nutrition) can carry "efficacy claims" on their labels. The KFDA amended the final version of its regulations, which were implemented on January 31, 2004, to address certain U.S. concerns regarding vitamins and minerals. However, KFDA has not addressed U.S. concerns regarding the lack of provision for sport nutrition or herbal products in the functional food categories, although these categories are widely accepted in other countries. For instance, according to industry, sports nutrition products, such as glutamine and creatine powder, and herbal ingredients, such as milk thistle, bilberry and garlic, are not permitted by KFDA for use in making functional foods although these ingredients are widely used in sports nutrition or herbal products in the United States. Further, according to KFDA requirements, only tablets, capsules, granules, liquids and powders may be marketed as functional foods although sports nutrition products also come in other forms such as nutrition bars.

Organic Foods

In 2004, KFDA changed its enforcement of regulations regarding imported organic foods. After reviewing the National Organic Program (NOP) of the United States, KFDA decided to accept copies of NOP certificates issued by USDA-accredited certification agents located in the United States for import clearance of processed organic food. However, KFDA only accepts certificates issued to producers, manufacturers, or processors even though certificates issued to brokers or other handlers also meet the NOP requirements. Further, an original ingredient statement issued by the manufacturer must be presented for import clearance.

Also, insufficient communication between KFDA headquarters and regional KFDA offices about the changes in required import clearance documents, and the arbitrary interpretation of regulations by KFDA field inspectors, continue to cause delayed clearance for imported organic products. The U.S. Government has expressed its concern with these practices and delays and urged the KFDA to take steps to eliminate them.

KFDA announced a revision of "Labeling Standards for Food," on March 7, 2005 which maintains a policy of zero tolerance for the presence of biotechnology products in processed food that is labeled as organic. According to the Korean government, this revision was a correction to a long-standing policy. In many countries, including the United States, Japan, and the European Union, organic standards are process-based (i.e. agriculture products must be produced and handled in certain ways in order to be certified as organic). As a result, the United States, Japan, the European Union and others have established regulations that allow for trace levels of biotechnology products in certified organic products. The United States will continue to urge

KFDA to recognize this system-based approach and to reconsider its zero tolerance policy for presence of biotechnology products in foods that are labeled as organic.

Pharmaceuticals and Medical Devices

The KFDA's Drug Master File (DMF) requirements call for manufacturers to submit significant quantities of proprietary manufacturing data to the KFDA as part of the drug approval process. By September 2005, Korea had implemented DMF requirements for 77 active pharmaceutical ingredients (APIs). Although the DMF does not discriminate between imported and locally-manufactured drugs or between innovative research-based drugs and generics, some concerns remain with respect to the scope of the data requirement, the lack of adequate protection of intellectual property, and the great difficulty in providing data for older products. In addition, site inspections appear to be automatically required as part of the DMF, which is particularly problematic to innovative companies with multiple APIs. U.S. industry has suggested that KFDA consider taking a risk-based approach to inspections, relying on the manufacturer's history of complying with Good Manufacturing Practices (GMP).

The frequent need for companies to duplicate clinical trials in Korea that have already been completed elsewhere is of particular concern because such trials are costly and delay market access for U.S. products. Duplicate trials were expected to decrease following Korea's 1999 announcement that it would implement the International Conference on Harmonization (ICH) guidelines, but the KFDA typically does not consider Koreans to be members of the general Asian population for drug testing purposes and presumes that the effect of drugs on Koreans is unique unless proven otherwise. The U.S. Government will continue to press Korea to adopt more streamlined clinical trial application processes.

The KFDA requires pharmaceutical importers to perform a full set of quality control tests for each imported batch prior to market release and to retain on file the locally issued Certificate of Analysis (CoA) for each subsequently imported batch. Similarly burdensome regulations exist for medical devices, with specific quantities of finished goods, high fees, and long timelines required for testing these products.

The KFDA also insists that importers must have or use local testing facilities in Korea. This is often impossible or prohibitively expensive. (*See also "Intellectual Property Rights Protection" and "Pharmaceuticals."*)

Telecommunications Standards

The U.S. Government has strongly encouraged the Korean Government to adhere to a policy of technology neutrality and avoid mandating trade-restrictive standards. The Korean government appears to be encouraging the development and selection of homegrown "Korea-only" technology standards, although there were no exclusive mandates of such standards in 2005. (*See also "Telecommunications."*)

Automotive Standards (See "Motor Vehicles.")

Labeling Requirements

U.S. exporters continue to cite Korea's non-transparent and burdensome labeling requirements as barriers to entry for a variety of goods, despite recent changes to these requirements by the Korean government. For instance, the distilled spirits industry has raised concerns with the cost of complying with both existing and constantly changing labeling requirements. The U.S. Government will continue to address these issues with the Korean government.

The U.S. Government continues to question Korea's rationale for restricting package size based on "gross dead space." The United States has argued that the "net space" displaced by such containers, once collapsed and measured (Korea's Ministry of Environment does not allow this), is minimal and well within the objective of the Korean standard.

Biotechnology: Korea has mandatory labeling requirements for biotechnology corn, soybeans, soybean sprouts, and fresh potatoes, and for processed foods containing biotechnology enhanced corn and soybeans. The United States has expressed concern to Korea that these labeling requirements appear far more burdensome than necessary to achieve their stated goal of providing Korean consumers clear information. As a result, MAF officials have agreed to exempt fresh potatoes from biotechnology labeling requirements as biotechnology potatoes are no longer produced in the United States. Korea also accepts a notarized self-declaration as certification that products meet the criteria for exemption from biotechnology labeling.

GOVERNMENT PROCUREMENT

The WTO Agreement on Government Procurement (GPA) entered into force for Korea on January 1, 1997. As a signatory to the GPA, Korea agreed to include coverage for the procurement of goods and services over specific thresholds by a number of Korean central government agencies, several provincial and city governments, and approximately two dozen government-invested companies. An area of concern remains Korea's high thresholds for the procurement of construction services by its sub-central government entities and government enterprises.

EXPORT SUBSIDIES

Korea has phased out known export subsidy programs that are not permitted under the WTO Agreement on Subsidies and Countervailing Measures or the OECD Export Credit Arrangement. However, Korea continues to promote economic development based on undue reliance on exports, particularly from its traditional export-oriented industries such as automobiles, semiconductors, shipbuilding, and steel. In addition, Korea is encouraging the development of export-oriented "next generation" industries, including semiconductors and telecommunications equipment. The U.S. Government continues to strongly urge Korea to ensure that its government support programs fully comply with its WTO obligations.

FOREIGN TRADE BARRIERS

In February 2002, the Korean government revised the "Act for the Export-Import Bank of Korea" to enable the Export-Import Bank of Korea (KEXIM) to become more active in undertaking risks and extending credit lines to exporters. Under these regulations, KEXIM is able to undertake risks that commercial banks are reluctant to assume. In addition, KEXIM's financing sources were expanded to include non-bank guarantee fees, thereby boosting exports from Korean companies. KEXIM financing was an issue in the trade dispute between Korea and the EU on alleged government subsidies to the Korean shipbuilding industry. On March 7, 2005, a WTO panel stated that certain individual KEXIM programs were prohibited export subsidies. The U.S. Government participated as a third party in the shipbuilding dispute and we will continue to monitor modifications made to the KEXIM Act to ensure that they are consistent with Korea's WTO obligations.

Government Support for Certain Industrial Sectors

The U.S. Government continues to be concerned with support extended to Hynix Semiconductor, Inc. (Hynix), Korea's second largest semiconductor manufacturer, by Korean government-owned financial institutions. A formal countervailing duty (CVD) investigation was conducted and completed by the U.S. Commerce Department and the U.S. International Trade Commission in 2003. As a result of this investigation, Hynix's exports to the United States have subsequently been subject to countervailing duties of 44.29 percent to offset the large subsidies provided to the company. In June 2003, Korea initiated dispute settlement proceedings in the WTO and a panel was established in January 2004 to review the Commerce Department's subsidy findings. On June 27, 2005, the WTO Appellate Body upheld the Commerce Department's final subsidy determination. The EU and Japan also have CVD orders on imports of semiconductors from Hynix.

The U.S. Government also continues to focus on concerns raised by the U.S. paper industry regarding targeted Korean government aid to its coated paper sector, including low-cost facility investment loans and loan guarantees, tax benefits for facility expansion, government-sponsored creation of a paper manufacturing complex and government sale of debt obligations. The U.S. Government will continue to consult closely with U.S. industry to determine the best course of action to address concerns in this sector.

The U.S. Government also has concerns about the role played by the government-owned Korea Development Bank (KDB) in supporting Korean industries across all sectors. Traditionally, the KDB has been one of the government's main sources for policy-directed lending to favored industries. Lending and equity investments by the KDB appear to have contributed to overcapacity of certain Korean industries. The U.S. Government will continue to monitor the lending policies of the KDB and other government-owned or affiliated financial institutions.

INTELLECTUAL PROPERTY RIGHTS (IPR) PROTECTION

Major improvements to Korea's intellectual property rights (IPR) protection regime were made in 2005. Korea was downgraded from the Special 301 "Priority Watch List" to the "Watch List" in April 2005 to acknowledge the meaningful measures the Korean government undertook during the review period. The meaningful improvements made by Korea include: introducing legislation that will create protection for sound recordings transmitted over the Internet (using both peer-to-peer and web casting services); implementing regulations that restore the ability of the Korea Media Rating Board to take necessary steps to stop film piracy; and increasing enforcement activities by Korea's Standing Inspection Team against institutions using illegal software. The Korean government also developed a "Master Plan" in 2005, under the leadership of the Prime Minister's Office, to provide overall policy guidance to the government as it works to improve IPR protection in the country. According to the Korean government, this "Master Plan" will continue to evolve to address new concerns as they arise.

The importance of IPR protection has increased in recent years, as the digitization of Korea's economy has significantly increased the opportunity for unauthorized copying of copyrighted material. With Korean films and music increasing in popularity throughout the Asia-Pacific region, and Korea's industrial products and trademarks enjoying global success, Korean creators of intellectual property would benefit from the improvements the United States has advocated, both to Korea's own intellectual property regime and internationally.

The U.S. Government continues to urge Korea to strengthen its legal regime to protect intellectual property in the following areas: protection of temporary copies, technological protection measures, internet service providers' (ISP) liability, *ex parte* relief, the lack of full retroactive protection for pre-existing copyrighted works and copyright term extension. In addition, concerns remain on book piracy in universities, street vendor sales of illegally copied DVDs, counterfeiting of consumer products, protection of confidential pharmaceutical test data, and lack of coordination between Korean health and IPR authorities to prevent marketing approvals for patent-infringing products.

IPR Enforcement

According to Korean government data on the level of fines and jail sentences imposed on infringers, there is an accelerating rate of investigations, trials and convictions in many areas. For instance, during the first three quarters of 2005, fines were issued in 17,015 cases involving IPR violations. Jail sentences were issued in 780 cases, with 103 cases resulting in imprisonment. The United States continues to urge Korea to further strengthen penalties for IPR violations in order to increase their deterrent effect against piracy.

The Standing Inspection Team (SIT) of the Ministry of Information and Communication has police powers and is authorized to conduct raids on commercial firms and other institutions suspected of using illegal software. Korean police and prosecutors' raids against software end-users have become more consistent and are more frequently based on leads provided by the software industry. The United States remains concerned, however, about the lack of

FOREIGN TRADE BARRIERS

transparency of the Standing Inspection Team's enforcement process, including whether the SIT acts on leads provided by industry and whether rights holders will be able to participate in raids to the maximum extent possible and be notified about all SIT raids, even when discovered infringements are minor.

The establishment of Korea's Copyright Protection Center (CPC) in 2005 for copyright investigations is an encouraging sign and the U.S. Government has urged the Korean government to make effective use of the CPC's investigative capabilities and to make its services available to all rights holders, Korean and international.

Temporary Copies

Currently, Korean law does not extend the reproduction right to cover copies made in the temporary memory of a computer, a significant and still growing manner for use of copyrighted works. The United States continues to urge Korea that both the Copyright Act and Computer Program Protection Act, Korea's two principal copyright laws, should be strengthened by revising the laws to clarify that the copyright owner has the exclusive right to make copies, temporary or permanent, of a work or phonogram.

Transmission Rights for Sound Recordings

Responding to concerns expressed by Korean and foreign music copyright holders, an amendment to the Copyright Act was proposed in 2005 that would give copyright holders, performers, and phonogram producers significantly enhanced rights to control the transmission of their phonograms. As of the publication of this report, that legislation remained pending at the National Assembly.

Copyright Act

In 2005, the Korean government proposed several measures to amend the Copyright Act to include provisions to protect rights to public performances of copyrighted works and eliminate the complaint requirement in certain cases. These measures were considered at the end of 2005, but as of the publication of this report, these copyright amendments had not been passed.

At the time the Copyright Act amendments were submitted to the National Assembly, a Presidential Decree strengthening the amendments was issued and went into effect in March 2006. This decree restricts unauthorized public performances of motion pictures in motels, computer game rooms, and public baths and saunas.

The United States continues to discuss further improvements to the Copyright Act with the Korean government. For instance, the Act does not appear to include technological protection measures (TPMs) that control who can access a work, nor does it prohibit the act of circumventing TPMs, only prohibiting the creation or distribution of circumvention tools. Secondly, while certain provisions of the Copyright Act that define internet service provider liability were harmonized with the Computer Program Protection Act (CPPA) in 2003, further

clarification is required. The Copyright Act amendments still leave unclear the scope of the underlying liability of service providers and the limitations on, and exceptions from, liability. In addition, there are concerns that the documentation requirements for the rights holders in a “takedown” request are too burdensome.

The U.S. Government has told the Korean government that the private copy exceptions in Article 27 and Article 71 of the Copyright Act should be re-examined in light of the growth of digital technologies. These exceptions generally should not be applicable to the Internet environment, which by its very nature extends far beyond private home use. In the digital environment, the market harm threatened by the unauthorized creation of easily transmittable perfect digital copies far exceeds the harm threatened by analog personal copying. Legislation on this issue was introduced in early 2005, but it remains unclear what next steps may be taken by Korea.

With regard to library exceptions under Korea’s Copyright Act, the U.S. Government believes that a notice period of at least 30 days should be given to rights holders prior to the unauthorized digitization of their works to minimize any negative effects. Under the current law, library exceptions still apply only to literary works and not to broadcasts, performances and sound recordings.

The U.S. Government has also urged Korea to delete the reciprocity limitations relating to database protection in the Copyright Act, as it discourages the introduction of databases from countries without such legislation, including the United States.

Korea currently provides copyright protection for the life of the author plus 50 years. In line with international trends, the United States is urging Korea to extend the term of copyright protection for works and sound recordings to the life of the author plus 70 years or 95 years from date of first publication where the author is a legal entity.

Computer Program Protection Act (CPPA)

The amendment of Korea’s Computer Program Protection Act (CPPA) to meet current challenges as well as to comply with new global norms continues incrementally. An amended CPPA has been proposed that would increase the power of the Program Deliberation and Mediation Committee (PDMC) and increase penalties for assorted violations of Korean IPR-related laws. The U.S. Government continues to urge the Ministry of Information and Communications (MIC) to further amend the CPPA to provide for protection of temporary copies, improved protection for technological protection measures, and a term of protection of the life of the author plus 70 years or, where the term is not calculated on the basis of a human life, 95 years from the date of publication. It is also important that the dispute mediation function of the PDMC be performed only where all parties to the dispute have voluntarily agreed to subject themselves to the judgment of the PDMC. Moreover, it is important that mediation by the PDMC not be a prerequisite for any civil, administrative, or criminal adjudication of rights. The U.S. Government believes that the amendments should include minimum penalties for offenses under the CPPA. The United States has also recommended that the Korean government clarify the availability of injunctive and *ex parte* relief in civil enforcement actions under the CPPA, as required under the TRIPS Agreement.

FOREIGN TRADE BARRIERS

Data Protection

KFDA decided on March 31, 2005 that slightly altered versions (such as using a different “salt”) of original drugs undergoing post-marketing surveillance (PMS) in Korea are subject to Korea's data protection regulations. This means that the manufacturers of the altered version have to supply a full portfolio of clinical data in order to obtain market approval if they intend to market their drug while the original drug is still under PMS, in line with Article 39.3 of the WTO TRIPS Agreement.

Book and Video-DVD Piracy

The Publication and Printing Business Promotion Act allows private sector involvement in enforcement measures against book piracy. The U.S. Government has urged Korean authorities to coordinate with foreign book publishers and rights holders in order to provide effective enforcement against book piracy, especially textbooks, and will continue to monitor implementation of this law.

Pirated audio-visual DVDs, sold on the street by informal vendors, continue to be a problem in Korea. This type of piracy is increasing due to the growing sophistication of illegal production facilities and advanced distribution technologies. The U.S. Government has urged the Korean government to meet this digital piracy challenge with stronger enforcement efforts and deterrent penalties.

Patent and Trademark Acts, and Trade Secrets

The Korean Intellectual Property Office (KIPO) has amended relevant laws to address U.S. concerns regarding restrictions on patent term extension for certain pharmaceutical, agrochemical and animal health products (which are subject to lengthy clinical trials and domestic testing requirements, see *"Standards, Testing, Labeling and Certification"*). An issue of continuing concern, however, has been the lack of coordination with the Korean Food and Drug Administration and the KIPO, which results in the granting of marketing approval for products that may infringe on existing patents. U.S. firms have also pointed to the Korean courts' apparent unwillingness to provide injunctive relief in cases where a rights holder's patent has been infringed, allowing the infringing products to remain on the market until a final determination has been made. Although Korean civil courts have the authority to issue injunctive relief, in practice they rarely, if ever, do so in patent-related cases.

Korea's Trademark Act has been amended over the years to strengthen provisions that prohibit the registration of trademarks without the authorization of foreign trademark holders by allowing examiners to reject any registrations made in "bad faith." Despite this change, the complex legal procedures that U.S. companies must follow to seek cancellation discourages U.S. companies from pursuing legal remedies. In particular, problems still arise with respect to "sleeper" trademark registrations filed and registered in Korea without authorization in the late 1980s and early 1990s, when KIPO was still developing a more effective and accurate trademark examination and screening process.

FOREIGN TRADE BARRIERS

The Korean government agreed to cooperate with the U.S. Government's "Strategy Targeting Organized Piracy" (STOP!) initiative in October 2004 in an effort to halt trade in counterfeit goods, and discussions continued on best practices and possible areas for cooperation during 2005.

Korean laws on unfair competition and trade secrets provide a basic level of trade secret protection in Korea, but are insufficient in some instances. For example, some U.S. firms, particularly certain manufacturers of chemicals, pet food, and chocolate, face continuing problems with government regulations requiring submission of very detailed product information, such as formula or blueprints, as part of registration or certification procedures. U.S. firms report that, although the release of business confidential information is forbidden by Korean law, in some instances, government officials do not sufficiently protect this proprietary information and the trade secrets were made available to Korean competitors or to their trade associations.

SERVICES BARRIERS

Korea continues to maintain restrictions on some service sectors. In these sectors, foreign investment is prohibited or severely circumscribed through equity or other restrictions. (*See also "Investment Barriers."*)

Advertising

Korea is among the world's top twelve largest advertising markets; however, the market remains highly restricted. Because broadcast advertising time is still sold exclusively through the state-sponsored Korea Broadcast Advertising Corporation (KOBACO), advertisers and their agencies must work through KOBACO to advertise on broadcast television. Further, U.S. industry has noted its concerns with Korean restrictions on broadcast advertising of beverage alcohol products containing 17 percent or greater alcohol by volume.

Screen Quota

On January 26, 2006, the Korean government announced that it will reduce its screen quota requirement to 73 days of the year. This reduction is scheduled for implementation on July 1, 2006. Korea had required that domestic films be shown on each cinema screen for a minimum of 146 days of the year, corresponding to a 40 percent market share.

The domestic market share for Korean films has, for the last several years, far surpassed 40 percent. In 2005, for instance, Korean films captured 55 percent market share in Seoul.

Foreign Content Quota for Broadcast Television

Korea restricts foreign activities in broadcast television by limiting the percentage of monthly broadcasting time (not to exceed 20 percent) that may be devoted to foreign programs. Annual quotas also limit broadcasts of foreign programming to a maximum of 75 percent for motion pictures, 55 percent for animation, and 40 percent for popular music. Foreign investment is not permitted for broadcast television operations.

Foreign Content Quota for Cable Television

Korea restricts foreign participation in the cable television sector by limiting per channel airtime for most foreign programming to 50 percent. Annual quotas limit foreign broadcast motion pictures to 70 percent and 60 percent for foreign animation. The Korean government also restricts foreign ownership of cable television-related system operators, network operators, and program providers to 49 percent. For satellite broadcasts, foreign participation is limited to 33 percent.

Satellite Re-Transmission

The Integrated Broadcast Law mandates that Korean firms that wish to re-broadcast satellite transmissions of foreign programmers must have a contract with the foreign program provider in order to obtain approval from the Korean Broadcasting Commission (KBC). Foreign re-transmission channels are limited to 20 percent of the total number of operating channels. This artificial restriction limits the amount of international broadcasting which could otherwise be made available to Korean consumers and limits foreign investment in the broadcasting sector.

Restrictions on Voice-overs and Local Advertisements

Presently, the Korean Broadcasting Commission's guidelines for implementation of the Broadcasting Act contain restrictions on voice-overs (dubbing) and local advertising for foreign re-transmission channels. Allowing Korean language voice-overs would make broadcasts more accessible to Korean consumers (especially for breaking news and children's cartoons); it would also benefit the Korean economy by creating more studio-production jobs and attracting foreign investment. The prohibition on local advertising for foreign re-transmission channels restricts the long-term viability of these channels in the Korean market

Legal Services

The Korean government announced in March 2005 that it intends to open the legal services market in stages. The first step would be to regularize the legal status of foreign legal consultants, and the Ministry of Justice is reportedly currently drafting the requisite legislation.

The U.S. Government has also been informed that the law being drafted would allow foreign law firms to open offices in Korea, although they would not be allowed to hire Korean attorneys or advise on domestic law. While the Korean government hoped to introduce this legislation in 2005, as of this writing it had not been submitted to the National Assembly.

The U.S. Government continues to urge the Korean government to allow foreign law firms to practice law in Korea.

Insurance

Korea is the second largest insurance market in Asia, with \$58.7 billion in premiums paid in the fiscal year ending March 31, 2005. Although Korea's laws and regulations do not restrict foreign entry into insurance markets, no life insurance licenses have been issued since 2001. Further, while there are no restrictions on partnering with Korean financial companies or on hiring Korean insurance professionals, a considerable gap remains between Korea's practices and those found in more developed insurance markets.

Korean and foreign companies (including U.S. firms) active in Korea's insurance and savings markets have complained that the Financial Service Office of the government-run Korea Post (KP) maintains an unfair advantage in these sectors. KP does not have to pay any corporate or local taxes and its assets are backed by a government guarantee. Korea Post is now the fourth largest insurer in Korea. It is also the eight largest banking entities, although it does not have to pay deposit insurance premiums and directly participates in the insurance and banking sectors. Commercial banks, although they are allowed to offer "bancassurance" products through insurance vendors, cannot directly combine banking and insurance activities.

Insurance companies and banks are regulated by experienced officials of the Korean Financial Supervisory Service (FSS). The Ministry of Information and Communication, which does not have the same regulatory expertise, oversees Korea Post. Unlike private sector insurance companies, which must follow more stringent regulations prior to introducing new products or in training new staff, KP enjoys a streamlined, less regulated ability to introduce new products and is not subject to the same training and exam restrictions for its insurance sales staff.

The United States raised these issues with the Korean government in 2005, urging it to consider ways to eliminate any unfair advantages Korea Post maintains over domestic and foreign firms in the insurance and financial sectors. In response, the Korean government appears to be considering ways to improve the Ministry of Information and Communication's regulation of Korea Post's financial activities. The United States government will continue to raise these issues with Korea.

Banking

Although almost all banks have been privatized, the Korean government-controlled Korea Deposit Insurance Corporation still owns nearly 79 percent of Woori Financial Holdings which fully controls Woori Bank, the country's second largest bank. The Korea Deposit Insurance Corporation also directly owns 67.7 percent of Industrial Bank of Korea, the fourth-largest bank in Korea.

Foreign banks are permitted to establish as subsidiaries or branches. Capital markets are open to foreigners, permitting foreign financial institutions to engage in non-hostile mergers and acquisitions of domestic financial institutions.

Korea allows foreign bank branches to borrow from their head offices and to include the net borrowing as "Class B capital." However, the Korean government does not allow foreign branches to use capital from head offices to meet regulatory lending limit requirements and continues to restrict the operations of foreign bank branches based on branch capital requirements. These restrictions limit: (1) loans to individual customers; (2) foreign exchange trading; and (3) foreign bank capital adequacy and liquidity requirements. Foreign banks are subject to the same lending ratios as Korean banks, which require them to allocate a certain share of their loan portfolios to Korean companies that are not one of the top four *chaebol* conglomerates and to small and medium-sized enterprises.

All banks in Korea continue to suffer from a lack of transparency in the regulatory system and must seek approval before introducing new products and services - an activity at which foreign banks are particularly adept. Korea has largely deregulated foreign exchange and capital account transactions for individuals, but a few restrictions (applied to both domestic and foreign institutions) on foreign exchange transactions and derivatives trading by corporations and financial institutions still remain. In January 2005, members of Korea's National Assembly introduced draft legislation that would have imposed nationality and residency requirements for members of the boards of directors of Korea's banks. This was seen as a reaction to the public perception that there was too much foreign investment in the financial sector. The bill did not pass, in part due to opposition from the Korean government. The United States has noted that the adoption of these or similar measures would send a negative signal to foreign investors in Korea's financial sector.

Securities

There are no limits on local currency issues of stocks and bonds by foreign firms. The Korean government places no limits on foreign ownership of listed bonds or commercial paper, does not restrict foreign ownership of securities traded in local markets, and has removed almost entirely foreign investment ceilings on Korean stocks. By the end of 2004, foreigners owned more than 40.1 percent (41.9 percent of KOSPI shares and 15.4 percent of KOSDAQ shares) of the shares on Korean stock exchanges, according to Korean government statistics. Despite this liberalization, foreign securities firms in Korea continue to face some non-prudential barriers to their operations.

INVESTMENT BARRIERS

The Roh Administration has continued Korean government support for the establishment of a more favorable investment climate in order to facilitate foreign investment in Korea. U.S. companies that made major announcements in 2005 regarding plans for investment in Korea included Intel, CSX World Terminal, Kimberly-Clark, and 3M.

The positive attitude toward foreign investment on the part of the Korean government, many in private industry, and by a growing number of Koreans, is helping to open the Korean economy. However, while progress has been made in recent years, additional reforms would make Korea more attractive to foreign investors, such as resolving certain labor market issues (e.g. better pension mobility, more flexibility in hiring and firing workers, expanded unemployment compensation, less rigid worker visa rules, and better job training and placement services), reducing labor-management disputes, and improving regulatory transparency.

Capital market reforms have eliminated or raised ceilings on aggregate foreign equity ownership, individual foreign ownership, and foreign investment in the government, corporate, and special bond markets. These reforms have also liberalized foreign purchases of short-term financial instruments issued by corporate and financial institutions. However, the Korean government still maintains foreign equity restrictions with respect to investments in various state-owned firms and many types of media, including basic telecommunications service providers, cable and satellite television services and channel operators, as well as schools and beef wholesalers.

Although the Korean government has taken several important steps to privatize state-owned corporations, there were no new privatizations in 2005. In addition, the government on November 30, 2005 announced that it would seek to more tightly control state-run companies and no longer had immediate plans to privatize Korea Gas Corporation or Incheon International Airport Service. As noted in the “Banking” section of this report, the Korean government has also postponed any announcement of a definitive schedule for the privatization of its nearly 79 percent share in Woori Financial Holdings, which owns the country’s second largest bank.

There are no restrictions on the direct purchase of land by foreigners. However, foreigners cannot produce certain agricultural products for commercial purposes nor remove agriculturally zoned land from agricultural production.

The Korean government also has opened Free Economic Zones (FEZs) with an extensive range of incentives including tax breaks, tariff-free importation, relaxed labor rules, and improved living conditions for expatriates in areas such as housing, education, and medical services. While establishing these zones is an important step in making Korea's business environment more open, liberal, and responsive to economic needs, the FEZ's is not likely to not address some of the key factors inhibiting additional foreign investment in Korea.

FOREIGN TRADE BARRIERS

ANTICOMPETITIVE PRACTICES

Competition Policy

The Korea Fair Trade Commission (KFTC) has been playing an increasingly active role both in enforcement of Korea's competition law and in advocating for regulatory reform and corporate restructuring. In addition to KFTC's powers to conduct investigations and to impose penalties, including broad authority over corporate and financial restructuring, KFTC can levy heavy administrative fines for violations or for failure to cooperate with investigations. In response to concerns raised by U.S. companies, the U.S. Government is monitoring KFTC activities closely and has encouraged it to develop a balanced approach to address its antitrust policy concerns without imposing unnecessary restrictions on commercial activity.

ELECTRONIC COMMERCE

Korea is considered to be a global leader in technology. Korea has more high-speed Internet connections per household than any other country in the world, and the government has actively pursued legislation to encourage electronic commerce.

The Korean government has been working to address data privacy issues by drafting a Personal Information Protection Act, formerly the Basic Privacy Act, and revising or adding sector-specific laws. Industry-specific issues will be addressed separately by regulations to be put in place over a period of six months to two years following the passage of the Act. However, as of the publication of this report, a draft of the Act remains pending in the National Assembly. The U.S. Government looks forward to working with Korea to ensure that resulting regulations do not inhibit the cross-border flow of information, which would negatively impact Korean and American companies and would limit consumer choice. Numerous privacy issues have been discussed on the margins of the APEC Privacy Framework, an initiative to which Korea has contributed. Non-governmental organizations in Korea are asking for stricter requirements in a number of areas which may impact cross-border data flows, thus hindering e-commerce. Korea is also considering establishment of a central office responsible for data privacy, similar to data protection authorities that exist in other countries.

OTHER BARRIERS

Regulatory Reform and Transparency

A lack of transparency in Korea's rule making and regulatory system is a cross-cutting issue affecting U.S. firms in many different sectors, including the automotive, pharmaceutical, agricultural, financial services and telecommunications sectors, and continues to be one of the principal problems cited by U.S. traders and investors seeking to compete in the Korean market. In an effort to address these systemic issues, beginning in 2004, the United States and Korea deepened their focus on regulatory reform and transparency issues.

FOREIGN TRADE BARRIERS

Korean laws, regulations, and rules often lack specificity, and Korean officials exercise a great deal of discretion in applying broadly drafted laws and regulations. This results in the inconsistent application of regulations and uncertainty for businesses on how to fully comply with them.

Korea's Administrative Procedures Act (APA) stipulates that the public comment period for draft regulations that are subject to the APA shall be no less than 20 days. However, in many cases, the 20-day time minimum is too abbreviated, and since ministries rarely provide more time, public comment periods are often unreasonably short. In 2005, the Korean Government promulgated a recommendation that all ministries provide a longer (60 day) time frame for public comment periods for regulations subject to the APA that are "economy-related," but there has been no evidence that this extended time frame is being followed. In many instances the final versions of regulations do not reflect the comments provided.

Regulations are applied inconsistently or can be reinterpreted and applied retroactively, resulting in penalties for those companies that followed prior Korean government guidance.

During bilateral trade consultations in 2005, the United States continued to emphasize the need for increased transparency in Korea's regulatory system. These bilateral efforts on regulatory transparency coincide with a Korean government focus on regulatory reform. In Korea, the Roh administration has charged the Deregulation Taskforce Team, the Corporate Difficulties Resolution Center, and the standing Regulatory Reform Committee to focus on different aspects of regulatory reform, both systemic and sector-specific. During trade consultations in 2005, Korea agreed that it would work closely with the United States and with the U.S. business community to include recommendations to these three bodies on which Korean regulations might usefully be eliminated or amended.

Motor Vehicles

During quarterly trade consultations with Korea over the past year, progress was made on a number of automotive standards issues of concern to the United States. On license plate size and shape, the Korean government agreed to allow small sellers to be exempted from a requirement to use European standards. On fuel economy, Korea agreed to extend until the end of 2009 a grace period for foreign vehicles to meet average fuel economy targets and to review the application of this system to foreign cars in the second half of 2009. Korea also revised an automobile emissions regulation to provide a grace period for compliance until the end of 2008 for small volume sellers of vehicles, including U.S. automakers, in the Korean market.

The United States and Korea have also worked together in the bilateral "Automotive Standards Experts Working Group" that was created in 2001. The meetings of this group have been productive, and the United States believes this forum offers the potential to build a stronger cooperative relationship on standards and certification issues. For instance, during 2005, the Working Group made progress in resolving concerns on radio frequencies associated with remote keyless entry systems and tire pressure monitoring systems.

The United States and Korea concluded a Memorandum of Understanding (MOU) in October 1998, designed to improve market access for foreign motor vehicles. Although the Korean government has implemented many of its commitments under the 1998 MOU, the United States continues to urge the Korean government to take additional meaningful actions to open the automotive sector, including eliminating or at least reducing Korea's eight percent tariff on imported automobiles, which is more than three times the U.S. tariff. The effect of the tariff is compounded by the cascading effect of multiple automotive taxes applied in addition to the tariff, which raises the effective rate to above 12 percent. A Korean study showed that if Korea's automotive tariff were reduced to 2.5 percent, foreign automotive market share could increase to 12 percent within five years – a level much closer to that of Korea's main automotive trading partners.

The United States has also expressed concern that Korea's current system of auto taxes discriminates against the larger vehicles that exporters tend to sell in the Korean market. Noting the MOU commitment to restructure and simplify the automotive tax regime in a manner that enhances market access for imported vehicles, the U.S. Government has urged the Korean government to lower the overall tax burden, reduce the number of taxes assessed on vehicles, and move away from engine-displacement taxes towards a value-based system. The U.S. Government has stressed that these commitments should be met through the development of a transparent and comprehensive plan, which would allow manufacturers and consumers adequate time to make adjustments. While the Korean government has taken some specific actions on automotive taxes over the last several years, to date, it has not produced a transparent plan to meet the long-term MOU goals. The U.S. Government will continue to press for Korea to lower automotive tariffs and to undertake reforms of its overall automotive tax system in an open and transparent manner that fully involves all stakeholders throughout the process and enhances market access for U.S.-made vehicles.

The U.S. Government appreciates the efforts made by the Korean government and Korean automotive industry in relation to public anti-import sentiments that might serve as barriers to the purchase of an imported automobile. Korea's first joint foreign-domestic automotive show was held in 2005, and featured attendance by Korean President Roh Moo-hyun.

Motorcycles

Although progress was made over the past several years to resolve U.S. concerns over Korea's noise standard on motorcycles, several market access issues remain including a highway ban, tariff and tax levels, absence of ownership titles, and standards and certification procedures. Korea's ban on driving motorcycles on expressways and on designated bridges severely restricts the market penetration potential for heavyweight motorcycles even though they are designed for safe highway use. Korea is the only major world market in which heavy motorcycles are denied access to major highways and designated overpasses in cities.

Pharmaceuticals

The U.S. and Korean governments worked extensively during 2005 through the quarterly consultative process to address a number of market access issues in the pharmaceutical sector, including encouraging transparency in pricing and reimbursement policies, and appropriately valuing innovation. In addition to governmental consultations, the government-industry pharmaceutical working group met once in 2005.

Transparency: A key focus of United States-Korea pharmaceuticals consultations during 2005 was the lack of transparency in Korea's procedures for pricing and reimbursing innovative drugs under its national health insurance system. During bilateral discussions on these issues, the United States made two proposals for improving transparency including: (1) establishment of a truly independent appeals mechanism to review contested reimbursement status and pricing decisions, working with the multinational pharmaceutical industry to design and implement such a mechanism; and (2) review of past decisions on awarding more favorable "A-7" pricing to new drugs with the goal of establishing consistent, objective criteria (*See discussion in this section on "Pricing" for a description of this methodology*).

The United States also raised concerns regarding proposals by the Health Insurance Review Agency (HIRA) that, if implemented, would change the calculation methodology of Korea's "triennial re-pricing exercise." MHW responded that it would take a "cautious" approach toward this matter.

Early in 2005, MHW began to provide written justifications for pricing decisions that differed from the applicant company's requested price, a key transparency improvement that the United States had long advocated. MHW has agreed to consider ways to improve the quality of these written justifications.

The United States has put forward suggestions on how Korea's HIRA reimbursement guideline-setting process could be more transparent; these suggestions are still under discussion. In addition, the United States is carefully watching developments related to a Korean government-commissioned health insurance reform study released in September 2004 to ensure that policy changes are made in consultation with all domestic and foreign stakeholders, including foreign industry and governments.

Pricing: In 1999, Korea announced how new "innovative" drugs were to be priced (based on the average ex-factory price of seven major developed markets: United States, United Kingdom, Germany, France, Italy, Switzerland, and Japan – called "A-7") and reimbursed (based on Actual Transaction Price [ATP]). Since its implementation, anomalies have surfaced. An industry survey revealed that A-7 prices were granted to only 24 percent of new products between April 2000 and June 2005, with most approvals occurring in the early months of A-7 implementation. Because of Korea's restrictive application of the A-7 pricing methodology, U.S. drug companies have decided not to introduce at least nine new products in Korea since 2000.

In addition, the ATP system, intended to deter corruption and market distortion, has been poorly enforced. ATP reimbursement prices are based on a weighted average of sales prices from the previous quarter. ATP was designed to end hospitals' fraudulent practice of demanding discounts from drug makers and then keeping for themselves the difference between the discounted price and the price reimbursed by the government-operated health insurance system. U.S. industry sources reported that such practices remained common in 2005. In 2005, the United States continued to press Korea to offer A-7 pricing to all new innovative medicines produced by U.S. companies and to better enforce the ATP system.

Reimbursement Guidelines: As part of its efforts to trim health-care costs, HIRA has applied restrictive reimbursement guidelines to the more expensive, newer drugs of foreign pharmaceutical companies without a rigorous, transparent scientific review or justification. The guidelines for a new product are initially set by the Korea Food and Drug Administration, but can later be modified by HIRA. The process by which HIRA establishes these modified guidelines lacks transparency. Although an appeals process exists, it is not codified in law and appeals are not considered by an independent panel, but by the same office that made the initial ruling. The U.S. Government has raised concerns regarding the guidelines with MHW and HIRA, and the United States continues to urge the Korean government to develop a transparent process for setting reimbursement guidelines.

Corruption in the Healthcare System

Corruption continues to be a widespread problem in the Korean healthcare system. As noted above, the complex distribution system and lack of transparency in the government decision-making process are large contributors to this problem. The U.S. Government will continue to work with the Korean government to bring about a more transparent, fair, science-based health care system that provides predictability for U.S. companies in pharmaceutical pricing, reimbursement guideline setting, and regulatory affairs.

Medical Devices

Since 2000, HIRA has taken actions that have resulted in the lowering of reimbursement prices for medical devices already on the market. Additional reductions were implemented in early 2004. These price reductions are based upon what appear to be subjective judgments of whether a product is an update to, or improvement upon, an existing medical device. This policy has resulted in several U.S. companies questioning whether to continue introducing innovative devices into the Korean market.

The Medical Device Act (MDA) went into effect in May 2004 and established a new legal framework for the regulation of medical devices, separate from the Pharmaceutical Affairs Act. The new legislation established a new four-class system which is consistent with global trends and should allow U.S. device firms to use global data for registration approvals with less need for data specific to Korea.

Nevertheless, instances of unnecessary and costly duplicative testing of medical devices continue to occur. In 2006, the U.S. Government will work with KFDA to assess how its safety concerns can be addressed while facilitating greater access to the Korean market for U.S. medical device manufacturers.

The KFDA requires re-registration of all products transferred to a manufacturing site outside its original country of origin. This re-registration is equivalent to a new registration, including the clinical trial requirements mentioned above. The U.S. Government would like to expand existing licenses to cover dual sites and permit notification of the change to KFDA without the need for re-registration.

The KFDA requires medical devices to include Directions For Use (DFUs) in the local language. The industry accepts this burden, as this practice better insures patient safety. It is currently accepted practice in many other regions to provide an electronic version of a DFU. The product package references a Website or CD-ROM containing the proper DFU. The U.S. Government has urged that KFDA formally create, publish, and implement guidelines that define how manufacturers can provide DFUs and required labeling in an electronic format.

Telecommunications

As one of the world's most advanced telecommunications markets, Korea is actively commercializing a variety of cutting-edge wireless technologies, as well as introducing terrestrial and satellite-based mobile digital TV broadcasting. Given the tremendous commercial opportunities provided by this market, the United States will continue to work with Korea to ensure that it sets standards and licensing requirements consistent with its bilateral and multilateral trade obligations, and that any such measures do not subject foreign firms to discriminatory treatment.

The Korean government has the ability to influence the development of the telecommunications sector both directly, through licensing conditions and mandated technology standards, and indirectly, through industry associations and quasi-governmental commissions. While no acute problems arose in this context in 2005, the U.S. Government will continue to encourage the Korean Government to adhere to a policy of technology neutrality and avoid mandating trade-restrictive standards.

The United States strongly advocated during quarterly trade discussions in 2005 for further liberalization of the Korean telecommunications services market, and called on Korea to remove limits on foreign shareholdings of Korean facility-based (Type I) telecommunications operators. The United States will continue in both bilateral and multilateral contexts to encourage Korea to eliminate such caps on foreign ownership in the telecom sector.