KORUS FTA IMPLEMENTATION SCORECARD

On-the-Ground Perspective of American Businesses in Korea

March 2019
U.S.-Korea Trade Relationship at a Glance

- Reduction in trade deficit in 2018: $5 Billion
- 6th largest trading partner to the U.S.
- Increase in automobile exports (2011-2018): 325%
- 86% of Koreans have favorable view of the U.S. (highest in the world)
- 2nd largest importer of U.S. oil and gas
- Increase in U.S. travel services (2011-2018): 84%
- New Korean FDI in the U.S. in 2017: $9.3 Billion

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|                                  | • Improve premium pricing of innovative medical devices by eliminating unjustified and Korea-unique requirements. |
|                                  | • Utilize Independent Review Body to increase transparency and accountability of medical device pricing. |
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|                                  | • High Concern                                                                       |
|                                  | • End server and data localization requirements that are unjustified, Korea-unique, and contrary to KORUS commitments. |
|                                  | • Harmonize data protection and certification requirements for cloud computing with global standards. |
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**INTRODUCTION**

The American Chamber of Commerce in Korea (AMCHAM) is pleased to present this report on the implementation of the Free Trade Agreement between the United States of America and the Republic of Korea (KORUS FTA).

As the oldest and largest foreign chamber of commerce operating in the Republic of Korea today, AMCHAM is the premier business organization promoting the bilateral U.S.-Korea economic relationship. As a strong advocate of the KORUS FTA since the origin of the agreement more than a decade ago, AMCHAM firmly supports the goal of fair and balanced trade with our trading partners, including South Korea. We have been a close partner and resource to the U.S. Government in this mission, working as a bridge between the two governments and business communities to secure a level playing field for U.S. companies in Korea.

This report will share the perspectives, concerns, and recommendations of the U.S. business community with regard to the implementation of the recently amended KORUS FTA and the broader business environment for American companies in Korea. By supporting the full and faithful implementation of the amended KORUS FTA, we hope that this report will contribute to strengthening the bilateral U.S.-Korea economic partnership to the benefit of businesses and consumers of both countries.

**Economic Impacts of the KORUS FTA**

Since the KORUS FTA entered into force on March 15, 2012, the scale and importance of U.S.-Korean trade has grown significantly. The U.S. rose from South Korea’s fifth-largest to second-largest trading partner since 2011, as two-way trade grew by 30%. 

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**AMCHAM at a Glance**

- 66 years in history
- 700+ corporate members and affiliates
- 1,200+ individual members
- 31 industry committees
- Board of Governors

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**Mission of AMCHAM Korea**

Promote the expansion of trade and investment partnerships between the U.S. and Korea by:

1. Supporting U.S. companies in Korea
2. Helping U.S. SMEs to enter the Korean market
3. Facilitating Korean companies’ investment in the U.S.
This growth in bilateral trade has taken place even as Korea’s trade with Japan, China and the EU declined by 33.4%, 4.2%, and 8.8% respectively. Between 2011 and 2018, Korean imports of U.S. goods grew 16.8%, while Korea’s imports from the world as a whole declined by 8.8%. As a result, the U.S. market share in Korea has increased markedly from 8.5% in 2011 to 11.0% in 2018.

Behind this growth in U.S. market share are significant market opening and tariff reductions under the KORUS FTA. Sectors such as legal services and telecommunications that were previously closed to foreign investment are now open to U.S. businesses. Six rounds of tariff cuts have reduced the average weighted tariff rate on U.S. exports to Korea to 1.6%, compared to Korea’s WTO average weighted tariff rate of 5.6%. Tariff cuts under the FTA give U.S. goods a vital competitive edge in Korea that leads to more U.S. exports and supports more good-quality jobs for American workers.

AMCHAM was an early and active supporter of ratifying the KORUS FTA, predicting that the agreement would grow U.S. exports to Korea and facilitate job-creating investment into the U.S. This prediction has been borne out. The expansion of the U.S.-Korea economic relationship under the KORUS FTA has had significant benefits for economic growth and job creation in the U.S. Korean investment in the U.S. and U.S. exports to Korea are estimated to support more than 500,000 jobs in the United States.

Criticisms and Shortcomings of the Agreement

While the KORUS FTA has brought significant benefits to American businesses and the American economy, it has also drawn criticism, especially over the persistent large trade deficits in goods between the U.S. and Korea.
Although the U.S. continues to show a large trade deficit in goods with Korea, this deficit has declined sharply since 2016. The trade in goods deficit fell from $27.7 billion in 2016, to $22.9 billion in 2017, to $17.9 billion in 2018. This steep decline in the trade deficit with Korea occurred even as in 2018 the overall U.S. trade deficit ($621 billion) and trade deficits with China ($419.2 billion), the European Union ($169.3 billion), and Mexico ($81.5 billion) were the highest on record. The U.S. also has a large and growing trade surplus in services with Korea, which nearly doubled under the KORUS FTA from $6.9 billion in 2011 to $12.2 billion in 2018.

In addition to concerns over the trade deficit, many U.S. companies exporting to or operating in Korea have felt that the agreement has fallen short of its potential due to deficiencies in implementation. U.S. companies have continued to face unfair market barriers in industries ranging from chemicals, to healthcare, to digital trade and financial services that are inconsistent with the spirit, if not the letter, of the KORUS FTA. Such non-tariff barriers have denied to many U.S. industries the market access and level playing field promised by the agreement.

Recent Amendment and Modification of the KORUS FTA

In September 2018, U.S. President Donald Trump and Korean President Moon Jae-in signed the agreed outcomes of the negotiations to amend and modify the KORUS FTA. The ratification of these outcomes by the Korean National Assembly in December 2018 marked the completion of the necessary domestic procedures for the implementation of the changes, and the amended and modified agreement entered into force in both countries at the beginning of 2019.
Reflecting the U.S. Administration’s focus on narrowing the trade deficit in goods and promoting the U.S. automotive industry, the agreement contains a number of outcomes that are likely to boost U.S. automotive exports to Korea. The agreement also addresses several of the U.S. industries’ concerns regarding the pharmaceutical and medical device industries. Finally, the new outcomes include a commitment by Korea to address concerns regarding customs procedures and verification of origin.

AMCHAM welcomes the revision of the KORUS FTA as a substantial win for both parties. It preserves the existing benefits of the agreement for U.S. businesses, while expanding market access by harmonizing standards and reducing technical barriers to trade. AMCHAM hopes the swift implementation of the revised KORUS FTA will provide certainty needed to further promote U.S. exports to Korea and Korean investment into the U.S.

Business Environment in Korea as of 2018

American businesses operating in Korea are major stakeholders in both economies. We support, through full and faithful implementation of the KORUS FTA, a transparent, predictable, and fair business environment in Korea that benefits companies and citizens of both the United States and Korea. AMCHAM and its member companies stand ready to assist the efforts of both governments to create a stronger, more vibrant, innovative and globally competitive bilateral economic and commercial partnership.

The Korean Administration is pursuing an economic agenda centered around economic justice, job creation, and income-led growth. As

Key Outcomes of Recent KORUS Negotiations:

- Extension of U.S. Truck Tariffs: U.S. to extend phase out of 25% tariff on trucks from 2021 to 2041.

- Greater Access for U.S. Auto Exports: Korea to double to 50,000 per maker the number of cars that can be imported under U.S. safety standards.

- Harmonization of Testing Requirements: U.S. gasoline vehicles can be imported with Korea’s emissions standards using same tests as in U.S.

- Recognition of U.S. Standards for Auto Parts: Korea to recognize U.S. standards for auto parts to service U.S. vehicles.

- Improvements to CAFE Standards: Korea to consider U.S. standards in setting next fuel economy targets and expand amount of “eco-credits” available.

- Customs Improvement: Korea to address concerns over origin verification through agreement on common principles and new working group.

- Pharmaceutical Pricing: Korea to amend “Premium Pricing Policy for Global Innovative New Drug” to be consistent with KORUS commitment
part of this agenda, the Korean Government is implementing sharp increases in the minimum wage and restrictions on maximum working hours. Additionally, the Korean Government has encouraged companies to convert workers in special types of employment, such as insurance agents, to regular employees.

AMCHAM fully supports the Korean Government’s goal of creating an economy that provides good-quality jobs for all Korean citizens. We encourage the Korean Government to hear and consider the input of both domestic and international industry in implementing economic policies. For example, there are five American insurance companies that collectively have 2,440 employees and 9,450 insurance agents in Korea. Recent movements by the National Assembly and Korean Government to extend social insurance application and three primary labor rights to special types of employment including insurance agents would impose a tremendous amount of additional cost and an excessive burden of labor management on these companies, disrupting the rights and responsibilities between insurers and insurance agents that U.S. insurers were able to expect when entering Korea. When introducing such economic policy changes, AMCHAM encourages the Korean Government to consult with domestic and international industry to ensure that due consideration is given to the unique conditions affecting each sector.

Transparency and predictability of regulation are vital for American companies to foresee with accuracy the environment for their investments in and exports to Korea. We welcome that after entering into the KORUS FTA, the Korean Government has substantially improved the transparency of the regulatory environment, especially with regard to giving prior notice of new rules and regulations affecting businesses. At the same time, we are concerned about rapid and

“This agreement will reduce bureaucracy and increase prosperity in both of our countries. Workers in South Korea and America will find new customers and new opportunities to expand and grow. Our teams will be working hard to ensure that the terms of the deal are fully implemented.”

- President Donald Trump, September 24, 2018

“I’m hopeful this will provide us with a platform upon which our bilateral economic ties will be elevated to a higher level in a freer, fairer, and more mutually beneficial direction.”

- President Moon Jae-In, September 24, 2018
dramatic changes to laws and regulation in response to media or National Assembly pressure. While we understand the need to be responsive to changes in the environment and new problems, we believe greater weight should be given to the predictability and consistency of the regulatory environment in Korea.

A favorable tax regime is another essential factor for American companies operating in Korea to recruit and retain vital personnel. AMCHAM is concerned over recently announced changes to Korean tax law, such as lowering of the reporting threshold for foreign financial assets including retirement assets, with steep penalties for failing to make the report or delayed reporting. We hope that adjustments will be made to these rules to exclude retirement accounts from reporting requirements, and to eliminate or lower the penalties to a more reasonable level.

AMCHAM is committed to working with the U.S. and Korean Governments to address the issues identified in this report through full and faithful implementation of the KORUS FTA. We will continue to advocate for a level playing field for foreign and domestic businesses in Korea so as to promote the vital bilateral trade and investment ties between Korea and the United States.
Agricultural trade is a prime example of how expanded U.S.-Korea economic and commercial ties have benefitted both countries. While South Korea imposes high tariffs averaging 57% on agricultural goods from non-FTA partners, under KORUS almost two-thirds of U.S. agricultural products are exempt from import duties. U.S. agricultural exports to Korea have increased by 28% since the KORUS FTA entered into force in 2012. In 2018, South Korea was the sixth-largest export market by value for U.S. agricultural products.

Meat and meat products are a prime example of how U.S. agricultural exports to Korea have benefitted from easing of trade restrictions. South Korea is today the United States’ second-leading export market for beef by value and third-leading by volume. Under the KORUS FTA, Korea has gradually reduced tariffs on U.S. beef from 40% in 2011 to 18.6% at present and is set to eliminate tariffs on U.S. beef completely by 2026. Such tariff reduction gives U.S. beef an important price advantage over competitors such as Australia. In 2017, the market share of U.S. beef in Korea exceed that of Australia for the first time since 2003. Significantly, Costco Korea officially began converting its imported chilled beef selection at its 13 warehouses from Australian beef to 100 percent U.S. product in 2017.

Although the recent amendment negotiations of the KORUS FTA did not deal with agricultural trade, U.S. agricultural exports are expected to benefit from improvement to customs and origin verification procedures that were agreed as part of the amendment package.
AMCHAM hopes that the U.S. and Korean Governments will continue to work together to promote the mutually beneficial trade in agricultural goods. In addition to addressing the issues below, another positive measure that Korea should consider is to lift its prohibition on the use of ethanol as a transportation fuel. Ethanol is a clean renewable energy source that is used by several of Korea’s neighbors in the region, including Japan, China, and the Philippines. Its use in Korea would not only improve Korea's trade balance with the U.S. but also see substantial benefits for reducing urban pollution and diversifying Korea's energy mix.

**ONGOING ISSUES**

**Agricultural Biotechnology**

Agricultural biotechnology contributes to higher crop yields, health and environment, and conservation of energy, soil, and water resources. Unfortunately, certain Korean laws and regulations, especially the Act on Transboundary Movements of Living Modified Organisms and other Related Matters (LMO Act), continue to create a challenging regulatory environment for U.S. agricultural biotechnology exports.

Currently the Ministry of Food and Drug Safety (MFDS) and the Rural Development Agency (RDA) under MAFRA have primary responsibility for ensuring the safety of biotech crops imported for food and feed use. However, as mandated by the LMO Act, three additional agencies – Korea Center for Disease Control and Prevention (KCDC) under MOHW, National Fisheries Research and Development Institute (NIFS) under MOF, National Institute of Ecology (NIE) under MOE – are part of the consultation process. Risk Review Consultations (RRC) by these three additional agencies have created unnecessary problems while adding no value to the safety

**Issue:** The process for risk review of living modified organisms is overly complicated and lacks predictability and transparency.

**Relevant Regulations:** The Act on Transboundary Movements of Living Modified Organisms and Other Related Matters (LMO Act)

**Relevant Agencies:** Ministry of Trade, Industry and Energy (MOTIE), Ministry of Food and Drug Safety (MFDS), Ministry of Agriculture and Rural Affairs (MAFRA), Ministry of Health and Welfare (MOHW), Ministry of Fisheries (MOF), Ministry of Environment (ME)

**Relevant KORUS Provisions:** Chapter 8, Article 3, Subparagraph 3(a)
assessment for biotech crops, with requirements such as fish feeding study or non-target organism studies for non-insect resistant traits. This redundant process has created issues of transparency and predictability of Korea’s biotech crop safety assessment.

Since 2008, major grain exporting countries and value chain stakeholders have repeatedly requested improvement of these regulations to resolve structural problems by amending the LMO Act to remove RRC by three additional agencies. However, there have been no meaningful improvements thus far.

**Recommendation:** Korea should streamline the burdensome approval process for safety review of genetically engineering crops by eliminating redundant and unnecessary procedures and increasing transparency and predictability.

It will also be important for the Korean government to clarify its position on how to regulate agricultural products that are increasingly being developed through new breeding techniques such as gene editing (e.g. CRSPR). Such regulation should be based on international standards and be implemented in a way that does not limit innovation.

**Market Access for Fruits and Vegetables**

Korea bans or restricts the import of a number of U.S. fruit and vegetable products due to pest concerns. Imports of apples and pears from the U.S. are currently banned. Imports of fresh blueberries are allowed only from the state of Oregon and not from other blueberry-producing states such as California and Washington. Imports of cherries are allowed only from California. Potatoes may be imported only from the Pacific Northwest, while market access is denied to potato-growers from California, Colorado, North Dakota, and other states.

**Issue:** Korea bans or restricts the import of certain U.S. fruits and vegetables.

**Relevant Regulations:** Plant Protection Act

**Relevant Agencies:** MFDS, Animal and Plant Quarantine Agency (QIA)

**Relevant KORUS Provisions:** Chapter 8
**Recommendation**: We encourage Korea to work with the U.S. federal and state governments and agricultural producers to develop measures that can allow market access to these U.S. agricultural products while ensuring their safety. Doing so would further improve the U.S.-Korea trade balance and enhance consumer choice in Korea.
AUTOMOBILES

OVERVIEW

U.S. automakers have seen significant benefits under the KORUS FTA thanks in large part to a reduction in tariff rates. Korea’s tariff rate on U.S. automobile imports fell from 8% in 2011 to 0% in 2016. In comparison, the U.S. tariff rate on Korean automobiles fell from 2.5% in 2011 to 0% in 2016. As a result, U.S. exports of passenger cars to Korea have grown 325% since 2011, while Korean exports of passenger cars to the U.S. grew 61% in the same period. The U.S. share of Korea’s imported automobile market has risen to second-highest, overtaking Japan.

While the U.S. records a large trade deficit in automobiles with Korea, this deficit has declined sharply by 24% from a peak of $16.0 in 2015 to $12.2 in 2018.

The revised KORUS FTA contains a number of outcomes with positive implications for the U.S. automotive industry. These improvements reflect a willingness by the Korean Government to improve market access for U.S. automobile exports in response to concerns voiced by the U.S. Government and business community. Improved market access under the amended KORUS FTA is likely to contribute to expanded exports of U.S. automobiles to Korea in the coming years, while the extension of the U.S. truck tariffs will provide significant protection for the U.S. industry and potentially encourage further investment by Korean automakers in the U.S.

While technical measures imposed in the name of environment or safety continue to create an unlevel playing field for U.S. automobiles in Korea, AMCHAM expects that U.S. automobile exports will grow as the KORUS FTA amendment takes effect and outstanding non-tariff barriers are
addressed. In this context, any protective measures, such as new tariffs on imports of automobiles and automotive parts, taken in the interest of protecting the U.S. automotive industry would be counterproductive and would risk undoing the significant gains that U.S. automakers have made in Korea under the KORUS FTA. AMCHAM hopes that both governments will cooperate with the industry to remove remaining barriers and refrain from imposing new barriers to bilateral automotive trade.

**ONGOING ISSUES**

**CAFE/CO\textsubscript{2} Standards**

As part of the KORUS FTA amendment, Korea committed to taking U.S. regulations into account when setting future fuel economy targets and include more lenient targets for small manufacturers. Korea’s Corporate Average Fuel Economy (CAFE) standards mandate an emission target of 97g/km average CO\textsubscript{2} emissions by 2020, which is much more stringent than that of the U.S. and poses a significant barrier for U.S. automakers. Although ME conducted a mid-term review in 2018 at the request of the U.S., it has stated that there is no plan to revise the existing 2020 targets.

**Recommendation:** The Korean government needs to create a more realistic CO\textsubscript{2} target for the anticipated 2021-2025 revision by consulting U.S. and other international standards. In addition, the Korean government should set a mitigated target (more than 19\%) for small volume importers.

**Bonus/Malus Program**

Motor vehicle manufacturers are very concerned about the introduction of a bonus/malus program for vehicle emissions in Korea. Korea’s bonus/malus regime was scheduled to be implemented in 2015 but was postponed to 2020. The bonus/malus proposal, as currently

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**Issue:** Korea’s emissions standards are much more stringent than those of the U.S.

**Relevant Regulations:** Regulations for Motor Vehicle Average Fuel Economy Standards, Greenhouse Gases Emission Standards, and Their Application and Management

**Relevant Agencies:** Ministry of Environment (ME)

**Relevant KORUS Provisions:** September 2018 KORUS Amendment and Modification Texts: Agreed Minutes
constructed, is inherently flawed and will not achieve its intended purpose. Such schemes can have the opposite of their intended effect, causing consumers to delay purchasing new, more technologically-advanced vehicles that emit less CO₂. The penalty aspect of the scheme may be seen as a veiled engine displacement tax, and such taxes are prohibited under the KORUS FTA. The proposed penalties would lessen the value of U.S. automakers’ tariff savings carefully negotiated under the KORUS FTA.

**Recommendation:** We urge Korea not to implement the Bonus-Malus program.

### End-of-Life Vehicle & Extended Producer Responsibility

Korea is implementing restrictions on hazardous materials in end-of-life vehicles (ELV). As the U.S. does not have such restrictions on hazardous materials, it is difficult for U.S. vehicles to comply with ELV requirements, and this will restrict vehicle exports to Korea unless the company invests additional expense to develop compliant parts.

In addition to current ELV restrictions, ME is pursuing legislation that would impose extended producers’ responsibilities (EPR) on automakers. In other words, automakers would have full responsibility for vehicle recycling, including collection, transport, recycling, post-recycling and air-conditioner gas recycling.

The extension of EPR would be discriminatory, in that the cost-per-vehicle burdens it would impose on importers are greater than those imposed on domestic manufacturers. Such extension would also be unnecessary and misguided. The proposed EPR extension ignores the concept of shared responsibility – automakers have fulfilled their obligations during design and production by

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**Issue:** Planned bonus-malus program would undo tariff savings under KORUS.

**Relevant Regulations:** Air Pollutants Reduction Act

**Relevant Agencies:** ME

**Relevant KORUS Provisions:** Chapter 2, Article 12

**Issue:** Regulations on hazardous materials in end-of-life vehicles and extended producers’ responsibility of vehicle recycling are unfairly burdensome to U.S. automakers.

**Relevant Law:** Act on the Promotion of Saving and Recycling of Resources

**Relevant Ministries:** ME

**Relevant KORUS Provisions:** Chapter 9, Article 7
complying with material restrictions and meeting the 85% recyclability rate requested by the government during the vehicle certification process. Under the current system, third-party recyclers achieve a 95% recycling rate. If recycling companies continue to do their part – which they can, at a profit – extended EPR legislation is not necessary. Furthermore, it is not within the competence of manufacturers to develop recycling technology for recyclers.

Recommendation: U.S. vehicles should be exempted from the hazardous material requirement, and the EPR extension should not be introduced.

Eco-Innovation Credits

Korea also committed to expanding the number of “eco-credits” available to help meet environmental and emissions standards as part of the KORUS FTA amendment. However, it is too difficult for U.S. companies to access even the currently available credits. The Korean authority makes excessive demands for documentation, which are particularly burdensome for foreign manufacturers as such documentation must be translated into Korean. The Korean authority also requests detailed and specific information even on already listed technologies. Companies report long delays in the approval process.

Recommendation: In addition to expanding the amount of available credits, the Korean government should ensure that approvals are granted in a timely manner, documentation requirements are reasonable, and listed technologies are accepted without delay.

Damage Disclosure Requirements

Korea requires an automaker to notify a purchaser (1) of any “defect” (e.g., a scratch in the paint) occurring between the time the vehicle was
released from the factory and its delivery to the purchaser and (2) whether the “defect” was repaired. The requirement imposes a much higher burden on imported automobiles, given the fact that the supply chain between manufacturer and consumer is longer and accordingly there is a higher chance that the vehicle might be scratched, etc., in transit. The burden is especially significant for low-volume importers.

Recommendation: Korea should align with many U.S. states by excluding damage to glass, tires, bumpers and other interior components if replaced with original equipment manufacturer (OEM) parts and setting a de minimis reporting threshold at 4.5% of manufacturer’s suggested retail price (MSRP).

Ban on Motorcycles on Expressways

Korea maintains a complete ban on driving motorcycles on expressways. This restriction is unique to Korea; no other country in the OECD forbids operating motorcycles on expressways. While Korea cites safety concerns as the reason for maintaining this ban, independent studies indicate that driving of fit-for-purpose heavy motorcycles on highways does not pose significant safety concerns. According to one such study by Dynamic Research Institute, riding of motorcycles on expressways is 16 times safer than on motorways. This restriction severely limits the import market for U.S. motorcycles. If the ban on driving of motorcycles on expressways is lifted, the market for heavy motorcycles in Korea is expected to double, opening a significant export opportunity for U.S. motorcycle manufacturers.

Recommendation: Driving of fit-for-purpose heavy motorcycles on highways should be permitted in Korea.

Issue: Requirement to report repair history is unfairly burdensome on imported vehicles.

Relevant Regulations: Motor Vehicle Control Act / Damage Disclosure Regulation

Relevant Agencies: ME, MOLIT

Relevant KORUS Provisions: Chapter 9, Article 7

Issue: Korea uniquely forbids driving of large motorcycles on expressways.

Relevant Regulations: Road Traffic Law - Article 63

Relevant Agencies: MOLIT, National Police Agency

Relevant KORUS Provisions: Chapter 9, Article 7
Warranty/Recall Requirements

Current recall regulations obligate automakers and importers to recall defective vehicles indefinitely. By comparison, Korean made cars exported to the U.S. face only ten years of recall regulations. Korea requires an automaker to notify all voluntary recalls and all recalls ordered by any other foreign country, even if the recall covers vehicles not sold by the automaker in Korea. Moreover, Korea requires the automaker to provide this notice within 14 days of the initial recall announcement.

The indefinite recall period imposes unreasonable financial costs on auto companies and discourages voluntary recall efforts. Requiring an automaker to notify a recall involving vehicles not sold by the automaker in Korea is unreasonable and unduly burdensome. It also may create confusion in the Korean market, undermining consumer confidence in the automaker. (For example, a car sold in India has different homologation requirements than a car sold in Korea. Recall of the Indian version of the vehicle would not necessarily affect the Korean version.) Furthermore, the reporting deadline of 14 days is unreasonably short and inconsistent with the deadline in other countries.

Recommendation: Automakers should be required to notify recalls only for vehicles or parts which are sold by the automaker in Korea. Moreover, the deadline for giving notice should conform to international norms and not be less than 30 days.

Noise Requirements

Korea has strong noise requirements covering pass-by noise, stationary noise and horn noise that mandate lower decibel levels than U.S. requirements. Such strict noise requirements require additional engineering and materials cost to modify U.S.-made vehicles.
Recommendation: Korea’s noise requirements should be harmonized to accept the maximum allowed by U.S. state laws.

Emissions-Related Components (ERC) Modification Certification

Korean law requires importers to obtain modification certifications before customs clearance in case of changes to emissions-related components. Key difficulties for U.S.-made vehicles under this scheme are: (1) The scope of vehicle changes subject to modification certification is overbroad and ambiguous; (2) vehicle importers are subject to de facto discrimination against domestic vehicle manufacturers in terms that it is difficult for importers to detect that ERC has been modified before customs clearance; and (3) in the U.S., automakers can make periodic reports in case of running changes and only important modifications should be reported event by event. It is the automaker’s direction on whether or not it is important modification as a technical judgment.

Recommendation: The regulation should be harmonized with the EPA method: only important modifications should be reported event by event, while minor modifications that will be no adverse effect on emissions should be reported periodically (e.g., once a year) on an ex-post basis, based on the automakers’ technical judgment of the importance of the modification.

LEV/ZEV Sales Quota Scheme

Under the Partial Amendment of the Clean Air Conservation Act (effective as of Jan. 2020), a Low/Zero-Emission Vehicle Sales Quota Scheme will be implemented across the nation. The main changes are: (1) this scheme will be expanded across the country from the Seoul metropolitan area at present; and (2) a quota for zero-emission
Issue: New zero-emission vehicle sales quota disadvantages automakers with no qualifying electric vehicles in Korea.

Relevant Regulations: Clean Air Conservation Act (CACA)

Relevant Agencies: ME, MOLIT

Relevant KORUS Provisions: Chapter 9, Article 7

Vehicle (ZEV) sales will be introduced in addition to the existing low-emission vehicle (LEV) quota. ME is currently formulating details necessary to fully apply the revised Act, reportedly with a target date of August 2019. The key concern for U.S. automakers is that if ME sets the ZEV sales target separately from LEV, it could disadvantage companies that have no supply of qualified EVs at this point.

Recommendation: Korea should (1) provide leniency for small-volume manufacturers (defined by a threshold of less than 4,500 vehicle sales in 2009); (2) impose no sales quota for ZEVs yet, as more time is needed to develop and acquire EVs to be sold on the market; (3) if the scheme is implemented, impose no penalty for not meeting the ZEV quota separately from the LEV quota; and (4) provide an alternative to offset the ZEV quota with LEV quota (e.g., higher sales target or actual performance of LEVs).
OVERVIEW

Although U.S. chemical exports to Korea have benefitted from duty-free treatment under the KORUS FTA, Korea’s regulatory environment remains a challenging one for U.S. companies due to a growing number of non-tariff technical burdens. Following highly publicized accidents involving toxic humidifier disinfectants in recent years, “chemophobia” has been widespread in Korean society. On multiple occasions, concerns about the safety of chemical substances in various household products have been inflated by sensationalist media reporting. In response, the Ministry of Environment (ME) and the Ministry of Employment and Labor (MOEL) have introduced a series of tightened regulations on chemical products. Korea’s Act on Registration and Evaluation of Chemicals (K-REACH), Chemical Control Act (CCA), Consumer Chemical Products and Biocides Safety Act (K-BPR) and Industrial Health and Safety Act (ISHA) are examples of Korean standards that are overly strict, surpassing U.S. and EU regulations. Such regulations create an unlevel playing field by imposing regulatory barriers that inhibit U.S. companies’ access to the Korean market.

ONGOING ISSUES

Disclosure of Confidential Business Information

K-REACH, CCA, and ISHA require the disclosure of the full composition information of chemical mixtures to the authorities. These are duplicate regulations but entail slightly different requirements and government systems, further complicating Korea’s chemical regulatory system. Such requirement for disclosure of full
composition information is especially burdensome for U.S. exporters of chemicals to Korea; U.S. exporters often cannot reveal such information due to concern over leakage of confidential business information, and U.S. exporters may not have full composition information in cases where raw materials are supplied by a third party, such as “mixture in mixture” products. If U.S. exporters cannot fulfill the disclosure requirement, export to Korea will be restricted.

Under the amended K-REACH, ME provides the OR (“only representative”, designated person in charge of registration and notification) method to comply with the registration and notification process for third-party importers. OR is only way to register/notify chemical substances imported by third parties. However, the Korean market volume is too small compared to global market volume to justify the cost and burden of complying with this process for global companies. Under the newly amended K-REACH, the penalty for the manufacture, importation, or sale of chemicals without registration is strengthened to up to 5% of the average annual sales of the company for three years prior to the year of violation.

Recommendation: While AMCHAM appreciates the importance of transparency to protect consumers from potentially dangerous chemical substances, this goal can be met by requiring companies to submit information only on hazardous substances so as to protect confidential business information. In addition, penalties for non-registration of substances should be adjusted to a level that is less severely punitive.

Expanded Scope of Consumer Chemical Product Regulations

K-BPR significantly expands the scope of consumer chemical products subject to registration and/or safety confirmation. The definition of
“Consumer Products” is broadened to cover not only household products but also industrial/professional products, meaning that the scope of those acts includes the household, industrial, and professional markets. As a result, U.S. companies that import or produce consumer chemical products must fulfill safety and labelling standards which entail significant costs and take on severe legal responsibility such as biennial reporting, testing at designated labs every three years, etc. Too frequent and redundant registrations are required even for minor formula changes, creating particular difficulty in the case of imported products.

Some products that were previously not subject to these requirements may fail to pass the newly required tests. In such cases, there will be a risk that the import and sale of such products will be discontinued. This will impact both U.S. exporters and Korean end users, especially where alternative products are not available that fulfill the new safety and labelling standards.

**Recommendation:** Companies should not be required to register changes that have no relevance for human health. Percent changes, changes in minor ingredients like perfume, and inert chemical changes in formulas are examples of irrelevant chemical changes that should be exempted. Redundant registration requirements – for example between CCA and K-BPR – should be eliminated. A sufficient grace period for registration of such changes should be granted to minimize difficulties for businesses.

**Test Methods for Consumer Chemical Products**

Under K-BPR, Korea's ME has its own safety testing methods for safety and labelling standards of consumer chemical products that are different from globally standardized testing methods.

**Issue:** Korea does not recognize globally standardized testing methods.

**Relevant Regulations:** K-BPR

**Relevant Agencies:** ME

**Relevant KORUS Provisions:** Chapter 9, Article 1 (Technical Barriers to Trade)
Certified testing agencies in Korea are mostly semi-governmental organizations and globally certified agencies are not recognized. These conditions put an extra burden on global companies, which are required to conduct additional sets of testing for certification and to modify products to meet ME’s safety standards when they import consumer chemical products from U.S. This can function as a barrier for global companies to enter the Korean consumer chemical product market.

**Recommendation:** Korea should harmonize its testing methods for safety and labelling standards of consumer chemical products with globally standardized testing methods. Testing results from globally certified testing agencies should be recognized as equivalent to results from certified testing agencies in Korea.
The importance of protecting fair competition is enshrined as a core pillar of the KORUS FTA. In Chapter 16 on Competition-related Matters, both parties committed to ensuring strengthened due process protections for subjects of competition law enforcement actions. The role of the Korea Fair Trade Commission (KFTC) in enforcing competition law is vital in allowing fair competition and redressing unfair practices so as to create a market environment in which both Korean and U.S. companies can succeed and thrive. AMCHAM fully recognizes the need and authority of the KFTC to audit companies’ compliance with the various matters that fall within the jurisdiction of the KFTC to include fair and free competition, consumer protection, avoidance of cartels and fair standard terms and conditions.

Under the current Korean Administration, there is a renewed passion for enforcement of the Fair Trade Law, and this has resulted in a significant increase in the number of audits. As part of the Korean Government’s goal of creating a fair society, the KFTC announced its intention to restructure and improve Korea’s competition law enforcement system so as to maximize efficiency. AMCHAM welcomes the KFTC’s determination to reform and improve the competition law and enforcement in Korea and we hope to work closely with KFTC towards that end.

ONGOING ISSUES
Due Process and Transparency Protections

Given the renewed passion for enforcement under the Moon Administration, some of the working-
level officials of the KFTC have been extremely passionate in the quest for information. International companies operating in Korea have voiced concerns that the KFTC targets international companies with more aggressive enforcement efforts. Some international companies have felt that they have been targeted by the KFTC with unnecessarily coercive investigations, including aggressive raids of company facilities without prior notice and without the presence of an attorney, even when such practices contradict the KFTC’s own investigative guidelines.

When obtaining information and data, it is important to follow proper procedures and due process in the conduct of investigations and the rules applicable to such investigations established by the KFTC. AMCHAM welcomes commitments by the KFTC to due process in their investigations and the publishing of such rules.

**Recommendation:** In the spirit of the KORUS FTA, the KFTC should review its investigative practices with a view to ensuring full and transparent enforcement of its investigative guidelines guaranteeing fair process and equal treatment for domestic and international companies. While we do not believe the investigators are intentionally avoiding or evading the rules established by the KFTC, we believe it would be appropriate for the KFTC to engage in regular training programs to ensure consistent adherence to such rules.

We believe it would be beneficial for the KFTC to adhere to rules similar to those required to be followed by the prosecutors, whereby evidence obtained in violation of rules of procedure established by the KFTC cannot be used by the KFTC in their investigation. This would contribute to transparency and predictability in by ensuring that procedural rules are followed.

**Issue:** International companies feel that they have been unfairly targeted with more aggressive enforcement efforts, including practices in violation of KFTC rules.

**Relevant Regulations:** Fair Trade Law

**Relevant Agencies:** KFTC

**Relevant KORUS Provision:** Chapter 16 (Competition-related Matters)
OVERVIEW
The KORUS FTA eliminates tariffs on over 95% of U.S. exports to Korea as of 2018. For this tariff elimination to yield meaningful benefits for exporters and consumers of both the U.S. and Korea, it is essential that the customs authorities of both countries fully and faithfully implement the agreement.

Under the revised KORUS FTA, Korea committed to address long-standing concerns with onerous and costly verification procedures through an agreed Customs Principles for conducting verification of origin on imported products under KORUS FTA and establish the Rules of Origin Working Group (under the Committee on Trade in Goods) to monitor and address future issues that arise. AMCHAM hopes that the operation of this working group, alongside regular meetings between U.S. Customs and Border Protection (CBP) and KCS in Korea and the U.S., will generate meaningful improvements on the customs origin verification issues outlined below and allow full opportunities for input from international companies.

ONGOING ISSUES
Origin Verification

We fully understand that the agreement provides enforcement provisions through verifications and audits as trade preferential treatments provide duty savings and may pose the risk of abuse in the form of false preferential claims.

We are concerned that the Korea Customs Service (KCS) has conducted unduly onerous verifications for claims of preferential tariff treatment for low-
risk imports under the KORUS FTA and levied unreasonable penalties on U.S. companies. Demands for excessive and unnecessary documentation have cost U.S. exporters considerable time and money and jeopardized preferential treatment for eligible U.S. exports. KORUS claims have been rejected by KCS for minor errors on certification of origin and supporting documentations and KCS has limited the ability for companies to correct minor errors for legitimately eligible/originating goods, preventing companies from taking advantage of KORUS FTA claims for originating U.S. products.

Companies exporting to Korea have expressed concerns that ports of entry within KCS have too much discretionary authority, with each office making different demands and providing inconsistent opinions on similar cases.

Companies have also expressed concern over KCS verification officers’ insistence on communicating with Korean importers rather than U.S. manufacturers’ or sellers’ appointed representatives in Korea, which may increase the risk of leakage of confidential business information.

**Recommendation:** The KCS should conduct origin verifications in a manner that facilitates trade in goods between the U.S. and Korea in line with the purpose of the KORUS FTA. KCS should verify the accuracy of information for imports identified as high risk for noncompliance and facilitate legitimate flows of imported goods as agreed as part of the recent KORUS renegotiations.

If appointed by the U.S. manufacturer, KCS verification officers should communicate clearly and willingly with U.S. firms’ appointed representatives.
DIGITAL TRADE & FINANCIAL SERVICES

OVERVIEW

Free movement of data across borders is essential to 21st century commerce and the Fourth Industrial Revolution. Unfortunately, Korea’s regulations impose highly stringent and globally unique requirements on cloud, internet and financial service providers. Such regulations restrict market access opportunities for U.S. and other global service providers who have difficulty complying due to the global nature of their business operations, thereby having the effect of favoring local providers to the detriment of global providers.

AMCHAM supports digital trade regulations that enable and facilitate the cross-border flow of data and avoid data localization requirements. Mandating that data be kept or processed within national boundaries does not make it safer from cybersecurity threats or natural disasters. U.S. industries are making significant investments in cloud data centers around the world to provide globally integrated services and achieve data storage security. Decisions on where data is stored and how it is processed should be determined by the free market and consumer choice rather than government mandate.

AMCHAM applauds recent actions by the Korean Government to better align Korea’s regulations on cloud and internet services with global standards and usher in the Fourth Industrial Revolution. In particular, we welcome the Financial Services Commission (FSC)’s well-intended deregulatory efforts to expand the usage of cloud services in the financial sector. However, we are concerned about recent legislation imposing new requirements that further restrict the free movement of data across borders.
borders by mandating localization of certain components of the cloud system in Korea. It is our hope that the Korean Government will cooperate closely with international businesses and the U.S. Government in order to address these concerns and create a truly level playing field for domestic and multinational companies in the digital trade and financial services sectors.

**ONGOING ISSUES**

**Localization of Servers**

Proposed bills in Korea’s National Assembly would impose an obligation on certain online service providers to take technical measures such as installing domestic servers, ostensibly for the purpose of ensuring stability of network services. Violations of this obligation are subject to an administrative fine of up to three percent of relevant revenues. In addition to grossly violating online service providers’ freedom to conduct business, such requirement goes against the spirit and letter of Korea's FTA commitments in several respects:

1. A requirement that global content providers capable of providing cross-border services install physical servers in Korea affects global content providers only, and thus effectively discriminates against them. It therefore violates the national treatment principle under the KORUS FTA, as well as Article 17 the World Trade Organization (WTO) General Agreement on Trade in Services (GATS).

2. To the extent it requires large-scale servers to be installed in Korea, and the allocation of devoted personnel on the ground to manage the server, this would violate the KORUS FTA provision that prohibits requiring a service supplier from the other country to establish or maintain a “local presence.”

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**Issue:** Recent legislation would require global companies to locate data centers in Korea.

**Relevant Regulations:** Act on the Promotion of Information and Communications Network Utilization and Information Protection

**Relevant Agencies:** Ministry of Science of ICT (MSIT)

**Relevant KORUS Provision:** Chapter 12, Article 2 (National Treatment) and Article 5 (Local Presence)
3. The proposed amendment restricts cross-border supply of services and thus violates the fundamental principles of the KORUS FTA. Supply of value-added services inevitably includes the cross-border transfer of data. Requiring global content providers to install servers in Korea and provide services only through them would result in data localization and actual restriction of services such as the free-flowing supply of data across borders.

The sever localization requirement is contrary to Korea’s commitments under the KORUS FTA. Moreover, such requirement is not an effective way to advance the purported goal of ensuring the stability of network services, as the quality of internet connections is managed and controlled by internet service providers and online service providers have no capability to guarantee the quality or speed of internet connections.

**Recommendation:** We urge Korea to repeal the server localization requirement and seek more effective ways to ensure stability of network services that are in line with global standards.

**Designation of a Domestic Agent**

Under legislation passed in 2018 by the National Assembly, a global internet service provider will be required to designate a domestic agent subject to various obligations and potential sanctions in Korea in case of any personal information leakage.

AMCHAM understands the intent of this act to promote the development of domestic e-commerce and to protect the rights and benefits of Korean users of online services of global service providers. However, such regulation would have the unintended consequence of making it practically impossible to provide services in Korea for certain U.S. service providers that cannot designate an agent in Korea, especially those U.S. service providers.

**Issue:** Recent legislation would require foreign service providers to designate a domestic agent

**Relevant Regulations:** Act on Promotion of Information and Communications Network Utilization and Information Protection, Etc. (the “Network Act”)

**Relevant Agencies:** Korea Communications Commission (KCC)

**Relevant KORUS Provisions:** Chapter 12, Article 2 (National Treatment) and Article 5 (Local Presence)
internet companies whose operations are relatively small.

The regulation runs counter to Article 12.5 of the KORUS FTA, which stipulates that neither party may require a service supplier of the other party to establish or maintain a representative office or any form of enterprise, or to be resident, in its territory as a condition for the cross-border supply of any service. Requiring the designation of a domestic agent would produce results similar to requiring the designation of a representative office.

The regulation is also inconsistent with Article 12.2 of the KORUS FTA that sets forth the obligation of national treatment. The requirement to designate a domestic agent applies only to foreign value-added telecommunication service providers in a discriminatory manner and would have a substantive effect on the competitive conditions for foreign service providers.

Recommendation: We encourage the Korean government to end the requirement for foreign telecommunications service providers to designate a foreign agent in Korea, which is likely to impose significant hardship on U.S. service providers and ultimately have adverse consequences for the domestic value-added telecommunications service market. We urge the Korean government to fully hear and consider the opinions of foreign service providers prior to introducing new regulations. In particular, we believe it is necessary to uphold the fundamental spirit and principles of the KORUS FTA and prevent potential disputes regarding sovereignty between countries.

Data Protection Standards

Korea’s data protection standards for cloud computing services in practice deter U.S. cloud service providers from entering the public market. The current Data Protection Standards for Cloud Computing Services for public institutions require
1) physical network separation, 2) discriminatory local and global CC certification, and 3) use of Korea-unique encryption modules (“ARIA” and “SEED”). Such Korean standards impose excessive security requirements compared to global standards that are overly burdensome for U.S. companies to comply with. This will ultimately deter cloud computing technologies from becoming ubiquitous in Korea and restrict consumer choice.

Guidelines of the Korea Internet Security Agency (KISA) and MSIT require public agencies to use SaaS (Software as a Service) only of cloud services providers that have obtained KISA certification. KISA requires the three criteria above and this serves as a barrier to foreign cloud service providers. This makes it more difficult for U.S.-based ICT companies to enter the SaaS as well as IaaS market for public institutions, including local governments, public corporations, schools, and research institutes.

**Recommendation:** AMCHAM encourages the Korean Government to allow logical rather than physical network separation of non-sensitive information of public sector, even if information deemed relevant to national security is excluded, and to alleviate restrictions on entering the public sector cloud services market such as CC certification required by the KISA certification process.

**Cloud Usage in Financial Services**

The FSC announced at the end of 2018 easing of regulations to allow cloud usage even for significant information processing involving personal credit and unique identification information. However, such regulatory changes initially apply only to cloud servers in Korea, with relaxation of regulations on overseas cloud systems to be reviewed in the mid- to long-term. The

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**Issue:** Korea-unique data protection standards for public cloud computing deter U.S. companies from entering the Korean market.

**Relevant Regulations:** Act on the Development of Cloud Computing and Protection of Its Users; Personal Information Protection Act, IT Network Use and Protection Act; Data Protection Standards for Cloud Computing Services

**Relevant Agencies:** MSIT, FSC, KISA

**Relevant KORUS Provisions:** Chapter 12, Article 2 (National Treatment) and Article 5 (Local Presence)
amended Electronic Financial Supervision regulations require cloud service providers to maintain a “control system” in Korea.

These requirements are difficult for globally operating companies to accommodate. Local subsidiaries and branches of global financial institutions use cloud services typically to take part in global projects under which data processing is increasingly moved to a cloud environment. They cannot carve out certain functions of data usage only for Korea and have relevant data stored in Korea, because for many services they provide internationally, data have to be in the global system in order to serve international clients.

The stated purpose of these requirements is to address potential cyber threats, legal disputes, jurisdiction conflict, and mounting concerns of civil societies and media over personal data protection. However, geographical location of data has no value for improving security or privacy. Concern over legal disputes and jurisdictional conflicts can be more effectively addressed through cooperation and agreements with other governments, like the CLOUD Act in the U.S. and the CBPR and GDPR systems.

**Recommendation:** We urge the FSC to allow as soon as possible the use of overseas cloud systems even for significant information processing involving personal credit and unique identification information in order to protect consumer choice.

**Supervision of Cloud Service Providers**

To expand cloud usage in the financial services sector, the FSC has strengthened reporting obligations and direct supervision of cloud service providers. Such changes risk creating an overly burdensome business environment, running counter to the good intentions of deregulatory plans.
In particular, the Financial Security Institute (FSI)'s new draft guidelines grant financial authorities and internal/external auditors of financial companies with expansive access to the systems of cloud service providers, including physical access to data centers. Such expansive access is not consistent with the public cloud model and may critically affect the security and stability of cloud systems.

**Recommendation:** A regulator should be able to carry out its critical supervisory functions by working directly with its regulated entities. Regulator audit rights therefore should be focused on its ability to obtain information and documents from the financial service institution itself to allow the regulator to carry out its supervisory functions, rather than direct access to the premises and systems and the financial books and affairs of the service provider.

We suggest limiting the scope and access to the cloud system by financial authorities and internal/external auditors of financial companies to the minimum level of access needed to conduct their investigation or audit. Further, we believe an exemption to such access would be preferable if a cloud service provider can provide financial companies, upon request, with regular audit reports certifying that the cloud service provider has met global security standards.

**Issue:** Reinforced supervision of cloud service providers may negatively affect the business environment for global companies.

**Relevant Regulations:** Data Protection Standards for Cloud Computing Services; Electronic Financial Supervision Regulations

**Relevant Agencies:** FSC

**Relevant KORUS Provisions:** Chapter 12, Article 2 (National Treatment) and Article 5 (Local Presence)
GOVERNMENT PROCUREMENT

OVERVIEW

The KORUS FTA contains government procurement provisions in which both countries commit to opening their procurement markets to the other party. Although both the United States and Korea were members of the WTO GPA before the entry into force of the KORUS FTA, U.S. companies' access to the Korean market was severely limited in practice. The KORUS FTA reflects and builds on the WTO GPA commitments by substantially lowering the threshold amount for coverage and expanding the scope of government agencies subject to the agreement.

ONGOING ISSUES

Designation of Products and Industries as Appropriate for SMEs

The Ministry of SMEs and Startups (MSS) has the authority to designate certain industries and products as "appropriate for SMEs." If an industry or product is so designated, central government agencies are required to procure the relevant products from domestic SMEs, excluding U.S. companies from the market.

In recent years, MSS has expanded the scope of products and industries subject to such definition, especially in newly emerging industries such as information technology. Rather than supporting the growth of domestic SMEs, such policies have had the unintended effect of more products from low-cost producer countries being sold in the Korean procurement market, due to those who import their products from these countries and sell these products as their own, to the detriment of U.S. products.

Issue: Designation of products and companies as appropriate for SMEs unfairly excludes U.S. vendors from the public procurement market.

Relevant Agencies: MSS

Relevant KORUS Provisions:
Chapter 12, Article 2 (National Treatment); Chapter 17 (Public Procurement)
As U.S. companies are leaders in technology and innovation and bring business to numerous Korean SMEs as channel partners in sales and service delivery, further restricting the scope of U.S. companies' participation in Korea's government procurement market would have negative consequences for innovation, employment, industrial development, and the quality of public service in Korea.

Although the KORUS FTA allows preference for domestic SMEs in government procurement, the expanded designation of industries and products as appropriate for SMEs seem designed to exclude multinational vendors from the market, going against the principle of national treatment set forth in the KORUS FTA.

**Recommendation:** We urge Korea to refrain from actions that would further limit the participation of U.S. companies in Korea’s government procurement market, such as expanding the scope of industries and products designated as appropriate for SMEs.
New medicines and devices not only extend life spans but also improve quality of life, reduce medical expenses, and can become a future growth engine for the economy. Transparency, predictability, and fairly rewarding the value of innovation are vital for supporting research and development of innovative drugs and medical devices, which can require many years and billions of dollars to develop. By preventing hospital visits and reducing the need for long-term care and hospital stays, the cost of rewarding such innovation more than pays for itself.

As U.S. companies continue to lead the world in research and development in the pharmaceutical and medical devices sectors, they have made great contributions to the quality of care for Korean patients. However, Korea's pricing and reimbursement policies for pharmaceutical and medical devices have not always recognized the value of such contributions by global innovative companies in a fair, transparent, and nondiscriminatory manner.

The renegotiated KORUS FTA includes new outcomes intended to ensure that the value of medical innovation by international companies is duly recognized and rewarded. AMCHAM and its member companies in the pharmaceutical and medical devices industries are appreciative of the opportunity to join in the effort to build a healthcare system in Korea that promotes and incentivizes innovation while providing affordable and accessible care for all.
**ONGOING ISSUES**

**Pricing of Global Innovative Drugs**

Korea’s pharmaceutical pricing and reimbursement policies significantly depress the price of new and innovative medicines, devaluing the innovative contributions of global pharmaceutical companies. Although Korea has introduced new pathways for reimbursement listing since KORUS, new drug prices remain low at around 61% of the OECD average. U.S. companies have expressed concerns regarding the lack of transparency and predictability of these policies.

As agreed during the KORUS FTA amendment negotiations, Korea’s Health Insurance Review and Assessment Service (HIRA) published a revision of the Global Innovative New Drug Pricing Benefit System on December 31, 2018. The new policy sets forth five conditions that new drugs must satisfy in order to qualify for premium pricing: (1) it should have a new mechanism or be a new substance; (2) there should be no alternative treatment; (3) it should have clinically meaningful data such as extending survival time for a significant period; (4) it should have the U.S. Food and Drug Administration (FDA)’s designation of Breakthrough Drug (BTD) or the European Medicines Agency (EMA)’s accelerated assessment of Priority Medicines (PRIME); and (5) it should be an orphan drug or an anticancer treatment. The pharmaceutical industry has expressed disappointment that despite requests for improvement made during the public comment period, these are unrealistic requirements that almost no new drugs will be able to satisfy. The industry is concerned that without further improvement, the new policy will have little to no benefit in terms of improving reimbursement for the value of global innovative drugs.

**Issue:** New drug pricing is not sufficiently fair or transparent and does not reflect value of innovation by global companies.

**Relevant Regulations:** Global Innovative New Drug Pricing Benefit System

**Relevant Agencies:** Ministry of Health and Welfare (MOHW), Health Insurance Review and Assessment Service (HIRA), National Health Insurance Service (NHIS)

**Relevant KORUS Provisions:** Chapter 5, Articles 1 and 2
Recommendation: To fulfill the commitment made during the KORUS FTA amendment negotiations to provide for meaningful consultation and transparency during the revision of its pharmaceutical pricing policy, AMCHAM urges Korea to organize a consultation body that includes the government, pharmaceutical industry, civic groups and patient advocacy groups for an active discussion on improving Korea’s premium pricing policy to appropriately recognize the value of global innovative drugs.

New Diagnosis Related Group System

In August 2018, the Korean Government announced the expansion of the pilot project of the New Diagnosis Related Group system (the “New DRG”) as a measure for strengthening coverage by national health insurance while at the same time maximizing financial stability. Although the Ministry of Health and Welfare (MOHW) dubs it as a pilot project, given that a total of 56 medical institutions participate as of 2019 (to be expanded to 69 by July), it can be seen as the government's efforts to reform the payment system, which is a key policy to control the total amount of medical expenditure under the current “fee-for-service” system. MOHW has already announced that it will add 37 more medical institutions in 2020.

The New DRG system is a hybrid payment system between the existing DRG (currently applied to seven disease groups) and fee-for-service systems, now applicable to in-patients within 559 disease groups. Pre-determined “bundled” payment will be provided to in-patients according to their disease groups, but separate compensation based on fee-for-service will be made for the doctors' direct procedures and some medical devices and medicines, which are categorized as “non-bundled”.

**Issue:** New pricing system is being implemented without sufficient dialogue with industry, does not provide adequate compensation for medical devices and pharmaceuticals

**Relevant Regulations:** New Diagnosis Related Group System

**Relevant Agencies:** MOHW, HIRA, NHIS

**Relevant KORUS Provisions:** Chapter 5, Articles 1 and 2
The medical devices industry’s concerns are that the government is creating the policy model of the New DRG without sufficient dialogue with the industry. According to the government model, 50% of the medical treatment costs (medical devices) under the New DRG are bundled, 43% are non-bundled and the remaining 7% are uncovered. The biggest problem is that for medical devices classified as non-bundled (products that should be compensated for their respective prices, as are under fee-for-service system), only 80% of the unit price under the fee-for-service system can be charged to the National Health Insurance Service. In other words, hospitals will not receive 100% cost compensation for the medical devices, which the medical device industry fears will ultimately lead to a price cut for their medical devices.

Such problem not only affects medical devices but also pharmaceuticals. The government also plans to classify some drugs, such as anti-cancer drugs, rare medicine and biological agents to be administered to in-patients of the disease groups under the New DRG, into non-bundled items and apply the “80% rule”.

**Recommendation:** Medical devices and pharmaceuticals in the non-bundled area under the New DRG should be compensated 100% as they are under the fee-for-service system. Since medical procedures under the non-bundled category can claim 100% reimbursement, the 80% rule applied to medical devices and drug is unbalanced.

**Independent Review Mechanism**

The KORUS FTA provides for the establishment of a transparent, independent review mechanism (IRM) to review the recommendations and determinations of the Korean Government’s pricing and reimbursement of pharmaceuticals and medical devices.

**Issue:** The Independent Review Mechanism needs to be more fully utilized to increase transparency and accountability in pricing of pharmaceuticals and medical devices.

**Relevant Regulations:** National Health Insurance Act

**Relevant Agencies:** MOHW, HIRA, NHIS

**Relevant KORUS Provisions:** Chapter 5, Articles 1 and 3; Confirmation Letter (Independent Review Body)
Since 2012, there is not a single case of the IRM reversing or influencing the original decision. Although the guidelines grant the Independent Review Body the right to host an expert group committee, there is little indication that the Independent Review Body is considering a second opinion from expert groups outside the government. Furthermore, the Korean Government has taken the position that reimbursed prices negotiated between NHIS and pharmaceutical companies do not qualify as “recommendations or determinations” and therefore are not subject to the IRM. This negates the core purpose of the IRM, which is to ensure the reimbursement decision making process is governed by transparent and verifiable rules and guided by science-based decision making.

**Recommendation:** We encourage Korea to ensure that the Independent Review Body is working to fulfill its original purpose of increasing transparency and accountability. Independent Review should be a real opportunity to appeal to an independent board when the decisions made by government authorities are believed not to be sufficiently fair and reasonable. As allowed in the guidelines, the Independent Review Body should take full account of the perspectives of third-party experts.

**Delayed Patient Access to New Medical Technologies**

South Korea requires consecutive patient access processes beginning with regulatory approval from Ministry of Food and Drug Safety (MFDS), new Health Technology Assessment (nHTA) approval from MOHW and the National Evidence-based Healthcare Collaborating Agency (NECA) and reimbursement coverage and pricing approval from MOHW and HIRA. To shorten the lead time of the sequential processes, MOHW has introduced the Parallel Review (PR) process which

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**Issue:** Delays in the approval process deny patients access to new medical technologies.

**Relevant Regulations:** National Health Insurance Act

**Relevant Agencies:** MOHW, HIRA, NHIS

**Relevant KORUS Provisions:** Chapter 5, Articles 1 and 2
concurrently review the regulatory approval and nHTA application by benchmarking the U.S. FDA and CMS parallel review process.

While the PR process contributes to shortening the patient access lead-time, the reimbursement coverage and pricing decision making process is not included in the PR process. In most cases, the reimbursement coverage and pricing decision making process, particularly for new and innovative medical devices that have gone through the nHTA process, takes significantly longer than other processes and often takes two to three years, exceeding the legally mandated timeframe of 100 days. Various factors are associated with this significant delay, including: 1) lack of coordination between relevant departments within HIRA; 2) lack of efficiency in administrative operation; 3) less streamlined communication with stakeholders (e.g., advisory healthcare professionals and specialty societies); 4) understaffed organization; and 5) lack of commitment to comply with legally required review timeframe.

Delayed patient access caused by lengthy the review time is disadvantageous to innovators, especially U.S. medical device manufacturers, because the product life cycles of medical devices are as short as 18 months. The delayed adoption of innovative medical devices therefore reduces the period of market exclusivity for innovators.

**Recommendation:** The process for reimbursement coverage and pricing approval from MOHW and HIRA should be accelerated to within the legally mandated timeframe of 100 days. Reimbursement coverage and pricing approval should be included in the PR process.
## Table of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviated</th>
<th>Expanded</th>
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<tbody>
<tr>
<td>AMCHAM</td>
<td>American Chamber of Commerce in Korea</td>
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<td>CAFE</td>
<td>Corporate Average Fuel Economy</td>
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<td>CBPR</td>
<td>Cross Border Privacy Rules System</td>
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<td>CCA</td>
<td>Chemical Control Act</td>
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<td>CLOUD Act</td>
<td>Clarifying Lawful Overseas Use of Data Act</td>
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<tr>
<td>CMS</td>
<td>Center for Medicare and Medicaid Services</td>
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<td>ELV</td>
<td>End-of-life Vehicle</td>
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<td>EPR</td>
<td>Extended Producers' Responsibility</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FSC</td>
<td>Financial Services Commission</td>
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<td>GATS</td>
<td>General Agreement on Trade in Services</td>
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<td>GDPR</td>
<td>General Data Protection Regulation</td>
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<tr>
<td>GPA</td>
<td>Government Procurement Agreement</td>
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<tr>
<td>HIRA</td>
<td>Health Insurance Review and Assessment Service</td>
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<td>ISHA</td>
<td>Industrial Safety and Health Act</td>
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<tr>
<td>K-BPR</td>
<td>Safety Control Act of Household Chemical Products and Biocidal Products</td>
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<td>KCC</td>
<td>Korea Communications Commission</td>
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<td>KCDC</td>
<td>Korea Center for Disease Control and Prevention</td>
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<td>KCS</td>
<td>Korea Customs Service</td>
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<td>KFTC</td>
<td>Korea Fair Trade Commission</td>
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<td>KISA</td>
<td>Korea Internet Security Agency</td>
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<tr>
<td>KORUS</td>
<td>Free Trade Agreement between the United States of America and the Republic of Korea</td>
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<td>K-REACH</td>
<td>Act on the Registration and Evaluation of Chemicals</td>
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<td>LMO</td>
<td>Living Modified Organism</td>
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<tr>
<td>MAFRA</td>
<td>Ministry of Agriculture, Food and Rural Affairs</td>
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<td>ME</td>
<td>Ministry of Environment</td>
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<td>MFDS</td>
<td>Ministry of Food and Drug Safety</td>
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<td>MOEL</td>
<td>Ministry of Employment and Labor</td>
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<td>MOF</td>
<td>Ministry of Fisheries</td>
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<td>MOHW</td>
<td>Ministry of Health and Welfare</td>
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<td>MOLIT</td>
<td>Ministry of Land, Infrastructure and Transportation</td>
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<td>MOSEF</td>
<td>Ministry of Strategy and Finance</td>
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<td>MOTIE</td>
<td>Ministry of Trade, Industry and Energy</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<td>MSIT</td>
<td>Ministry of Science and ICT</td>
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<td>MSS</td>
<td>Ministry of Startups and SMEs</td>
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<td>nHTA</td>
<td>New Health Technology Assessment</td>
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<td>NIE</td>
<td>National Institute of Ecology</td>
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<td>NIFS</td>
<td>National Fisheries Research and Development Institute</td>
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<tr>
<td>OECD</td>
<td>Organization for Economic Cooperation and Development</td>
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<tr>
<td>OEM</td>
<td>Original Equipment Manufacturer</td>
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<td>OR</td>
<td>Only Representative</td>
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<tr>
<td>PR</td>
<td>Parallel Review</td>
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<td>RCT</td>
<td>Randomized Controlled Trial</td>
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<td>RDA</td>
<td>Rural Development Agency</td>
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<td>RRC</td>
<td>Risk Review Consultations</td>
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<td>RWD</td>
<td>Real-World Data</td>
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<td>SMEs</td>
<td>Small and Medium-Sized Enterprises</td>
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<td>VAS</td>
<td>Value Appraisal Setting</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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