



Since 1953
AMCHAM
American Chamber of Commerce in Korea

2026 Business Environment Insight Report





About AMCHAM Korea

The American Chamber of Commerce in Korea (AMCHAM Korea) was founded in 1953, with a broad mandate to encourage the development of investment and trade between Korea and the United States.

AMCHAM Korea is the largest foreign chamber in Korea with approximately 800 member companies and affiliates with diverse interests and substantial participation in the Korean economy.

For any inquiries regarding the report, please contact governmentaffairs@amchamkorea.org.

TABLE OF CONTENTS

TABLE OF CONTENTS	1
REPORT SUMMARY: KEY FINDINGS	5
INTRODUCTION	15
A TRANSFORMATIVE PHASE IN THE U.S.-KOREA ECONOMIC PARTNERSHIP	16
REBUILDING MANUFACTURING THROUGH STRATEGIC U.S.-KOREA INVESTMENT	17
U.S.-KOREA AI PARTNERSHIP AS A NEXT-GENERATION GROWTH ENGINE	19
AEROSPACE & DEFENSE	21
OVERVIEW	22
DAPA OFFSET GUIDELINES ALLOW UNFAIR ADVANTAGE FOR CONTRACTORS WITH COMMERCIAL BUSINESS / AFFILIATES	24
NEED CLARITY OVER EQUIPMENT PROVISION OFFSET CRITERIA	26
NEED CLARITY OVER RECOGNITION OF KNOW-HOW FEE FOR MANUFACTURING AND EXPORT PROJECTS	28
NEED CLARITY OVER DAPA'S REQUEST FOR INDUSTRIAL COOPERATION (IC) PLANS	30
ONEROUS PENALTY PROVISIONS IN OFFSET TERMS & OBLIGATIONS	32
AGRICULTURE	35
OVERVIEW	36
STREAMLINING AGRICULTURAL BIOTECHNOLOGY APPROVALS AND ELIMINATING THE BACKLOG OF U.S. APPLICATIONS	37
AUTOMOBILES	39
OVERVIEW	40
ADOPTION OF A PRE-CERTIFICATION REGIME FOR KEY EMERGING AUTOMOTIVE TECHNOLOGIES	42
FULL AUTHORIZATION OF U.S.-EQUIVALENT LEVEL 2 AUTONOMOUS DRIVING TECHNOLOGIES	44
RELAXATION OF ROBOTAXI REGULATIONS TO PROMOTE MOBILITY RIGHTS	46
SIMPLIFICATION OF EMISSIONS CERTIFICATION PROCEDURES UNDER THE KOREA -U.S. TARIFF NEGOTIATIONS	48
STRENGTHENING CARBON EMISSION TRADING SYSTEM IN THE TRANSPORTATION SECTOR	50
AUTO GHG/CAFE RULES FOR 2026-2030	52
DISCRIMINATORY EV SUBSIDY POLICY AGAINST NON-TARGET COMPANIES UNDER THE LOW-EMISSION VEHICLE SUPPLY MANDATE (LEVSM)	53
DUPLICATION OF PENALTY SYSTEMS: LEV/ZEV MANDATE AND GHG REGULATIONS	54
NACS CHARGING STANDARD ADOPTION	56
OVERLAPPING REGULATIONS ON ELECTRIC VEHICLES	57
CHEMICALS	59
OVERVIEW	60
STREAMLINING COMMUNICATION OBLIGATIONS FOR CHEMICAL SUBSTANCES REGISTERED OR NOTIFIED UNDER ARTICLE 29-1 OF K-REACH	61

SIMPLIFYING NOTIFICATION REQUIREMENTS FOR SELLERS OF HAZARDOUS CHEMICALS UNDER ARTICLE 29-2 OF THE CHEMICAL SUBSTANCES CONTROL ACT.....	63
FACILITATING CONFIDENTIAL BUSINESS INFORMATION APPROVALS FOR TRADE SECRET INGREDIENTS IN R&D SAMPLES	65
ALIGNING THE LIST OF EXISTING CHEMICALS BETWEEN K-REACH AND OSHA.....	66
CLARIFYING BIOCIDAL PRODUCT LABELING REQUIREMENTS UNDER THE CONSUMER CHEMICAL PRODUCTS AND BIOCIDES SAFETY ACT.....	68
EASING HAZARDS AND RISK DATA SUBMISSION CRITERIA FOR FRAGRANCES IN BIOCIDAL PRODUCTS	70
RECOGNITION OF INTERNATIONALLY APPROVED BIOCIDAL SUBSTANCES AND PRODUCTS	72
RECOGNITION OF INTERNATIONALLY APPROVED PRESERVATIVES USED IN BIOCIDAL-TREATED PRODUCTS	74
REQUEST FOR REGULATORY AMENDMENT TO FACILITATE MARKET ENTRY OF CONCENTRATED INDUSTRIAL CHEMICAL PRODUCTS	76
CLARIFYING REGISTRATION REQUIREMENTS FOR INGREDIENTS IN HYGIENE PRODUCTS UNDER THE HYGIENE PRODUCTS STANDARDS.....	78
DIGITAL ECONOMY	79
OVERVIEW.....	80
DIGITAL INFRASTRUCTURE & NETWORK INTERCONNECTION.....	81
ONLINE PLATFORM REGULATIONS AND KFTC ENFORCEMENT	83
APPLICATION OF THE CLOUD SECURITY ASSURANCE PROGRAM (CSAP).....	85
ARTIFICIAL INTELLIGENCE.....	87
DESIGNATION OF A LOCAL REPRESENTATIVE.....	90
LEGISLATIVE BILL ON SAFETY MANAGEMENT OF DIGITAL DISASTERS AND FAILURES	92
PERSONAL INFORMATION PROTECTION ACT (PIPA)	94
ENERGY & ENVIRONMENT	96
OVERVIEW.....	97
NEED FOR FAST-TRACK SYSTEM TO SUPPLY POWER FOR DATACENTERS	99
ENERGY SUPPLY AND RENEWABLE PROCUREMENT CONSTRAINTS FOR AI AND DIGITAL INFRASTRUCTURE	101
BILATERAL AGREEMENTS FOR CO ₂ TRANSPORT AND STORAGE AND THE ESTABLISHMENT OF COMMON CO ₂ STORAGE STANDARDS.....	103
NEED FOR STRENGTHENING THE HYDROGEN SECTOR	105
POLICY IMPROVEMENT FOR THE DISTRIBUTED POWER SECTOR	107
ENABLING THE USE OF SUPPLIER-PROVIDED TECHNICAL DOCUMENTATION FOR ROHS SUBSTANCE COMPLIANCE UNDER THE ACT ON RESOURCE CIRCULATION OF ELECTRICAL AND ELECTRONIC EQUIPMENT AND VEHICLES	108
FINANCIAL SERVICES	110
OVERVIEW.....	111
GENERAL ISSUES	113
RELAXATION OF NETWORK SEPARATION STANDARDS	113
UPDATE OF THE VERIFICATION PRACTICES UNDER THE REAL NAME ACT.....	117
BANKING & SECURITIES	120
RECOGNITION OF HEAD OFFICE CAPITAL	120
MACRO-PRUDENTIAL STABILITY LEVY	122
RELAXATION OF FOREIGN EXCHANGE POSITION LIMITS	124
INCREASE IN CASH POOLING MANAGEMENT LIMIT	126

AUTHORIZATION – APPROVAL OF MSD INVESTMENT DEALING LICENSE	127
CONSISTENCY IN THE APPLICATION OF LICENSE REQUIREMENTS	128
IPO UNDERWRITER LOCK-UP AND RETENTION REQUIREMENTS	129
ENFORCEMENT FOR BREACH OF SHORT SELLING REQUIREMENTS	132
INSURANCE & ALTERNATIVE INVESTMENT	134
SCOPE 3 IMPLEMENTATION: THE NEED FOR INSURANCE-SPECIFIC GUIDANCE FOR FOREIGN-INVESTED COMPANIES	134
UNCERTAINTY AROUND THE EQUITY REPO BUSINESS IN KOREA	136
EXCESSIVE REGULATORY CONTROL ON FINANCIAL PRODUCTS	138
LABOR	139
OVERVIEW	140
INTERPRETATION GUIDELINES FOR THE AMENDED TRADE UNION AND LABOR RELATIONS ADJUSTMENT ACT (“YELLOW ENVELOPE ACT”)	141
EXPANSION OF THE DEEMED WORKING HOURS SYSTEM FOR DISCRETIONARY WORK	144
ENSURING INCLUSIVE REPRESENTATION IN LABOR MANAGEMENT COUNCILS	146
MEDICAL DEVICES	148
OVERVIEW	149
IMPROVEMENT OF DIAGNOSIS-RELATED GROUP (DRG) SYSTEM	150
NEEDS FOR IMPROVEMENT OF NEW HEALTHCARE TECHNOLOGY ASSESSMENT (NHTA) SYSTEM	152
NECESSITY OF REFORMING AND INTRODUCING GREATER FLEXIBILITY IN THE NHTA PROCESS FOR TECHNOLOGIES TARGETING SEVERE AND CRITICAL DISEASES	154
POLICY SUPPORT FOR MEDICAL DEVICES NECESSARY FOR CANCER DIAGNOSIS AND TREATMENT	156
NECESSITY OF EXPANDING SUPPORT FOR SUPPLIERS TO ENSURE THE STABLE SUPPLY OF PEDIATRIC MEDICAL DEVICES AND THERAPEUTIC MATERIALS	159
ESTABLISHING A FOUNDATION FOR IMPROVING HOME-BASED AND TELEMEDICINE SYSTEMS AND EXPANDING THE USE OF DIGITAL HEALTH	161
REGULATORY OVERLAP IN DIGITAL MEDICAL DEVICE GMP AUDITS	163
PHARMACEUTICALS	165
OVERVIEW	166
INNOVATIVE MEDICINES: VALUE AND PATIENT ACCESS	167
PRICING INNOVATIVE MEDICINES BASED ON TRUE VALUE (ENHANCING ICER THRESHOLDS FOR INNOVATION)	167
EXPEDITED LISTING AND REIMBURSEMENT PATHWAYS FOR NEW MEDICINES	170
EXPANSION OF FLEXIBLE PRICE CONTRACT SYSTEM	173
INTRODUCTION OF INDICATION-BASED PRICING	176
ENSURING PREDICTABLE OFF-PATENT AND GX PRICING REFORM	178
OPEN PARTNERSHIP FOR THE BIOPHARMACEUTICAL ECOSYSTEM	180
ENHANCING THE INNOVATIVE PHARMACEUTICAL COMPANY (IPC) DESIGNATION FRAMEWORK TO ENSURE FAIR RECOGNITION AND MEANINGFUL INCENTIVES	180
REGULATORY FRAMEWORK FOR VACCINES AND IMMUNIZATION POLICIES	182
IMPROVING THE PREDICTABILITY OF THE NATIONAL IMMUNIZATION PROGRAM (NIP) TO ENSURE EFFECTIVE INFECTIOUS DISEASE MANAGEMENT	182
INTELLECTUAL PROPERTY PROTECTION FOR PHARMACEUTICALS	185
INTELLECTUAL PROTECTION CHALLENGED BY THE AMENDMENT TO THE PATENT ACT	185
TAXATION	187

OVERVIEW..... 188
EDUCATION TAX.....189
EXEMPTION FROM WITHHOLDING TAX ON KTBS AND MSBs 191
PRE-PAYMENT REQUIREMENT FOR TAX DISPUTES193
ENSURING TAX NEUTRALITY AND COMPETITIVENESS FOR THE BEER INDUSTRY195
ENHANCING PREDICTABILITY AND PROPORTIONALITY IN TAX AUDITS AND ENFORCEMENT197
TABLE OF ABBREVIATIONS 199
APPENDIX: AMCHAM BUSINESS SURVEY 2026202

Report Summary: Key Findings

Industry	Key Issues	Recommendations
Aerospace & Defense	DAPA Offset Guidelines Allow Unfair Advantage for Contractors with Commercial Business / Affiliates NEW	Remove the Article 17.3.3 restriction that limits non-defense offset export proposals only to OEM affiliates, or exclude non-defense items from offset eligibility entirely to ensure fair competition.
	Need Clarity Over Equipment Provision Offset Criteria NEW	Add "Provision of Equipment" as an eligible item under Article 13.3 to provide clearer guidance and enable greater flexibility for OEMs to strengthen Korea's defense capabilities.
	Need Clarity Over Recognition of Know-How Fee for Manufacturing and Export Projects NEW	Remove Article 16.4.2.b to allow Know-How Fees for manufacturing and export projects without restrictions, thereby incentivizing OEMs to transfer more advanced and globally competitive technology.
	Need Clarity Over DAPA's Request for Industrial Cooperation (IC) Plans	Provide guidance and clarification regarding the Industrial Cooperation plans to enable OEMs to deliver the best solutions for Korea's defense industry
	Onerous Penalty Provisions in Offset Terms & Obligations	Incorporate an additional provision in the Offset Guidelines so DAPA could consider replacement projects by the contractor that has greater offset value than the shortfall.
Agriculture	Streamlining Agricultural Biotechnology Approvals and Eliminating the Backlog of U.S. Applications	Streamline LMO Act procedures by eliminating redundant multi-agency reviews for FFP imports, establishing MOTIR-led structural reforms, and enabling MFDS and RDA as sole risk assessors, with early enactment of pending legislation to align with international standards and reduce non-tariff barriers.

Automobiles	Adoption of a Pre-Certification Regime for Key Emerging Automotive Technologies NEW	Consider transitioning back to the existing self-certification-based system after a validation period to minimize regulatory overlap.
	Full Authorization of U.S.-Equivalent Level 2 Autonomous Driving Technologies NEW	Grant greater flexibility for advanced Level 2+ functionalities and align with international regulatory approaches like those in the U.S.
	Relaxation of Robotaxi Regulations to Promote Mobility Rights NEW	Enhance regulatory flexibility for fully driverless services to address mobility needs and accelerate deployment.
	Simplification of Emissions Certification Procedures under the U.S.-Korea Tariff Negotiations NEW	Provide clear, detailed guidance on vehicle eligibility, effective dates, and timelines for the streamlined procedures as agreed upon in the Joint Fact Sheet.
	Strengthening Carbon Emission Trading System in the Transportation Sector NEW	Enhance regulatory clarity, expand coverage to key transport sub-sectors (e.g., logistics and public transit), strengthen consistent and transparent enforcement to build market confidence, and streamline compliance procedures to support broader participation.
	Auto GHG/CAFE Rules for 2026-2030	Adopt transparent procedures and foster open communication with industry stakeholders in setting realistic GHG/CAFE rules for 2026-2030.
	Discriminatory EV Subsidy Policy Against Non-Target Companies under the Low-Emission Vehicle Supply Mandate (LEVSM)	Revise the LEVSM eligibility criteria to reflect recent EV sales instead of 2009 vehicle sales record, fostering EV adoption, market participation, and Korea's carbon neutrality goals.
	Duplication of Penalty Systems: LEV/ZEV Mandate and GHG Regulations	Reconsider the LEV/ZEV Supply Target Policy, either by abolishing it or revising the associated penalty system to eliminate redundant regulatory burdens.
	NACS Charging Standard Adoption	Revise the Act on the Promotion of Development and Distribution of Environment-Friendly Automobiles to include NACS as an accepted charging standard.
	Overlapping Regulations on Electric Vehicles	Minimize industry burden and avoid redundant rules through government-wide consultation and review.

Chemicals	Streamlining Communication Obligations for Chemical Substances Registered or Notified under Article 29-1 of K-REACH NEW	Establish GHS-aligned concentration thresholds and recognize SDS-based communication for mixtures to reduce duplication and administrative burden.
	Simplifying Notification Requirements for Sellers of Hazardous Chemicals under Article 29-2 of the Chemical Substances Control Act NEW	Delete or exempt duplicative CCA provisions by recognizing SDS submission as sufficient for hazardous chemical information requirements.
	Facilitating Confidential Business Information Approvals for Trade Secret Ingredients in R&D Samples	Exempt trade secret ingredients in R&D samples from Non-Disclosure Approval under OSHA to accelerate innovation.
	Aligning the List of Existing Chemicals between K-REACH and OSHA	Harmonize chemical inventories and thresholds under K-REACH and OSHA to improve consistency and reduce duplicate compliance burdens.
	Clarifying Biocidal Product Labeling Requirements under the Consumer Chemical Products and Biocides Safety Act NEW	Provide clear labeling transition rules, including a one-year grace period and guidance on products in circulation.
	Easing Hazards and Risk Data Submission Criteria for Fragrances in Biocidal Products	Expand and recognize a broader scope of hazard data for biocidal product approval.
	Recognition of Internationally Approved Biocidal Substances and Products NEW	Introduce mutual recognition for biocidal approvals from trusted foreign authorities and adopt a risk-based re-evaluation model.
	Recognition of Internationally Approved Preservatives Used in Biocidal-Treated Products NEW	Apply science-based criteria under Article 23(2) for biocidal recognition, focusing on essential identity over formal differences.
	Request for Regulatory Amendment to Facilitate Market Entry of Concentrated Industrial Chemical Products NEW	Allow evaluation of concentrated products based on final use concentration and establish a dedicated regulatory category.
	Clarifying Registration Requirements for Ingredients in Hygiene Products under the Hygiene Products Standards NEW	Accept manufacturer- or importer-issued documentation for registration and clarify the negative list transition timeline.

Digital Economy	Digital Infrastructure & Network Interconnection NEW	Eliminate the 2016 “Sender-Pays” interconnection framework and adopt Settlement-Free Peering to restore competition and attract digital infrastructure investment.
	Online Platform Regulations and KFTC Enforcement	Discontinue the proposed legislation and engage in comprehensive stakeholder consultation to ensure harmonized Korea–U.S. technology regulation and avoid trade friction.
	Application of the Cloud Security Assurance Program (CSAP)	Extend logical network separation to the Moderate tier and revise Korea-specific data residency and cloud requirements to align with global standards.
	Artificial Intelligence	Leverage the AI regulatory grace period to incorporate industry feedback, clarify narrow criteria for High-Impact AI, establish clear training data rules, and align PIPA enforcement with a risk-based accountability model.
	Designation of a Local Representative	Refrain from expanding and roll back requirements that compel foreign service providers to designate a local agent or domestic representative in Korea.
	Legislative Bill on Safety Management of Digital Disasters and Failures	Reevaluate the proposed bill to ensure tailored, proportionate obligations that preserve constitutional principles and minimize undue business burdens.
	Personal Information Protection Act (PIPA)	Align personal information protection regulations with global standards by allowing voluntary certifications, setting reasonable administrative fines, and facilitating cross-border data transfers.
Energy & Environment	Need for Fast-track System to Supply Power for Datacenters NEW	Establish a fast-track approval system enabling AI datacenters to operate as energy prosumers with on-site generation and streamlined permitting, while maintaining grid stability safeguards.
	Energy Supply and Renewable Procurement Constraints for AI and Digital Infrastructure NEW	Enhance predictability and transparency in electricity policy by providing early grid capacity signals, improving inter-agency coordination, and strengthening renewable procurement frameworks.

	Bilateral Agreements for CO ₂ Transport and Storage and the Establishment of Common CO ₂ Storage Standards		Expand bilateral CCUS agreements and align international standards to enable timely CO ₂ transport and storage, while establishing a comprehensive domestic and cross-border regulatory framework to support long-term industry development and emissions reduction goals.
	Need for Strengthening the Hydrogen Sector		Refine and stabilize the Clean Hydrogen Power System (CHPS) to better reward emissions reductions, reduce commercial risk, and ensure predictable auction timelines that support long-term investment.
	Policy Improvement for the Distributed Power Sector		Ensure greater microgrid independence and introduce clear regional pricing and differential tariff guidelines reflecting transmission costs and local demand.
	Enabling the Use of Supplier-Provided Technical Documentation for RoHS Substance Compliance under the Act on Resource Circulation of Electrical and Electronic Equipment and Vehicles NEW		Recognize foreign-issued compliance documentation and extend the implementation timeline for hazardous substance restrictions to facilitate smoother global supply chain compliance.
Financial Services	General Issues	Relaxation of Network Separation Standards NEW	Ease the network separation requirements for secure networks (e.g., leased lines, internal business terminals) connected to Overseas Affiliates or institutional investors, or recognize the business necessity of such connections as exceptions to the requirement. Apply the same approach behind recognition of SaaS-related network separation exception to connections between onshore IT systems and terminals of Overseas Affiliates over secure private or dedicated networks, and clarify the applicable criteria under the Detailed Enforcement Rules of the EFSR and refine the framework based on risk-based criteria for network separation requirements so as to permit exceptions where appropriate alternative data protection controls are in place.
		Update of the Verification Practices under the Real Name Act NEW	Deem compliance with the CDD requirements under the Specified Financial Transaction Act to satisfy the real-name verification obligation under the Act on Real Name Financial Transactions and Confidentiality. Permit financial institutions to implement verification procedures aligned with international standards, provided that such procedures do not undermine the statutory objectives of the Act on Real Name Financial Transactions and Confidentiality and the Specified Financial Transaction Act.

Banking & Securities	Recognition of Head Office Capital NEW	Amend the Bank Act to recognize all or a significant portion of the head office's capital as the capital of a foreign bank branch.
	Macro-prudential Stability Levy NEW	Exclude short-term borrowings from the head office or offshore affiliates from the macro-prudential stability levy calculation base.
	Relaxation of Foreign Exchange Position Limits NEW	Implement measures to enable foreign bank branches and RFIs to compete on an equal footing, either by revising the equity capital calculation methodology or granting specific exemptions from the limits for foreign bank branches.
	Increase in Cash Pooling Management Limit NEW	Raise the cash pooling limit from USD 50 million to USD 100 million.
	Authorization – Approval of MSB Investment Dealing License NEW	Consider granting investment dealing business licenses for MSBs to domestic banks, including foreign bank branches, possibly limiting the business scope to transactions exclusively with foreign investors to mitigate conflict with securities firms.
	Consistency in the Application of License Requirements NEW	Amend or clarify the legal framework to apply exemptions consistently and fairly across different restructuring scenarios and post-restructuring maintenance.
	IPO Underwriter Lock-Up and Retention Requirements NEW	<p>30-Day Lock-Up Requirement for Underwriter in Cases of Undersubscription: Reconsider the interpretive ruling to permit a foreign underwriter to sell the undersubscribed shares to its overseas affiliate post-acquisition, notwithstanding the 30-day lock-up.</p> <p>Underwriter Retention Requirement in Cases of Lock-Up Allocation Shortfall: Grant exceptions to the new IPO preferential allocation requirements for foreign underwriters of domestic IPOs that allocate shares to foreign investors, aligning with global market practices.</p>

		<p>Enforcement for Breach of Short Selling Requirements NEW</p>	<p>Amend the short sale regulatory regime to provide a basis for a more equitable level of sanctions for breaches due to inadvertent error or mistake that do not involve intentional market abuse; and establish a channel for industry consultation in connection with the ongoing rationalization of short-selling regulations and the enhancement of reporting requirements under the Naked Short Selling Detection System (NSDS).</p>
	<p>Insurance & Alternative Investment</p>	<p>Scope 3 Implementation: The Need for Insurance-Specific Guidance for Foreign-Invested Companies NEW</p>	<p>Recommend aligning Korea’s Scope 3 framework with internationally recognized disclosure standards to avoid unnecessary divergence and developing insurance-specific Scope 3 guidance to allow flexible calculation methodologies that reflect the structural characteristics of the insurance sector.</p>
		<p>Uncertainty around the Equity Repo Business in Korea NEW</p>	<p>Enhance regulatory transparency to support the continued development of Korea’s capital markets, eliminate uncertainty arising from non-transparent barriers affecting foreign institutions, and provide clear best practice guidelines for equity repo transactions to ensure compliance with the Financial Investment Services and Capital Markets Act.</p>
		<p>Excessive Regulatory Control on Financial Products</p>	<p>Adopt a principles-based approach that balances consumer protection with innovation, allowing flexibility in product design while ensuring USD-denominated financial products receive fair treatment vis-à-vis KRW-denominated products to enhance choice and market efficiency.</p>
<p>Labor</p>		<p>Interpretation Guidelines for the Amended Trade Union and Labor Relations Adjustment Act (“Yellow Envelope Act”) NEW</p>	<p>Refine and clarify the interpretation guidelines to enhance legal predictability, clearly define employer status and bargaining obligations, and ensure judicial review for collective agreement violations.</p>
		<p>Expansion of the Deemed Working Hours System for Discretionary Work NEW</p>	<p>Broaden eligibility for the deemed working hours system to include investment banking professionals and introduce greater flexibility for highly compensated professionals in line with international standards.</p>
		<p>Ensuring Inclusive Representation in Labor Management Councils NEW</p>	<p>Amend the Workers’ Participation Act to ensure proportionate and inclusive representation of all employees, including non-union and non-regular workers, in Labor Management Councils.</p>

Medical Devices	Improvement of Diagnosis-Related Group (DRG) System		Enhance the DRG system by expanding patient choice through appropriate cost-sharing, enabling timely inclusion of innovative technologies, and strengthening stakeholder engagement in DRG revisions.
	Needs for Improvement of New Healthcare Technology Assessment (nHTA) System		Reform the nHTA and new procedure fee review processes to improve efficiency, predictability, and patient-centeredness by better reflecting clinical value and innovation while eliminating redundant assessments.
	Necessity of Reforming and Introducing Greater Flexibility in the nHTA Process for Technologies Targeting Severe and Critical Diseases NEW		Introduce greater flexibility in the nHTA framework for severe and critical diseases by establishing expedited review tracks, adopting proportionate evidentiary standards, recognizing broader clinical endpoints, and expanding the use of real-world evidence.
	Policy Support for Medical Devices Necessary for Cancer Diagnosis and Treatment		Establish appropriate reimbursement and alternative payment models for innovative medical devices, including active implementation of conditional reimbursement mechanisms to ensure timely and equitable patient access.
	Necessity of Expanding Support for Suppliers to Ensure the Stable Supply of Pediatric Medical Devices and Therapeutic Materials NEW		Safeguard a sustainable supply of essential pediatric medical devices through priority reimbursement, flexible pricing adjustments, and strengthened cross-agency coordination.
	Establishing a Foundation for Improving Home-Based and Telemedicine Systems and Expanding the Use of Digital Health		Establish a sustainable framework for home-based care and digital health by introducing permanent reimbursement codes and phased expansion for high-impact services.
	Regulatory Overlap in Digital Medical Device GMP Audits		Adopt mutual recognition of GMP audits for digital medical devices and expand authorized audit bodies to streamline certification and accelerate market entry.
Pharmaceutical	Innovative Medicines: Value and Patient Access	Pricing Innovative Medicines Based on True Value (Enhancing ICER Thresholds for Innovation)	Strengthen value-based pricing for innovative medicines by expanding NHI investment, raising and tiering ICER thresholds to reflect disease severity and innovation, incorporating broader societal value, and modernizing comparator standards.
		Expedited Listing and Reimbursement Pathways for New Medicines	Ensure timely and effective implementation of expedited reimbursement pathways for innovative medicines through clear timelines, reduced duplication, and early, continuous dialogue with industry stakeholders.

		Expansion of Flexible Price Contract System	Ensure the prompt rollout of the Flexible Pricing Contract System with clear operational guidance, broader eligibility including RSA medicines with refund components, and safeguards to protect confidential transaction prices.
		Introduction of Indication-Based Pricing	Introduce an indication-based pricing system that reflects indication-specific clinical value and budget impact, supported by pilot implementation and clear operational rules.
		Ensuring Predictable Off-patent and Gx Pricing Reform NEW	Implement Gx pricing reform in a predictable and phased manner through structured industry consultation, adequate grace periods, reasonable reduction rates, and transparent timelines to safeguard supply stability and investment.
	Open Partnership for the Biopharmaceutical Ecosystem	Enhancing the Innovative Pharmaceutical Company (IPC) Designation Framework to Ensure Fair Recognition and Meaningful Incentives	Reform the IPC designation framework to fairly recognize innovation by multinational as well as domestic companies, including global R&D and partnership contributions, and link designation to meaningful, predictable incentives.
	Regulatory Framework for Vaccines and Immunization Policies	Improving the Predictability of the National Immunization Program (NIP) to Ensure Effective Infectious Disease Management	Strengthen NIP governance through clear timelines, transparent evaluation criteria, structured stakeholder consultation, faster inclusion of innovative vaccines, and stable long-term budget support.

	Intellectual Property Protection for Pharmaceuticals	Intellectual Protection Challenged by the Amendment to the Patent Act	Amend the Patent Act to better protect pharmaceutical innovation by aligning PTE rules with global standards, safeguarding coverage for future indications, and carefully reviewing compulsory licensing provisions.
Taxation	Education Tax NEW	Reform the education tax regime to ensure equitable treatment across industries and prevent taxation in the absence of actual income.	
	Exemption from Withholding Tax on KTBs and MSBs NEW	Exempt foreign Investors from withholding tax exemption documentation requirements when foreign status is verifiable, ensuring a level playing field between offshore iCSDs and onshore institutions.	
	Pre-Payment Requirement for Tax Disputes NEW	Introduce a balanced tax dispute framework with a formal stay-of-collection mechanism and OECD-aligned safeguards to reduce undue business disruption during bona fide disputes.	
	Ensuring Tax Neutrality and Competitiveness for the Beer Industry NEW	Consider a partial reduction of the beer excise tax to restore tax neutrality, ease industry cost pressures, and support sector sustainability.	
	Enhancing Predictability and Proportionality in Tax Audits and Enforcement	Enhance predictability and proportionality in tax audits by aligning interpretations with OECD guidance and reserving criminal enforcement for clear cases of tax evasion.	

Note: "New" refers to new regulatory issues that have arisen since last year's AMCHAM report.

INTRODUCTION

As the largest foreign chamber of commerce in Korea, the American Chamber of Commerce (AMCHAM) is pleased to present the 2026 edition of our annual *Business Environment Insights* report. The U.S.-Korea commercial relationship stands at a critical juncture, as technological competition, supply chain resilience, and the rapid advancement of AI reshape global priorities.

Amid renewed U.S. policy focus on balanced trade, fair competition, and reshoring, both countries are engaging in active dialogue to realign bilateral trade and investment frameworks. Korea – now Asia’s 4th largest economy and a global leader in semiconductors, advanced displays, and automotive manufacturing – has emerged as a key economic, technological, and security partner to the U.S.

In this evolving landscape, regulatory alignment has become central to unlocking deeper cooperation. AMCHAM’s *Buy America* campaign, launched in 2025 to address non-tariff barriers and promote U.S. goods and services, has already delivered tangible outcomes across key sectors, including automotive, energy, AI, retail, and infrastructure. Continued progress will depend on transparent, predictable, and globally aligned regulatory frameworks.

This report highlights Korea-specific regulatory challenges that affect the entry and expansion of U.S. companies – ranging from divergence from global standards to complex and evolving rules that may constrain innovation. Addressing these issues is essential to strengthening Korea’s position as a regional headquarters and innovation hub.

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.

AMCHAM AT A GLANCE

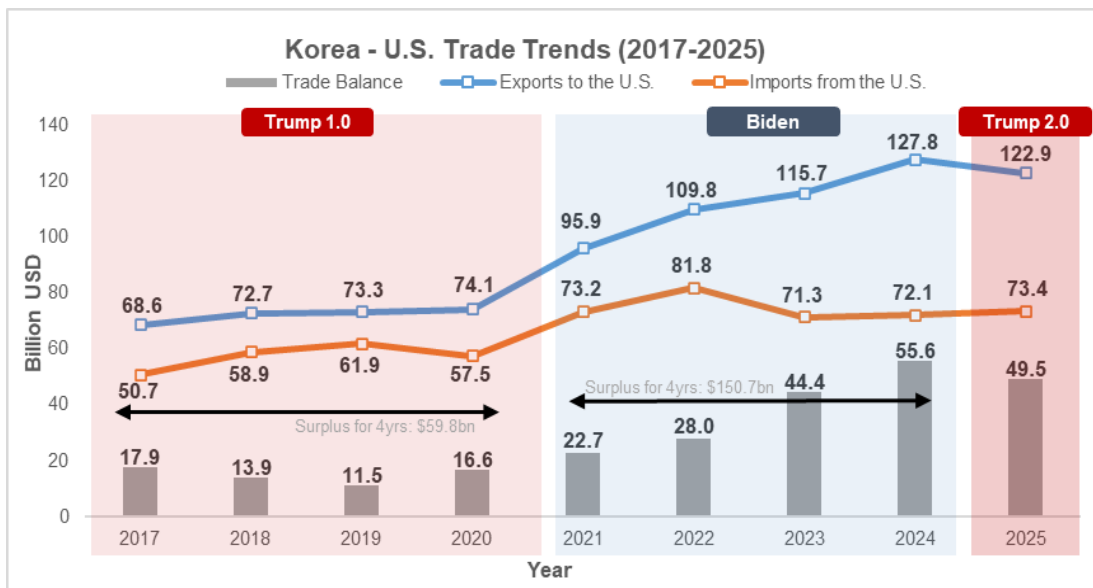


73 years in history
800+ corporate members and affiliates
1,500+ individual members
28 industry committees
Board of Governors

A TRANSFORMATIVE PHASE IN THE U.S.-KOREA ECONOMIC PARTNERSHIP

The U.S.-Korea partnership has entered a new phase, expanding beyond trade and security into a comprehensive strategic relationship encompassing technology and economic security. The bilateral commercial ties between the two countries have deepened considerably over the past decade, with the total trade in goods increasing by more than 60%, from \$119.4 billion in 2017 to \$196.2 billion in 2025.

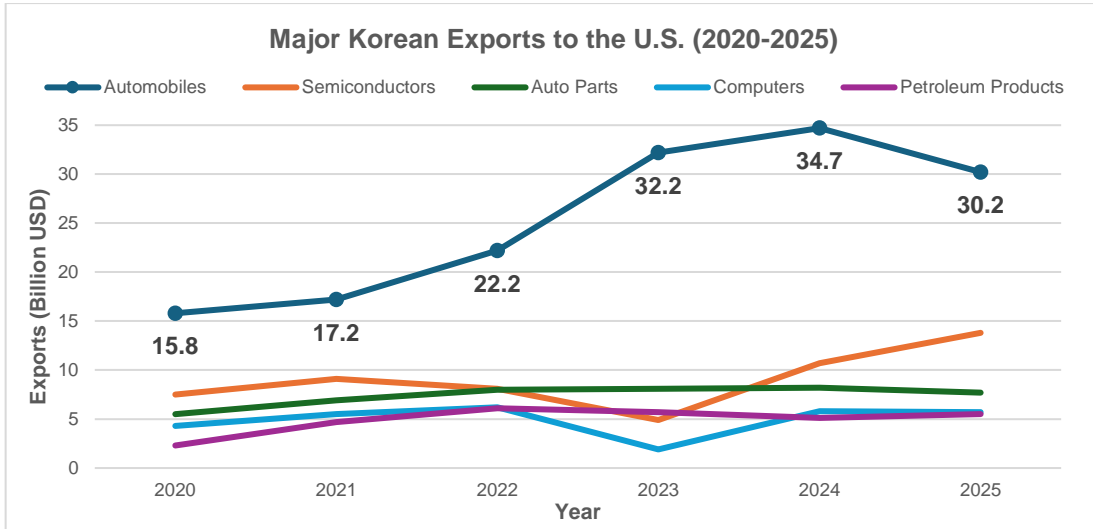
U.S. exports to South Korea increased from \$50.7 billion to \$73.4 billion during this period, while Korean exports to the U.S. grew from \$68.6 billion to \$122.9 billion.¹ More recently, Korea’s trade surplus with the U.S. narrowed from \$55.6 billion in 2024 to \$49.5 billion in 2025, driven by a slight 1.8% decline in Korea’s exports to the United States in 2025, including a 13.2% drop in automotive exports.² Even so, the broader trajectory of bilateral trade remains firmly upward, reflecting the growing depth, resilience, and strategic importance of the bilateral economic relationship.



SOURCE: KOREA INTERNATIONAL TRADE ASSOCIATION (KITA)

¹ “Exports and Imports by Country”, Korea International Trade Association (KITA)

² “Exports and Imports by Country”, Korea International Trade Association (KITA)



SOURCE: KOREA INTERNATIONAL TRADE ASSOCIATION (KITA)

In parallel with these developments, the Lee Jae-myung administration has identified the ABCDEF industries – AI, Bio, Contents and Culture, Defense, Energy, and Factory – as strategic priorities for Korea’s next phase of growth. With foreign investment, global engagement, and regulatory reforms at the center of this agenda, the U.S.–Korea partnership will remain an important pillar of implementation. AMCHAM will continue working closely with the Korean government and industry stakeholders to help advance cooperation across these sectors.

REBUILDING MANUFACTURING THROUGH STRATEGIC U.S.–KOREA INVESTMENT

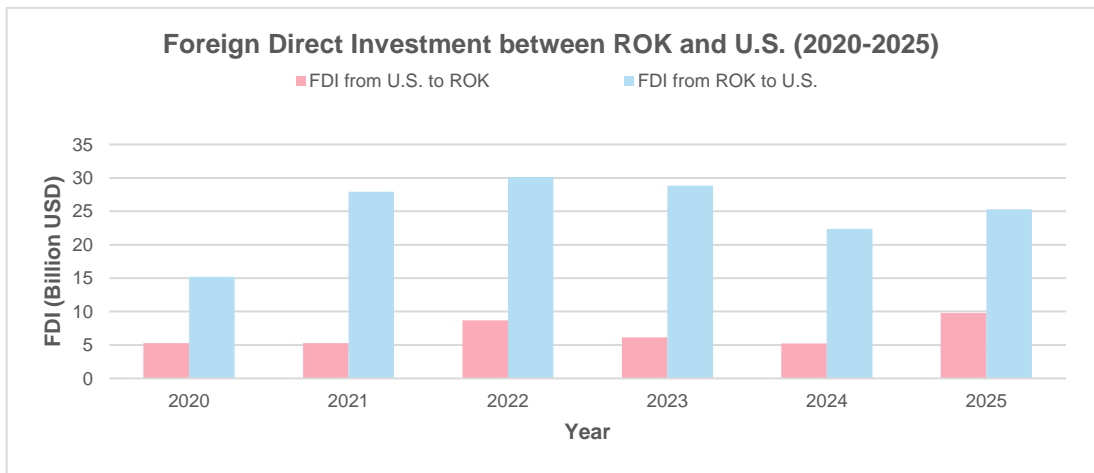
The U.S. and South Korea continue to demonstrate unprecedentedly strong economic ties, particularly across manufacturing and high-tech industries. Bilateral investment flows reached historic highs in 2025, highlighting both the scale and strategic significance of the partnership. The Joint Fact Sheet, released in November 2025 alongside the recent trade agreement, serves as a key roadmap for future collaboration, including plans for Korean companies to invest more than \$350 billion annually in the U.S. over the next decade.

In 2025, Korea’s outbound investment to the U.S. reached \$25.27 billion, up 12.9% from 2024.³ U.S. foreign direct investment into Korea also surged to \$9.77 billion –

³ “Statistics of Foreign Direct Investment”, Korea Export-Import Bank

the highest level on record. This 86.6% increase⁴ from the previous year was largely driven by major greenfield investments in strategic high-tech sectors, including AI data centers and advanced materials manufacturing.⁵

Manufacturing cooperation is also expanding across shipbuilding, batteries, semiconductors, and automobiles – industries central to the economic and national security interests of both countries. Major investments by leading Korean companies in semiconductor, EV, and battery production are helping strengthen the U.S. industrial base while reinforcing Korea’s role in critical supply chains.



SOURCE: KOREA EXPORT-IMPORT BANK; MINISTRY OF TRADE, INDUSTRY AND RESOURCES

At the same time, both governments are taking steps to address long-standing non-tariff barriers that have constrained trade and investment. The Joint Fact Sheet highlights long-standing issues across sectors such as automotive, food and agriculture, and digital services, while outlining commitments to improve market access, reduce regulatory frictions, and enhance transparency.

These efforts are expected to advance through the KORUS Joint Committee, providing an institutional mechanism for implementation and accountability. If fully realized, they could strengthen investor confidence and support a more predictable and competitive business environment.

Key non-tariff issues addressed under the Joint Fact Sheet are summarized in the table below.

⁴ “Foreign Direct Investment Statistics”, Ministry of Trade, Industry and Resources

⁵ “Press Releases”, Ministry of Trade, Industry and Resources

Sector	Key Issues
Automotive	<ul style="list-style-type: none"> • Elimination of the cap on FMVSS-compliant U.S. vehicles • Reduction of duplicative emissions certification requirements
Food and Agriculture	<ul style="list-style-type: none"> • Streamlining the regulatory approval process for agricultural biotechnology products • Establishment of a dedicated U.S. desk for horticultural products • Preservation of market access for U.S. meats and cheeses
Digital Services	<ul style="list-style-type: none"> • Commitment to nondiscriminatory treatment of U.S. firms under digital-related laws and policies, including network usage fees and online platform regulations • Facilitation of cross-border data transfers, including location, reinsurance, and personal data • Support for the WTO moratorium on customs duties on electronic transmissions
Competition Policy	<ul style="list-style-type: none"> • Strengthening procedural fairness in competition proceedings, including recognition of attorney-client privilege
Intellectual Property	<ul style="list-style-type: none"> • Continued steps toward accession to the Patent Law Treaty
Labor Rights	<ul style="list-style-type: none"> • Cooperation to protect internationally recognized labor rights and combat forced labor, including goods made with forced labor
Environment	<ul style="list-style-type: none"> • Commitment to ensure differences in environmental protection do not distort trade and investment • Effective enforcement of environmental laws, including implementation of the WTO Agreement on Fisheries Subsidies

U.S.–KOREA AI PARTNERSHIP AS A NEXT-GENERATION GROWTH ENGINE

Artificial intelligence has emerged as a defining pillar of the U.S.-Korea economic partnership. The U.S. leads in AI models, platforms, and services, while Korea complements these strengths with world-class capabilities in semiconductors, advanced manufacturing, and large-scale deployment – creating a highly synergistic ecosystem.

The Korean government is advancing an ambitious strategy to position the country as a global AI leader through expanded infrastructure, large-scale investment, and ecosystem development. This presents a significant opportunity for U.S.-Korea collaboration at a time when both countries are seeking to enhance technological competitiveness and economic resilience.

Recognizing AI's strategic importance, AMCHAM is launching the *AI Leadership Council* to facilitate structured engagement with senior policymakers and contribute industry-driven perspectives to Korea's evolving AI policy framework.

At the same time, regulatory challenges remain a key concern. According to *2026 AMCHAM Business Environment Survey*, nearly 70% of respondents view Korea's regulatory environment as restrictive. Korea ranked third as a preferred regional headquarters location – behind Singapore and Hong Kong – reflecting concerns over labor policies and Korea-specific regulations. In the AI sector, priority reforms include establishing predictable, business-friendly regulatory frameworks and enabling cross-border data flows.⁶

In this context, AMCHAM remains committed to serving as a bridge between the U.S. and Korea – advancing policy alignment, strengthening regulatory transparency, and fostering deeper collaboration in next-generation industries.

⁶ For full survey results, please refer to the comprehensive report at the end of this publication.



AEROSPACE & DEFENSE

TABLE OF CONTENTS

NO.	ISSUE	STATUS
	Overview	
01	DAPA Offset Guidelines Allow Unfair Advantage for Contractors with Commercial Business / Affiliates	NEW
02	Need Clarity Over Equipment Provision Offset Criteria	NEW
03	Need Clarity Over Recognition of Know-How Fee for Manufacturing and Export Projects	NEW
04	Need Clarity Over DAPA Request for Industrial Cooperation (IC) Plans	
05	Onerous Penalty Provisions in Offset Terms & Obligations	

AEROSPACE & DEFENSE

OVERVIEW

South Korea remains a primary market for U.S. aerospace and defense exports. From August 2024 to July 2025, U.S. aerospace and defense exports to South Korea totaled approximately \$4.67 billion, accounting for about 7.2% of total exports to APEC economies and ranking as the 6th largest destination among the APEC countries.⁷ In parallel, South Korea has recently emerged as one of the world's fastest-growing defense exporters, rising from its 31st place in 2000 to become the 9th largest arms exporter globally as of 2025.⁸ As part of President Lee Jae-Myung's ABCEDF policy agenda, defense exports have been designated a strategic priority sector, with the Korean government aiming to position Korea among the world's top four defense exporters by 2027⁹.

The Aerospace and Defense industry has witnessed significant strides in cooperation between the U.S. and South Korea, marked by the signing of the Security of Supply Arrangement (SOSA) in November 2023, to enable priority delivery requests for defense-related goods between the two countries. Furthermore, both the U.S. and Korean governments are engaged in discussions concerning the Reciprocal Defense Procurement (RDP) Agreement, which, if signed, would establish a structured framework for reciprocal market access and sustained defense industrial cooperation in areas such as co-production and sustainment. These efforts are reinforced by the recent U.S.-ROK Joint Fact Sheet, which highlights Korea's plan to increase defense spending to 3.5% of its GDP and commit \$25 billion to purchases of U.S. military equipment by 2030. The Joint Fact Sheet further underscores both governments' commitment to enhancing combined defense capabilities through the acquisition of advanced U.S. weapons systems and expanded bilateral defense industrial cooperation in high-technology weapons systems.

In light of these developments, AMCHAM strongly believes that efficient reform of Korea's defense acquisition policy will foster robust, high-value industrial

⁷ U.S. Department of Commerce, International Trade Administration. (2025). *Aerospace & Defense Exporter Alert (December 2025)*. <https://www.trade.gov/aerospace-defense-exporter-alert-dec-2025>

⁸ Stockholm International Peace Research Institute (SIPRI), Trends in International Arms Transfers, 2025 (2026) https://www.sipri.org/sites/default/files/2026-03/fs_2603_at_2025.pdf

⁹ Office of the President of the Republic of Korea. (2025). *President highlights ambition to position Korea as a leading global defense and aerospace power*. <https://www.korea.kr/news/policyNewsView.do?newsId=148952420>

collaboration between the U.S. and Korea. As part of these efforts, the proposed Offset Policy Improvement Plan announced in June 2025 by the Defense Acquisition Program Administration (DAPA) represents a noteworthy and constructive step toward addressing longstanding industry concerns, including the easing of penalty structures through reduced rates and greater reliance on implementation extensions, the introduction of performance-based incentives, the expansion of eligible offset categories, and enhanced flexibility and transparency in the evaluation and execution of offset obligations. While the proposed measures signal a positive direction, they have yet to be formally implemented, and their implementation is expected to be closely tied to the conclusion of RDP-A. In this regard, timely progress on both the RDP-A and the offset policy reforms will be critical to deepening bilateral defense industrial cooperation.

AMCHAM remains committed to supporting Korea's national security interests and industrial objectives as well as the U.S.-ROK Alliance. AMCHAM urges both governments to collaborate closely with the industry to refine acquisition policies, thereby enhancing Korea's long-term capacity to advance its defense industry objectives globally. Such efforts will also bolster Korea's strategic deterrence capabilities.

DAPA Offset Guidelines Allow Unfair Advantage for Contractors with Commercial Business / Affiliates NEW

Under Article 17.3.3 of the Offset Guidelines, only affiliates of the contractors are allowed to propose export of non-defense items for offset.

This greatly disadvantages contractors that specialize exclusively in defense products and solutions. OEMs that do not own subsidiaries or have affiliates specializing in commercial items may otherwise rely on third parties to purchase from the Korean industry and thereby fulfill the spirit and intent of the Offset policy. However, under the current Guidelines, this is not possible. By contrast, OEMs with both defense and commercial businesses are not affected by this restriction and are able to freely propose the purchase of commercial items for offsets. Where these different types of OEMs are competing for the same contract, this creates a significant issue of fairness in competition.

- **Issue**

Article 17.3.3 of the Offset Guidelines limits non-defense offset proposals to contractor affiliates, placing defense-only OEMs without commercial affiliates at a disadvantage and creating unequal competitive conditions when competing against diversified OEMs in defense procurement.

- **Relevant Regulations**

DAPA Offset Guidelines, Article 17.3.3: However, in the case of subparagraph 9 of Article 13(3), only the affiliates of the concerned Foreign Contractor pursuant to subparagraph 12 of Article 2 of the Monopoly Regulation and Fair Trade Act can be approved on a case by case basis, and the undersigned or the issuer of the subcontract, purchase order, etc. shall be the same entity as the Eligible Party(ies).

- **Relevant Agencies**

Defense Acquisition Program Administration (DAPA)
Korea Research Institute for Defense Technology Planning and Advancement (KRIT)

- **Recommendation**

AMCHAM respectfully requests that DAPA either remove the restriction under Article 17.3.3 that limits the proposal of exports of non-defense items for offsets to OEM affiliates – by allowing reputable third parties to propose such exports subject to prior

DAPA approval – or, alternatively, remove non-defense items from offset eligibility altogether.

Need Clarity Over Equipment Provision Offset Criteria ^{NEW}

Under Article 16.4.3 (Offset Valuation), the provision of equipment is recognized as one of the criteria for offset evaluation; however, it is not defined as a standalone eligible offset category under Article 13.3.

There may be cases – as there have been in the past – where the provision of important equipment to the ROK Military, government, or industry could constitute an offset project in its own right. While DAPA may allow standalone equipment provision offset project under Article 13.3.8 (“Other items contributing to the national interest with regard to the improvement of the Republic of Korea’s defense capability”), this is a subjective provision and entirely at DAPA’s discretion. Contractors often develop high-value equipment provision offset projects without guidance or certainty on whether such projects may be accepted.

- **Issue**

The absence of equipment provision as a standalone offset category under Article 13.3, despite its recognition for valuation under Article 16.4.3, creates uncertainty and discretionary outcomes in offset planning.

- **Relevant Regulations**

DAPA Offset Guidelines, Article 13.3

DAPA Offset Guidelines, Article 16.4.3: Provision of Equipment and Tools;

(a) In the event that the Foreign Contractor provides used equipment and tools, two times the evaluated amount may be acknowledged, and if the Foreign Contractor provides new equipment and tools, three times the amount shall be approved. The Offset value of know-how shall not be acknowledged additionally.

- **Relevant Agencies**

Defense Acquisition Program Administration (DAPA)
Korea Research Institute for Defense Technology Planning and Advancement (KRIT)

- **Recommendation**

AMCHAM respectfully requests DAPA to consider adding the Provision of Equipment as an eligible item under Article 13.3. This would enable OEMs to more freely offer key equipment and tooling for ROK beneficiaries that would result in enhanced capability for Korea's defense industry and national security.

Need Clarity Over Recognition of Know-How Fee for Manufacturing and Export Projects ^{NEW}

Under Article 16.4.2.b (Offset Valuation), “the Technology Transfer fee related to item (a) shall not be acknowledged”; however, an exception may be made if the Know-How Fee can be proposed as separate projects under a different category.

This has led to and continues to create confusion as to whether, and to what extent, the Know-How Fee can be recognized for manufacturing and export projects. Contractors have consistently experienced significant – and at times complete – devaluation of the Know-How Fee for manufacturing and export projects by KRIT, because the basic principle of the Guidelines clearly provides that Know-How Fee will not be recognized for such projects. This, however, does not reflect the reality of manufacturing and export offset projects. From the smallest enterprises to large prime contractors across the domestic defense industrial base, companies that have not previously produced specific parts need extensive training, equipment and tooling, technical assistance by OEM experts, and follow-on support, not to mention development of technical documents and manuals, in order to begin manufacturing parts that meet the specifications and requirements of military and defense products. All of these items require substantial investment by OEMs, and these costs, as well as the associated intellectual property and past investments, are currently not being reflected in offset valuation. Where the Guidelines state that the Know-How Fee will not be allowed while also indicating that alternative approaches may exist, this gives rise to uncertainty and differing interpretations. In addition, this uncertainty, as well as the reluctance by KRIT to recognize the Know-How Fee, discourages OEMs from considering more complex, advanced, and globally competitive parts for local companies to build, because doing so usually requires greater investment and risk.

- **Issue**

Article 16.4.2.b of the Offset Guidelines excludes Know-How Fees for manufacturing and export projects in principle while allowing limited exceptions, thereby creating uncertainty and resulting in discretionary valuation by KRIT that fails to reflect the technical investment required for defense manufacturing and discourages higher-value offset projects.

- **Relevant Regulations**

DAPA Offset Guidelines, Article 13.3

DAPA Offset Guidelines, Article 16.4.2.b

- **Relevant Agencies**

Defense Acquisition Program Administration (DAPA)
Korea Research Institute for Defense Technology Planning and Advancement (KRIT)

- **Recommendation**

AMCHAM respectfully requests DAPA to remove Article 16.4.2.b from the Offset Guidelines and allow Know-How Fee for manufacturing and expert projects without any restrictions or exceptions. This would greatly incentivize OEMs to offer manufacturing of more complex, advanced, and globally competitive parts by the Korean industry and lead to the enhancement of the overall defense industrial capabilities of local companies.

Need Clarity Over DAPA's Request for Industrial Cooperation (IC) Plans

Recently, for several large-scale programs, DAPA IPTs (Integrated Project Teams) have been exempting offset requirements in order to optimize program costs, while requesting OEMs to submit Industrial Cooperation (IC) plans. According to the IPTs, these IC plans are non-binding, cannot add cost to the contract, and are captured in the form of an MOU between DAPA and the OEMs. We understand that these MOUs will be part of the overall approval process for DAPA's procurement source selection and contract execution.

As far as we are aware, the IC plan is not currently part of any regulation or guideline of the Korean government. It is being requested on a case-by-case basis by individual DAPA IPTs for each program. As a result, one business area within an OEM may be requested to submit IC plans in lieu of offset, while another business area in the same OEM may be required to develop a traditional offset proposal. This is causing confusion among OEMs, and therefore AMCHAM requests the following clarification from DAPA:

- ❑ Even though IC plans are intended to be non-binding, is there expectation from the Korean government that OEMs make significant effort to implement IC initiatives described in the plans? What, if any, are the expectations for reporting and monitoring of the IC effort? Would this on-going monitoring be performed by the IPT or by the Defense Industrial Cooperation Division (formerly the Offset Division)?
- ❑ Do IC plans need to be directly connected to the system being procured? (e.g. For a fighter procurement, do IC plans need to be related to that fighter platform?)
- ❑ Do IC plans need to have a fixed period of performance?
- ❑ Do IC plans need to be evaluated by KRIT (Korea Research Institute for Defense Technology Planning and Advancement)?
- ❑ Is there any long-term plan by DAPA to eventually codify IC plan requirements in their regulation?
- ❑ What happens if offset is waived for a program, but OEMs fail to submit IC plans as requested by the IPT?

- **Issue**
DAPA's inconsistent requests for Industrial Cooperation plans generate confusion among OEMs
- **Relevant Agencies**
Defense Acquisition Program Administration (DAPA)
- **Recommendation**
AMCHAM requests DAPA to provide guidance and clarification regarding the Industrial Cooperation plans in order for the OEMs to deliver the best solutions for Korea's defense industry while ensuring compliance with the rules and requirements of each procurement.

Onerous Penalty Provisions in Offset Terms & Obligations

DAPA's most recently released Offset Guidelines in October 2024 maintains Articles 23.3 and 23.4 (see below) which state that, in the event of non-performance, 10% of residual offset obligation will be confiscated from the offset performance bond if the obligation is not completed by the end of the agreed Proof of Performance (PoP); if the Overseas Contractor is still unable to perform the remainder of the obligation within the one additional year from the end of PoP, then 50% of the residual offset value will additionally be confiscated, and the remainder of the offset obligation will be liquidated.

This topic has been discussed between DAPA and AMCHAM on a number of occasions, and we very much appreciate DAPA's willingness to engage and provide detailed explanation for the continuation of the current penalty provision. However, it is nevertheless an unavoidable reality for OEMs that these articles pose an undue financial burden and make the U.S.-ROK industrial collaborations challenging as detailed below:

The total amount of confiscation if the contractor fails to perform, while liquidating, is very high. For example, for a \$100m offset program, the bond will be placed at \$10m; if \$20m remains at the end of PoP, \$2m will be confiscated at that point, and after one year, additional \$10m will be confiscated, making it a total of \$12m in terms of the confiscated amount. A contractor therefore would have completed 80% of their obligation, but still be subject to a payout of additional \$12m in an actual cost to close out the remaining \$20m offset value. In addition, the performance bond is not sufficient to cover the total amount of confiscation, while performance bonds cost money and impact the overall procurement cost.

This issue is compounded by the fact that DAPA's credit award for completed performance does not take place immediately, but rather several weeks or even months afterwards due to: offset implementation reports needing to wait until the preceding performance period is over before being prepared; DAPA's administrative backlog for individual managers; and occasional personnel changeovers on either side.

The restrictive penalty provision in the Offset Guidelines binds the DAPA as much as it binds overseas contractors. A contractor may fail to perform its offset obligation for a variety of causes that are not directly attributable to the contractor, and some may not be readily covered under the Force Majeure clause: there may be unforeseen downturn in market conditions which reduce expected production quantities; or there may be ambiguities or mistakes in the Offset Memorandum of Agreement (MOA) or

Technical Assistance Agreement (TAA) that are interpreted differently or even disputed by successive project managers, forcing the contractor to deviate from the original plan. At that point, it may be in the interest of all parties (DAPA, an overseas contractor, and the ROK industry alike) to seek alternative offset projects that may deliver an equal or greater benefit to Korea rather than resorting to punitive measures. However, because of Article 23, DAPA Defense Industrial Cooperation Division (formerly the Offset Division) has no choice but to impose the prescribed penalties.

AMCHAM strongly believes that a viable alternative or supplementary provision in the Offset Guidelines can be introduced, which reduces undue risk for OEMs while delivering greater value to Korea's beneficiaries in the event of non-performance. We respectfully request DAPA to review the inclusion of the following provision as Article 23.5:

- *Notwithstanding the preceding Article 23.3 and 23.4, if the Foreign Contractor submits a replacement offset project which is evaluated by KRIT to be of higher value than the amount of unfulfilled offset value caused by non-performance solely attributable to the Foreign Contractor, DAPA may negotiate and accept the replacement offset project without requiring confiscation from the Foreign Contractor.*

Article 23.3. and 23.4 of DAPA Offset Guidelines, October 2024

(3) "If the Foreign Contractor fails to fulfill its Offset obligation within the implementation period of the Offset MOA, the Director General shall confiscate 10% of the unfulfilled portion of said obligation from Offset performance bond as a penalty for contract violation.

(4) Even in case of above paragraph (3), the Foreign Contractor shall be obligated to continue to implement its unfulfilled obligation for 1 year upon the expiry of the implementation period. If the Foreign Contractor fails to complete its unfulfilled obligation, the Director General shall additionally confiscate 50% of the unfulfilled portion of the said obligation and extinguish the remaining unfulfilled value.

- **Issue**
Onerous and excessive penalty terms in Offset Guidelines

- **Relevant Regulations**
October 2024 DAPA Offset Guidelines, Offset Memorandum of Agreement, Technical Assistance Agreement, Offset Guidelines
- **Relevant Agencies**
Defense Acquisition Program Administration (DAPA)
- **Recommendation**
An additional provision needs to be included in the Offset Guidelines so that DAPA would have the option to consider replacement projects proposed by the contractor that have a greater offset value than the shortfall.



AGRICULTURE

TABLE OF CONTENTS

NO.	ISSUE	STATUS
	Overview	
01	Streamlining Agricultural Biotechnology Approvals and Eliminating the Backlog of U.S. Applications	

OVERVIEW

Agricultural trade remains one of the clearest success stories of the U.S.–Korea economic partnership. Although South Korea maintains high agricultural tariffs on non-FTA partners (on average around 57%), the KORUS FTA has eliminated duties on the majority of U.S. agricultural exports. When the agreement entered into force in 2012, nearly two-thirds of U.S. farm exports became duty-free immediately, with most remaining tariffs phased out over time. These preferential terms have supported steady growth in bilateral agricultural trade.

In 2024, U.S. agricultural and related exports to Korea reached approximately \$8.9 billion, making Korea the fifth-largest single-country market for these products. Key U.S. exports include beef, pork, corn, and other grains, reflecting strong Korean demand. Korean agri-food exports to the U.S. have also expanded significantly, reaching a record \$1.8 billion in 2025 (up 13.2% year-on-year), with the U.S. now serving as Korea’s largest overseas market for food exports.

In late 2025, both governments committed to further strengthening agricultural trade under a Joint Fact Sheet within a Strategic Trade and Investment Initiative. Korea agreed to address regulatory barriers by streamlining the regulatory approval process for agricultural biotechnology products, clearing backlogs of U.S. crop trait applications, ensuring full implementation of sanitary and phytosanitary agreements, facilitating horticultural imports through a dedicated “U.S. desk,” and maintaining market access for U.S. meat and cheese products using common food names. These measures aim to improve transparency and predictability in agricultural trade.

In this context, agricultural trade continues to serve as a key pillar of the U.S.–Korea economic relationship. Building on recent commitments under the Joint Fact Sheet, AMCHAM encourages both governments to further strengthen cooperation on tariff implementation and regulatory alignment to sustain current growth momentum and support the sector’s long-term development.

INDUSTRY ISSUES

Streamlining Agricultural Biotechnology Approval Process and Eliminating the Backlog of U.S. Applications

Agricultural biotechnology is essential to U.S. growers and traders, as more than 90% of U.S. corn, soybeans, and upland cotton are currently produced using biotech and supports productivity, sustainability, and resource conservation.

Since Korea is a major food/feed importer, Korean authorizations for biotech traits are critical for commercial launches in the U.S., as any presence of traits unauthorized by Korea is tightly restricted in commodity shipments. As a result, delays and unpredictability in Korea's approvals directly postpone the availability of innovative seed products for U.S. growers.

Korea's extraordinary regulatory measures for import approval of biotech crops, particularly the multi-agency Risk Review Consultation (RRC) under the Act on Transboundary Movements of Living Modified Organisms and Other Related Matters ("the LMO Act") resulting in each agency imposing specific data requirements, remain an unresolved non-tariff barrier despite sustained engagement by exporters, value-chain stakeholders, and the U.S. government for over a decade.

Without structural reform, Korea risks becoming a preeminent global choke point for the introduction of new biotech traits and the adoption of advanced agricultural technologies vital to U.S. growers.

- **Issue**
The excessively complicated multi-agency RRC process under the LMO Act on the U.S. agricultural biotech products delays the commercial launches of innovative seed products resulting in lack of availability of the products for U.S. growers.
- **Relevant Regulations**
The Act on Transboundary Movements of Living Modified Organisms and Other Related Matters (LMO Act)
- **Relevant Agencies**
Ministry of Trade, Industry and Resources (MOTIR)
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 Climate, Energy, and Environment (MCEE)

- **Relevant KORUS Provisions**

Chapter 8 (Sanitary and Phytosanitary Measures) Article 3 (Committee on Sanitary and Phytosanitary Matters), Subparagraph 3(a)

- **Recommendation**

Consistent with the 2025 U.S.-ROK Joint Fact Sheet for the Agriculture Sector, Korea should uphold and implement the agreed commitments to address non-tariff barriers by streamlining the multi-agency RRC under the LMO Act, resolving the backlog of biotech import applications. To prevent non-tariff barriers in Korea's biotech grain trade, which amounts to \$2.5 billion a year, MOTIR, the national authority for the LMO Act, should take responsibility and lead the initiative. The "streamlining" commitment in the Fact Sheet should be interpreted as requiring structural, legally binding process reform, including the elimination of the current RRC for food, feed, or processing (FFP). For imported-commodities not intended for environmental release (food/feed), the MFDS and Rural Development Administration (RDA) should act as the sole risk assessors without additional multi-agency consultations. The bill introduced by Assemblyman Kang Seungkyoo on January 16, 2026, seeks to eliminate redundant multi-agency consultations for FFP imports and aims to align with internationally recognized standards and practices. It is imperative that this legislation be enacted at the earliest opportunity.



AUTOMOBILES

TABLE OF CONTENTS

NO.	ISSUE	STATUS
	Overview	
01	Adoption of a Pre-Certification Regime for Key Emerging Automotive Technologies	NEW
02	Full Authorization of U.S.-Equivalent Level 2 Autonomous Driving Technologies	NEW
03	Relaxation of Robotaxi Regulations to Promote Mobility Rights	NEW
04	Simplification of Emissions Certification Procedures under the Korea-U.S. Tariff Negotiations	NEW
05	Strengthening Carbon Emission Trading System in the Transportation Sector	NEW
06	Auto GHG/CAFE Rules for 2026-2030	
07	Discriminatory EV Subsidy Policy Against Non-Target Companies Under the Low-Emission Vehicle Supply Mandate (LEVSM)	
08	Duplication of Penalty Systems: LEV/ZEV Mandate and GHG Regulations	
09	NACS Charging Standard Adoption	
10	Overlapping Regulations on Electric Vehicles	

OVERVIEW

The U.S.-Korea automotive relationship operates within the framework established by the KORUS FTA, which sets the baseline for tariff treatment, regulatory engagement, and integrated supply chains across vehicles and automotive parts. This framework continues to serve as the primary reference point for bilateral automotive trade and investment.

In 2025, South Korea's global automobile exports reached a record high of approximately USD 72 billion¹⁰, confirming the automotive sector's position as the core pillar of Korea's export economy. The U.S. remains Korea's largest single automotive export market, with finished vehicle exports amounting to roughly USD 30.2 billion¹¹. Bilateral integration is also most evident in automotive parts and intermediate goods. In 2025, the U.S. accounted for approximately 36% of Korea's total auto parts exports¹², reflecting closely linked manufacturing, sourcing, and logistics networks. This level of integration means that changes in market access conditions or regulatory treatment tend to have implications across the broader automotive value chain, rather than affecting finished vehicle trade alone.

Recent high-level bilateral engagement has produced concrete outcomes, as reflected in the Joint Fact Sheet. Commitments, including the removal of the volume cap on U.S.-origin vehicles compliant with Federal Motor Vehicle Safety Standards and the streamlining of emissions certification procedures, represent targeted efforts to improve the regulatory environment affecting the automotive industry. As these outcomes move toward implementation, the establishment of clear follow-up procedures and consistent application will be important to ensure that the agreed commitments translate into predictable and practical results for the industry.

Beyond near-term trade considerations, our bilateral automotive relationship is increasingly shaped by technological transition. The shift toward software-defined

¹⁰ Ministry of Trade, Industry and Resources. (2026). *Auto Exports Hit Record \$72 Billion in 2025*. <https://www.korea.kr/briefing/pressReleaseView.do?newsId=156739832>

¹¹ Ministry of Trade, Industry and Resources. (2026). *Auto Exports Hit Record \$72 Billion in 2025*. <https://www.korea.kr/briefing/pressReleaseView.do?newsId=156739832>

¹² Korea International Trade Association. (2026). *Exports and Imports by Country*. <https://stat.kita.net/stat/kts/ctr/CtrltemImpExpList.screen>

vehicles and autonomous driving is influencing competitiveness and cooperation across data, semiconductors, artificial intelligence, and real-world testing environments, with implications for future investment and industrial collaboration between our two countries.

Against this backdrop, AMCHAM will continue to serve as a constructive platform for dialogue between the industry and both governments, supporting the effective implementation of recent commitments and facilitating practical engagement on emerging policy and regulatory issues.

INDUSTRY ISSUES

Adoption of a Pre-Certification Regime for Key Emerging Automotive Technologies ^{NEW}

The Ministry of Land, Infrastructure and Transport (MOLIT) has introduced a pre-certification (type-approval) regime for vehicles and systems equipped with emerging technologies – including battery systems, cybersecurity technologies, and AI-enabled autonomous driving systems – with the objective of enhancing the safety and reliability of Korea’s vehicle certification framework. For such technologies, this regime replaces the previously applicable self-certification system under Korea’s vehicle management regime.

Electrified and autonomous vehicles incorporate not only conventional vehicle components, but also additional parts and systems related to battery safety, cybersecurity architecture, and autonomous driving functions. Consequently, these vehicles may be subject to approval requirements under both the existing self-certification regime and the newly introduced pre-certification (type approval) framework.

This dual-track approval structure may result in extended certification timelines, increased administrative complexity and compliance costs, and heightened regulatory uncertainty for innovative technologies. In turn, these factors may affect the timely introduction and commercialization of advanced automotive technologies in the Korean market.

- **Issue**

The introduction of a pre-certification (type-approval) regime for emerging automotive technologies has created a dual-track approval structure alongside the existing self-certification system. This overlap may extend certification timelines, increase compliance burdens, and introduce regulatory uncertainty, potentially affecting the timely deployment of innovative vehicle technologies in Korea.

- **Relevant Regulations**

Motor Vehicle Management Act

- **Relevant Agencies**

Ministry of Land, Infrastructure and Transportation (MOLIT)
Korea Transportation Safety Authority (KOTSA)

- **Recommendation**

AMCHAM respectfully requests that, following an appropriate period of operation under the type-approval regime and sufficient validation of the safety of the relevant emerging technologies, consideration be given to transitioning back to Korea's existing self-certification-based vehicle management system. Such a transition would help minimize regulatory overlap and reduce potential confusion in the implementation of the certification framework.

Full Authorization of U.S.-Equivalent Level 2 Autonomous Driving Technologies ^{NEW}

Korea's current safety standards for autonomous driving are largely aligned with Europe's relatively conservative regulatory framework. As a result, these standards differ from the more flexible and innovation-oriented regulatory environment in the U.S., which benefits from internationally recognized leadership in AI-driven and autonomous vehicle capabilities. In particular, the regulatory requirements for Level 2 autonomous driving systems remain disproportionately stringent.

The existing regulatory framework, largely shaped by Europe's cautious approach, differs from that of the United States in both the pace of technological advancement and the degree of regulatory flexibility. Consequently, the overly stringent safety requirements and driver monitoring obligations applied to Level 2 systems may constrain technological development and limit service accessibility for vehicles equipped with Level 2 capabilities. These regulatory conditions present challenges not only for automakers and startups seeking to compete effectively in the global market, but also for mobility-vulnerable groups, including the elderly and persons with disabilities, who could potentially benefit from broader access to Level 2 system services. Moreover, a highly cautious regulatory environment at the intermediate Level 2 stage may constrain meaningful progress at this critical phase of development, while also affecting the pace of transition toward higher levels of automation – an objective closely aligned with the Korean government's stated ambition of global leadership in autonomous driving.

- **Issue**
Korea's comparatively stringent regulatory framework for Level 2 autonomous driving may constrain technological deployment, limit consumer access, and slow progress toward higher levels of automation.
- **Relevant Regulations**
Motor Vehicle Management Act
- **Relevant Agencies**
Ministry of Land, Infrastructure and Transportation (MOLIT)
- **Recommendation**
AMCHAM respectfully requests greater flexibility at the Level 2 stage, recognizing it as a critical intermediate phase in the technological and regulatory progression toward higher levels of automation. In particular, the government should consider

permitting increased flexibility for advanced Level 2+ functionalities, including through closer alignment with internationally recognized regulatory approaches, such as those applied in the U.S. Enabling broader deployment of advanced Level 2 systems would allow a wider range of consumers to gain practical experience with autonomous driving technologies, thereby fostering trust, data accumulation, and ecosystem maturation. By facilitating the structured integration of autonomous driving systems into routine on-road use, such adjustments would strengthen public confidence and create the necessary operational foundation for the scalable transition to Level 3 and Level 4 systems, ultimately advancing Korea's pathway toward fully autonomous driving.

Relaxation of Robotaxi Regulations to Promote Mobility Rights

NEW

Korea's current regulatory framework for autonomous vehicles still requires the presence of a safety driver in the vehicle and restricts the commercial operation of fully driverless Robotaxi services. Under existing law, autonomous vehicles in operation must have a person capable of immediately taking control, and current enforcement rules do not permit driverless commercial passenger services on public roads. As a result, Korea's regulatory environment differs from that of the U.S., where fully driverless Robotaxi services are already operating at commercial scale.

As Korea experiences rapid population aging, shortages within the taxi workforce – an essential component of public transportation – have become increasingly pronounced. This trend disproportionately affects mobility-vulnerable groups, including older adults and persons with disabilities, who often rely on taxis for essential transportation. In this context, regulatory constraints on driverless technologies may limit opportunities to expand transportation supply and enhance accessibility. With elderly drivers accounting for 26% of transport workers in 2025 and 21.6% of traffic accidents in 2024, these structural demographic shifts underscore the importance of exploring innovative mobility solutions. Continued limitations on Robotaxi deployment may affect the pace at which such solutions can contribute to addressing emerging mobility challenges, particularly in aging and rural communities.

- **Issue**

Current regulations requiring a safety driver and prohibiting fully driverless passenger services may limit Korea's ability to deploy innovative mobility solutions, particularly amid rapid population aging and taxi workforce shortages.

- **Relevant Regulations**

Motor Vehicle Management Act

Act on Promotion and Support for Commercialization of Autonomous Vehicles

Passenger Transport Service Act

- **Relevant Agencies**

Ministry of Land, Infrastructure, and Transportation (MOLIT)

- **Recommendation**

AMCHAM respectfully recommends enhancing regulatory flexibility for fully driverless mobility services, including Robotaxi

systems, to address Korea's growing mobility needs amid rapid population aging. By allowing greater flexibility for advanced autonomous features, the Korean government can accelerate the responsible deployment of driverless passenger operations and expand overall transportation supply. This approach would enable a broader range of citizens, including older adults and persons with disabilities, to access innovative mobility solutions while fostering public trust in autonomous technologies. Facilitating the gradual integration of driverless systems into routine on-road operations would strengthen Korea's innovation ecosystems and support its broader ambition of global leadership in AI and autonomous mobility.

Simplification of Emissions Certification Procedures under the U.S.-Korea Tariff Negotiations ^{NEW}

agreed commitments in the areas of Korea-U.S. trade and security cooperation. The document explicitly states that “Korea will ease regulatory burdens for U.S. automotive exports by not requiring additional documentation in its emissions certification process other than those submitted to U.S certification authorities.”

Notwithstanding this commitment, the relevant authorities – including the Ministry of Climate, Energy and Environment (MCEE) and the National Institute of Environmental Research (NIER) – have yet to issue implementing guidance clarifying the operational parameters of the measure. In particular, uncertainty remains regarding (i) the categories of vehicles to which the commitment applies; (ii) the specific emissions certification procedures and documentation requirements subject to adjustment; and (iii) the anticipated timeline and administrative process for implementation. In the absence of such clarification, companies face material uncertainty in interpreting the policy framework and preparing for operational compliance.

- **Issue**

The lack of implementation guidance following the Joint Fact Sheet has created uncertainty regarding the application of eased emissions certification requirements, resulting in compliance and operational uncertainty for affected companies.

- **Relevant Regulations**

MCEE Notification: Regulations on Certification and Inspection Procedures for Manufactured Motor Vehicles

- **Relevant Agencies**

Ministry of Climate, Energy, and Environment (MCEE)
National Institute of Environmental Research (NIER)

- **Recommendation**

AMCHAM respectfully recommends that the Korean government provide clear and detailed guidance on the following points:

- whether the simplified certification measures will be limited to vehicles originating in the U.S. pursuant to the Korea–U.S. FTA;
- the effective date from which eligible vehicles may benefit from the streamlined certification procedures; and

- ❑ whether additional consultations with the U.S. side are required, and if so, the expected timeline and process for such discussions.

Timely clarification on these matters would provide greater predictability for industry stakeholders and support effective compliance and planning.

Strengthening Carbon Emission Trading System in the Transportation Sector ^{NEW}

Current carbon trading mechanisms applicable to the transportation sector in Korea remain limited, with administrative procedures that would benefit from further institutional refinement and enforcement practices that lack consistency. Existing frameworks primarily focus on heavy industries and power generation, while transport-related entities such as logistics operators and public transit providers are not comprehensively integrated. Although vehicle manufacturers and importers are subject to mandatory greenhouse gas credit obligations, variations in enforcement practices may affect overall participation levels.

The fragmented structure does not fully reflect the transportation sector's significant share of national greenhouse gas emissions, and inconsistencies in monitoring and reporting standards create compliance gaps that weaken regulatory effectiveness. Institutional and policy support to facilitate participation in the Emissions Trading System remains limited, including the need for greater transparency through information disclosure, improved oversight of market conditions, and the development of supporting platforms, potentially constraining innovation. Greater regulatory clarity regarding carbon credit trading procedures, together with enhanced stakeholder engagement and predictable enforcement practices, would strengthen market confidence, encourage broader participation, and support Korea's broader carbon neutrality objectives.

- **Issue**

Structural limitations in Korea's transport-related carbon trading mechanisms – including fragmented coverage, limited enforcement, and insufficient institutional and policy support to facilitate participation – reduce regulatory effectiveness and hinder the sector's transition toward low-carbon mobility.

- **Relevant Regulations**

Clean Air Conservation Act

- **Relevant Agencies**

Ministry of Climate, Energy, and Environment (MCEE)

- **Recommendation**

AMCHAM respectfully requests strengthening the Emissions Trading System in the transport sector to enhance regulatory clarity, market confidence, and broader participation. Expanding coverage to additional transport sub-sectors, including logistics

and public transit, would promote consistency and a fairer competitive landscape. To reinforce effective compliance and market credibility, enforcement practices should be applied in a transparent, predictable, and proportionate manner. Simplifying compliance procedures would further reduce administrative burdens and facilitate participation. These measures would reinforce Korea's NDC framework and support sustainable transport innovation.

Auto GHG/CAFE Rules for 2026-2030

As part of the KORUS FTA amendment, Korea committed to considering U.S. regulations when setting future fuel economy targets and to adopting more flexible targets for small manufacturers. However, in early 2021, the Korean government announced a 40% reduction in national emissions by 2030 (NDC, Nationally Determined Contribution) from the 2018 baseline to strengthen its climate change commitments. Since the current Corporate Average Fuel Economy (CAFE) targets for 2026~2030 are set based on the previous NDC, the government decided to revise CAFE. Leveraging the mid-term review scheduled for 2025, as stipulated in the existing regulations, the government aims to introduce stricter CAFE targets for 2026-2030. The Ministry of Environment (ME), now the Ministry of Climate, Energy and Environment (MCEE), began working with academic institutions in 2022 to conduct commissioned research, which culminated in a stakeholder meeting in November 2023 to discuss the findings. The study recommended more stringent targets, with improvements ranging from 18% to 40% compared to current benchmarks, such as the 2030 passenger car target of 70g/km. ME initially planned to draft the new targets by 2024, hold negotiations with stakeholders, and finalize the CAFE targets by 2025. However, the negotiation process has been delayed until 2025, raising concerns that it will be challenging to finalize the detailed implementation plans on time.

- **Issue**
Korea's stringent greenhouse gas emissions standards
- **Relevant Regulations**
Regulations for Motor Vehicle Average Fuel Economy Standards, Greenhouse Gases Emission Standards, and Their Application and Management
- **Relevant Agencies**
Ministry of Climate, Energy and Environment (MCEE)
- **Relevant KORUS Provisions**
September 2018 KORUS Amendment and Modification Texts: Agreed Minutes
- **Recommendation**
Korea should adopt transparent procedures and maintain open communication with the industry when developing new GHG/CAFE regulations for 2026-2030. It is also crucial to set reasonable targets, considering factors such as automakers' current compliance status, shifts in domestic EV demand, and adjustments to U.S. CAFE standards.

Discriminatory EV Subsidy Policy Against Non-Target Companies under the Low-Emission Vehicle Supply Mandate (LEVSM)

Every year, the Korean government implements an EV subsidy program to reach a cumulative target of 4.2 million EVs by 2030. However, as of February 2026, only around 940,000 EVs are on Korean roads.¹³ Under the subsidy program, companies subject to the LEVSM receive an additional subsidy of up to 1.4 million KRW per EV. However, eligibility is restricted to companies that sold more than 4,500 vehicles in 2009. Given that mass-produced EVs were first introduced in Korea in 2010, and the EV market only began to expand significantly in the mid-2010s, this policy unfairly disadvantages new entrants in the Korean EV market.

- **Issue**

The LEVSM eligibility criteria should be revised to eliminate barriers for new vehicle manufacturers that did not sell more than 4,500 vehicles in 2009. This adjustment will help the Korean government more effectively promote EV adoption and advance sustainability goals.

- **Relevant Regulations**

Clean Air Conservation Act

- **Relevant Agencies**

Ministry of Climate, Energy and Environment (MCEE)

- **Recommendation**

AMCHAM recommends revising the eligibility criteria for the LEVSM to better support the expansion of EV adoption and the achievement of carbon neutrality in Korea. Instead of basing eligibility on total vehicle sales in 2009 – a period before EVs were introduced in Korea – the criteria should be updated to reflect more recent EV sales data, such as the past three years. This revision would encourage greater participation from new entrants in the EV market, aligning with Korea’s goals for increased EV adoption and long-term sustainability.

¹³ Ministry of Land, Infrastructure and Transport (MOLIT), Automobile Registration Status Report (Total Registered Motor Vehicles), February 2026, MOLIT Statistics Portal (Stat MOLIT).

Duplication of Penalty Systems: LEV/ZEV Mandate and GHG Regulations

With the revision and promulgation of the Clean Air Conservation Act in 2021, Korea introduced the Low and Zero-Emission Vehicle (LEV/ZEV) Mandate alongside its existing Greenhouse Gas (GHG) regulation system, making it the only country to enforce both policies simultaneously. Currently OEMs are complying with GHG regulations to meet the government’s eco-friendly vehicle supply targets.

However, the LEV/ZEV Mandate and GHG regulations have separate penalty systems, meaning that companies facing unavoidable circumstances, such as a pandemic or other business challenges, may incur overlapping penalties under both the CAFE (Corporate Average Fuel Economy) standards and the LEV/ZEV Mandate. Furthermore, the selective adoption of the highest-level regulations from various countries, without due consideration of global trends or the unique industrial and market characteristics of Korea, has resulted in an exceptionally burdensome environmental regulatory framework.

This creates one of the highest environmental compliance burdens globally, posing significant barriers to entry and growth for foreign companies while introducing uncertainty due to the complex and unique regulatory landscape. In contrast, other countries tailor their regulations to better align with their own industrial and market conditions.

Regulation	US	JPN	EU	KOR
Exhaust Gas Emission	○	○	○	○
CAFE/GHG	○	○	○	○
LEV/ZEV Mandate	△ (in some states such as California)			○

- **Issue**
The separate penalty system for the LEV/ZEV mandate duplicates the existing greenhouse gas regulations
- **Relevant Regulations**
Clean Air Conservation Act
Greenhouse Gases Emission Standards
Low and Zero-Emission Vehicle Mandate
- **Relevant Agencies**
Ministry of Climate, Energy and Environment (MCEE)

- **Recommendation**

AMCHAM recommends that the Korean government reconsider the LEV/ZEV Supply Target Policy, either by abolishing it or revising the associated penalty system to eliminate redundant regulatory burdens.

NACS Charging Standard Adoption

Korea remains the only country that continues to recommend CCS Combo1 (CCS1) as the preferred charging standard, while North America is transitioning to the North America Charging Standard (NACS). The majority of global automakers have announced their shift to NACS, contributing to market standardization and enhancing customer experiences to accelerate EV adoption. Moreover, Korean regulations require parking lots above a certain size to install Electric Vehicle Supply Equipment (EVSE) for either 2% or 5% of total parking spaces, with penalties of up to 30 million KRW for non-compliance. However, installing NACS-compatible EVSE does not count toward this requirement, meaning property owners must install CCS1, CCS2, or Type 1 chargers separately to meet regulatory compliance.

- **Issue**

Korea is the only country in the world recommending CCS1 in lieu of NACS. Automakers selling EVs in Korea face the inefficiency of having to produce CCS1-standard EVs exclusively for the Korean market. Additionally, regulations only recognize CCS1, CCS2, and Type 1 chargers for mandatory EVSE installations in parking spaces, further complicating the compliance process.
- **Relevant Regulations**

Act on the Promotion of Development and Distribution of Environment-Friendly Automobiles
- **Relevant Agencies**

Ministry of Trade, Industry and Resources (MOTIR)
- **Recommendation**

AMCHAM recommends that the Act on the Promotion of Development and Distribution of Environment-Friendly Automobiles be revised to include NACS as an accepted charging standard, allowing it to count toward the obligation to install a specified amount of EVSEs in parking lots.

Overlapping Regulations on Electric Vehicles

As the spread of electric vehicles expands in the Korean market, various new regulations for electric vehicles are being established by relevant ministries. Recently, the Ministry of Land, Infrastructure and Transport has planned to implement follow-up management of electric vehicles' driving distance on a single charge, energy consumption efficiency, and a preliminary certification system for electric vehicle battery safety through the revision/promulgation of the Automobile Management Act. The Ministry of Trade, Industry, and Resources (MOTIR) plans to implement an electric vehicle energy consumption efficiency rating system from the beginning of April this year. The Ministry of Climate, Energy, and Environment (MCEE) is also seeking to strengthen verification of electric vehicle certification (mileage per charge, etc.) and subsidy evaluation by revising related laws. These regulations carry strong penalties for violation (imprisonment/fines, penalty surcharge, and consumer compensation, etc.), acting as a major obstacle to the industry's efforts to popularize electric vehicles.

- **Issue**
Regulations related to electric vehicles and batteries are diversifying and strengthening, and these regulations are being indiscriminately established by each ministry without prior coordination, which is acting as a major obstacle to the industry's spread of electric vehicles.
- **Relevant Regulations**
Clean Air Conservation Act
Motor Vehicle Management Act
Act on Promotion of Development and Distribution of Environmentally Friendly Vehicles
- **Relevant Agencies**
Ministry of Climate, Energy, and Environment (MCEE)
Ministry of Land, Infrastructure and Transport (MOLIT)
Ministry of Trade, Industry and Resources (MOTIR)
- **Relevant KORUS Provisions**
Chapter 9 (Technical Barriers to Trade) Article 7 (Automotive Standards and Technical Regulations)
- **Recommendation**
In relation to the establishment of new electric vehicle and battery regulations by ministries, it is necessary to minimize the burden on

the industry's efforts to popularize electric vehicles by only promoting core policies after sufficient consultation and review at the government-wide level to ensure that there are no duplicate regulations.



CHEMICALS

TABLE OF CONTENTS

NO.	ISSUE	STATUS
	Overview	
01	Streamlining Communication Obligations for Chemical Substances Registered or Notified under Article 29-1 of K-REACH	NEW
02	Simplifying Notification Requirements for Sellers of Hazardous Chemicals under Article 29-2 of the Chemical Substances Control Act	NEW
03	Facilitating Confidential Business Information Approvals for Trade Secret Ingredients in R&D Samples	
04	Aligning the List of Existing Chemicals between K-REACH and OSHA	
05	Clarifying Biocidal Product Labeling Requirements under the Consumer Chemical Products and Biocides Safety Act	NEW
06	Easing Hazards and Risk Data Submission Criteria for Fragrances in Biocidal Products	
07	Recognition of Internationally Approved Biocidal Substances and Products	NEW
08	Recognition of Internationally Approved Preservatives Used in Biocidal-Treated Products	NEW
09	Request for Regulatory Amendment to Facilitate Market Entry of Concentrated Industrial Chemical Products	NEW
10	Clarifying Registration Requirements for Ingredients in Hygiene Products under the Hygiene Products Standards	NEW

OVERVIEW

The regulatory environment for chemical products in Korea remains complex and stringent. Since the 2011 humidifier disinfectant incidents, public awareness of chemical safety has increased, shaping policy and regulatory approaches. Continued media attention and consumer interest support the government's emphasis on stricter safety standards and reporting requirements.

The Ministry of Climate, Environment and Energy (MCEE) and the Ministry of Employment and Labor (MOEL) have continued to introduce a series of tightened regulations on chemical products. Key regulatory frameworks, including the Act on Registration and Evaluation of Chemicals (K-REACH), the Chemical Substances Control Act (CCA), the Consumer Chemical Products and Biocides Safety Act (K-BPR), and the Occupational Safety and Health Act (OSHA), impose requirements that are often more stringent than those in the U.S. or the EU. These regulations cover product registration, safety confirmation, labeling, and occupational exposure, creating significant administrative and technical challenges for foreign and domestic companies alike.

In 2026, industry continues to face practical barriers, including regulatory misalignment across key frameworks, duplicative or overlapping compliance requirements, limited recognition of internationally approved substances, and extensive ingredient disclosure obligations, alongside evolving implementation challenges in specific regulatory areas. Regulatory interpretations frequently require additional documentation beyond international standards, resulting in high compliance burdens.

Despite these regulatory challenges, chemical substances and products play a critical role across industries including semiconductors, electronics and display manufacturing, and battery production, as advanced technologies such as AI drive national economic growth. Safety-verified chemical substances are also widely used in consumer products. When managed at a reasonable and science-based level, these materials can serve as a key foundation for both industrial value chains and everyday consumer applications in manufacturing-focused economies like Korea. A balanced regulatory approach remains essential to ensure chemical safety while maintaining industrial competitiveness.

INDUSTRY ISSUES

Streamlining Communication Obligations for Chemical Substances Registered or Notified under Article 29-1 of K-REACH ^{NEW}

Pursuant to Article 29-1 of the Act on Registration and Evaluation of Chemicals (K-REACH), entities that register or notify chemical substances are required to communicate safety-related information to downstream users. This communication must include the registration or notification number, substance name, hazard information, and other prescribed details, and must be provided using Form 25 or Form 26 together with a Korean Safety Data Sheet (SDS).

While AMCHAM acknowledges the importance of ensuring effective risk communication throughout the supply chain, the current implementation of Article 29-1 creates regulatory inefficiencies and imposes excessive administrative burdens, particularly for mixtures.

First, **K-REACH does not establish a concentration threshold** for communication obligations when registered or notified substances are present in mixtures. As a result, communication is required even when substances are present at very low concentrations (e.g., below 0.1%), levels that generally do not affect mixture classification under the UN Globally Harmonized System (GHS). This leads to regulatory misalignment between SDSs prepared in accordance with GHS requirements and the information disclosed via Forms 25 and 26. In some cases, companies may be compelled to disclose substances through Forms 25/26 that are not required to be listed in SDS Section 3, raising concerns regarding consistency and the protection of confidential business information.

In addition, downstream users often experience confusion, as Forms 25 and 26 do not clearly indicate whether a registered or notified substance is present in a given mixture at a level relevant for risk management. Since downstream users typically handle mixtures rather than individual substances, the practical utility of Forms 25/26 is limited, potentially undermining the effectiveness of risk communication.

Second, **the administrative burden associated with the communication obligation is expected to increase significantly**. As K-REACH registration deadlines approach for lower tonnage bands (10–100 tons/year and 1–10 tons/year), the number of registered substances will expand substantially. This will likely require companies to prepare and disseminate hundreds or even thousands of Forms 25 and 26 linked to mixtures, creating significant operational and compliance burdens for

both registrants and downstream users without a commensurate improvement in safety outcomes.

AMCHAM recommends introducing a GHS-aligned concentration threshold for communication obligations in mixtures and recognizing SDS-based communication as sufficient under Article 29-1 to reduce duplication and administrative burden.

- **Issue**

Excessive and unclear information communication obligations for mixtures under Article 29-1 of K-REACH, leading to regulatory inconsistency, downstream user confusion, and escalating administrative burdens

- **Relevant Regulations**

Act on Registration and Evaluation of Chemicals (K-REACH), Article 29-1

- **Relevant Agencies**

Ministry of Climate, Environment and Energy (MCEE)

- **Recommendation**

AMCHAM recommends that the Korean government take the following actions:

- Establish a **concentration threshold** for communication obligations when registered or notified substances are present in mixtures, aligned with GHS disclosure cut-off criteria, to ensure consistency and focus on risk-relevant information.
- Reassess the **communication method for mixtures** to improve practicality and clarity for downstream users. In particular, AMCHAM recommends integrating or recognizing SDS-based communication (including extended SDS where applicable) as sufficient for mixtures, in order to avoid duplication, reduce administrative burden, and minimize confusion across the supply chain.

Simplifying Notification Requirements for Sellers of Hazardous Chemicals under Article 29-2 of the Chemical Substances Control Act NEW

With the amended Chemical Substances Control Act (CCA), which came into effect on August 7, 2025, sellers of hazardous chemicals are required to provide buyers with information on substance use and hazardous chemical content, either through container labeling or by supplying a summary information sheet (Form 47-2). Under the CCA, this obligation is deemed fulfilled when the same information has already been provided in accordance with Article 29 of the Act on Registration and Evaluation of Chemicals (K-REACH).

While AMCHAM recognizes the importance of ensuring that users receive adequate information to safely handle hazardous chemicals, the current implementation of Article 29-2 creates overlapping and duplicative regulatory requirements, particularly for mixtures and for substances manufactured or imported in quantities of less than 1 ton per year.

In practice, workplaces already receive comprehensive safety and hazard information through Safety Data Sheets (SDS) prepared and provided in accordance with the Occupational Safety and Health Act (OSHA). However, the CCA imposes an additional obligation to provide a separate summary information sheet when hazardous chemicals are sold, even where an SDS has already been supplied. This results in duplicative compliance requirements for the same information.

Furthermore, while Form 47-2 may be effective for single-substance products, its utility is limited for mixtures that are classified as hazardous based on the concentration of individual components. In such cases, the SDS provides more detailed and relevant information for workplace risk management. Requiring both the SDS and Form 47-2 for hazardous mixtures may lead to confusion among downstream users and undermine effective risk communication.

- **Issue**
Overlapping and duplicative notification obligations for sellers of hazardous chemicals under CCA, despite the provision of SDSs under OSHA
- **Relevant Regulations**
Chemical Substances Control Act (CCA), Article 29-2
Occupational Safety and Health Act (OSHA)

- **Relevant Agencies**

Ministry of Climate, Environment and Energy (MCEE)

Ministry of Employment and Labor (MOEL)

- **Recommendation**

AMCHAM recommends deleting the relevant provision or introducing an exemption clause under CCA so that the provision of an SDS is deemed sufficient to fulfill the information summary requirement for hazardous chemicals, thereby eliminating duplicative obligations and improving regulatory efficiency.

Facilitating Confidential Business Information Approvals for Trade Secret Ingredients in R&D Samples

MOEL requires that any person who manufactures or imports a material controlled under the MSDS (Material Safety Data Sheet) system must prepare and submit an MSDS to KOSHA (Korea Occupational Safety and Health Agency) prior to manufacturing or importing. Additionally, they must obtain Non-Disclosure Approval for any confidential business information regarding trade secret ingredients in MSDS Section 3. This approval allows for the use of alternative name(s) and the alternative content(s) and content descriptions instead of revealing the hazardous ingredients names and contents that are considered trade secrets.

While MSDS submission is exempted for R&D samples, the requirement for Non-Disclosure Approval for trade secret ingredients in MSDS Section 3 applies to these samples. R&D samples are usually urgent materials used in new products or technology development. The time spent waiting for Non-Disclosure Approval for trade secret ingredients can significantly delay R&D activities in Korea, hindering the timely development of new products and technologies.

- **Issue**
Korean regulations that require the disclosure of confidential business information
- **Relevant Regulations**
Occupational Safety and Health Act (OSHA) Article 112
- **Relevant Agencies**
Ministry of Employment and Labor (MOEL)
- **Recommendation**
Non-Disclosure Approval for trade secret ingredients in R&D samples should be exempted under OSHA to accelerate R&D activities in Korea

Aligning the List of Existing Chemicals between K-REACH and OSHA

The Act on Registration and Evaluation of Chemicals (K-REACH) and the Occupational Safety and Health Act (OSHA) define and regulate new chemical substances under different criteria. Under K-REACH, substances that were previously designated as existing chemicals following hazardousness assessments conducted under the former Toxic Chemicals Control Act are regarded as already registered substances. In contrast, OSHA does not recognize such substances unless they are separately registered or reported under OSHA.

In addition, K-REACH requires the registration of new chemical substances manufactured or imported in quantities of 1 ton or more per year, whereas OSHA requires the submission of a Hazardousness and Risk Assessment Report for substances handled in quantities of 100 kg or more per year. Exemption criteria for new chemical substances also differ between the two laws. As of January 1, 2025, K-REACH raised the threshold for small-quantity new chemical substances from less than 100 kg to less than 1 ton per year, further widening the regulatory gap between the two regulatory regimes.

As a result, the chemical inventories maintained under K-REACH and OSHA are not aligned, creating inconsistencies in regulatory treatment for the same substances.

- **Issue**
Inconsistencies in existing and new chemicals between K-REACH and OSHA, leading to compliance challenges in handling the substances
- **Relevant Regulations**
Act on Registration and Evaluation of Chemicals (K-REACH)
Occupational Safety and Health Act (OSHA)
- **Relevant Agencies**
Ministry of Climate, Environment and Energy (MCEE)
Ministry of Employment and Labor (MOEL)
- **Recommendation**
AMCHAM recommends enhanced coordination between MCEE and MOEL to reduce regulatory duplication and improve consistency. Specifically, AMCHAM recommends:

- Align the chemical inventories under K-REACH and OSHA by enabling mutual recognition of substances classified as existing chemicals to avoid inconsistent regulatory treatment of the same substances.
- In particular, substances recognized as existing chemicals under K-REACH should be consistently recognized under OSHA, and regulatory thresholds (e.g., 1 ton vs. 100 kg) should be reviewed to improve regulatory coherence.

Clarifying Biocidal Product Labeling Requirements under the Consumer Chemical Products and Biocides Safety Act^{NEW}

With the amendment of the Regulations on Labeling of Biocidal Products announced by the Ministry of Climate, Environment and Energy (MCEE) on May 28, 2025, the government intends to clarify and enhance the labeling requirements for biocidal products. The revision introduces specific guidance on labeling methods to strengthen consumer safety and align with the government's broader biocidal product management policies.

While the industry fully supports the government's objective to enhance biocidal product safety and has been committed to complying with the updated requirements, practical challenges have emerged during implementation. Certain areas require clear guidance to ensure smooth adoption and minimize unintended operational impacts.

A key area of concern is the application of the grace period for biocidal product labeling. The industry believes that it is reasonable to apply labeling requirements only to products manufactured or imported one year after approval, allowing companies to continue distributing existing inventory without the need for immediate relabeling. In contrast, the Ministry's position is that labeling should be applied immediately upon approval, and by the one-year mark, all products in circulation throughout Korea should comply with the updated labeling requirements. Given the complexity of Korea's distribution system, including numerous small retailers in rural areas, applying labeling retroactively to all existing products is practically difficult. This could lead to increased costs, unnecessary waste, and logistical challenges. It is noted that similar guidance under the Ministry of Food and Drug Safety for food, food additives, and hygiene products allows already manufactured or imported products to be sold until their expiration date, reflecting a practical and industry-friendly approach.

- **Issue**
Ambiguity in the grace period for applying biocidal product labeling, creating practical challenges for industry compliance
- **Relevant Regulation**
Consumer Chemical Products and Biocides Safety Act (K-BPR)
Regulations on Labeling of Biocidal Products
- **Relevant Agency**
Ministry of Climate, Environment and Energy (MCEE)

- **Recommendation**

AMCHAM recommends that clear guidelines be issued allowing the labeling requirement to be applied to products manufactured or imported one year after approval, reflecting practical distribution realities. Additionally, the government should provide explicit guidance on the permissible sale or handling of any products in circulation that remain unlabeled during the transition period.

Easing Hazards and Risk Data Submission Criteria for Fragrances in Biocidal Products

The 'Notice on Hazards and Risk Data Submission Criteria for Fragrances in Biocidal Products' (National Institute of Environmental Research, NIER, 2024.04.18) requires hazard data submission for biocidal products containing fragrances. For products with inhalation exposure, hazard data submission is exempt if the fragrance content is below 0.1%. However, substances of concern (SoC) and allergens present above 0.1% and 0.01% respectively require submission regardless of exposure route. These requirements are stricter than previous standards, creating practical difficulties for industry compliance, particularly with the approval grace period for Group 1 products ending late 2025.

The notice is also unclear about the scope of acceptable hazard data, including whether only classification labels suffice or original supporting data are required. Compared to general consumer chemical products, these requirements are considered excessive, as fragrance components have long been marketed without such obligations.

International standards, including GHS, EU CLP, and EU BPR, consider very low-concentration fragrance components (<0.1%) negligible for toxicity classification. Current requirements for biocidal products are thus more stringent than internationally recognized risk assessment practices. Moreover, generating high-reliability "6-pack" data for individual fragrance components is often unrealistic, and alternative methods such as QSAR or read-across may not fully replace certain endpoints like acute dermal toxicity. These factors create significant practical barriers for industry compliance.

- **Issue**

Hazard data submission requirements for fragrances in biocidal products are unclear and stricter than for general consumer chemical products, creating excessive compliance burdens. Individual fragrance components containing SoC must submit full hazard data regardless of concentration, conflicting with international standards and practical feasibility.

- **Relevant Regulations**

Consumer Chemical Products and Biocides Safety Control Act Notice on hazards and risk data submission criteria for fragrances in biocidal products (NIER, 2024.04.18.)

- **Relevant Agencies**

Ministry of Climate, Environment and Energy (MCEE)

National Institute of Chemical Safety (NICS)

National Institute of Environmental Research (NIER, previously responsible authority)

- **Recommendation**

- Modify Submission Criteria: Hazard data should only be submitted when fragrances and allergens are present above 0.1% and 0.01%, respectively, as individual fragrance components in products, rather than the total sum.
- Expand the Recognize Data Scope:
 - Expand the scope of acceptable data for biocidal product approval, allowing open data (e.g., URLs) from sources such as ECHA, RIFM, etc., to confirm classification labels or toxicological values, without requiring additional information such as reference purchase certificates.
 - Apply end points used in risk assessment to substances already evaluated and designated as hazardous chemicals by the MCEE.

Recognition of Internationally Approved Biocidal Substances and Products ^{NEW}

Biocidal substances and products are evaluated and approved in multiple jurisdictions, including the U.S., the EU and the UK, and differences in procedures, timelines, and evaluation criteria are common. . In Korea, however, strict domestic-only review, mandatory renewal, and rigid criteria regarding approval timelines or minor differences can crease excessive administrative burdens, delay product availability, and disrupt global supply chains. By focusing on the essential identity, efficacy, function, and safety of substances rather than formal administrative criteria, regulatory authorities can help ensure safe use while maintaining stable supply chains and industrial competitiveness.

Recognizing internationally approved biocidal substances and adopting a risk-based review approach would reduce unnecessary administrative burden while safeguarding safety and supporting the stability and competitiveness of domestic industry. For example, the UK Health and Safety Executive (HSE) is considering recognition of biocidal substances and products approved by foreign authorities with comparable evaluation standards, combined with a risk-based “call-in” mechanism that allows re-evaluation only when necessary.

- **Issue**
Korea’s review and renewal requirements do not adequately recognize evaluations already completed by recognized foreign authorities, resulting in duplicated assessments, inefficient use of regulatory resources, and delays in product availability.
- **Relevant Regulations**
Consumer Chemical Products and Biocides Safety Act,
Enforcement Decree Article 23(2)
- **Relevant Agencies**
Ministry of Climate, Environment and Energy (MCEE)
- **Recommendation**
AMCHAM recommends introducing a regulatory mechanism that allows the recognition or reference of biocidal substances and products already evaluated and approved by foreign authorities with comparable scientific and regulatory standards, such as under the EU BPR, U.S. EPA, or UK GB BPR frameworks. Consistent with the approach currently under consideration by the UK Health and Safety Executive (HSE), Korea could also consider

adopting a risk-based regulatory model that reduces reliance on fixed approval renewal cycles and instead enables authorities to request re-evaluation (“call-in”) when new risk concerns arise.

Recognition of Internationally Approved Preservatives Used in Biocidal-Treated Products NEW

Article 23(2) of the Enforcement Decree of the Consumer Chemical Products and Biocides Safety Act (K-BPR) provides that biocidal products whose safety has been verified through approval or confirmation by a foreign government are deemed to meet domestic safety standards. This provision reflects Korea's intent to recognize international regulatory systems and avoid unnecessary duplication of safety assessments.

In industrial practice, preservatives used in biocidal-treated products are manufactured and distributed through global supply chains, with products of the same specifications commonly produced in multiple countries, including China and Southeast Asia. Differences in manufacturing location, manufacturer, and purity are normal and unavoidable. Due to geographic proximity and cost considerations, sourcing preservatives from neighboring regions rather than exclusively from major regulatory jurisdictions such as the EU or the U.S. is often an inevitable business reality.

It is also important to distinguish between biocidal products and biocidal-treated products. Biocidal products are intended to be used directly for disinfection, preservation, or sterilization, whereas biocidal-treated products contain only small amounts of preservatives to prevent product deterioration and involve very low potential for direct human exposure. Despite this low exposure risk, recent regulatory interpretations have required that biocidal products used in biocidal-treated products must have identical manufacturing location, manufacturer, and purity. This interpretation does not sufficiently reflect the use characteristics and risk profile of biocidal-treated products and diverges from both the original intent of Article 23(2) and industrial realities.

In practice, importers have no effective control over international variations in manufacturing location or purity for the same substance. Requiring strict formal identity in these elements creates impractical and excessive regulatory burdens, potentially leading to duplicate substance or product approvals, increased data submission costs, and supply chain disruptions. This is particularly problematic given that many preservatives have already been evaluated and approved under international regimes such as the EU BPR, and re-approval based solely on formal differences risks undermining the recognition principle embedded in Article 23(2).

- **Issue**
Rigid interpretation of manufacturing location, manufacturer, and purity requirements for preservatives used in biocidal-treated products undermines the recognition of internationally approved substances and creates excessive administrative and supply chain burdens.
- **Relevant Regulations**
Consumer Chemical Products and Biocides Safety Act (K-BPR)
Enforcement Decree of the Consumer Chemical Products and Biocides Safety Act, Article 23(2)
- **Relevant Agencies**
Ministry of Climate, Environment and Energy (MCEE)
- **Recommendation**
Regulatory authorities should clearly uphold the principle of Article 23(2) by recognizing biocidal substances approved or confirmed by foreign governments based on their essential identity. Evaluation should focus on core composition, function, safety, and efficacy, rather than formal criteria such as manufacturing location, manufacturer, or minor purity differences. Removing these formal requirements and applying science-based assessment criteria would support stable raw material supply, preserve global supply chains, and enhance the competitiveness of domestic industry while maintaining a high level of safety.

Request for Regulatory Amendment to Facilitate Market Entry of Concentrated Industrial Chemical Products NEW

Under the current regulatory framework, even products intended for professional users who have received proper training for safe industrial use are subject to mandatory safety confirmation if they are used in areas accessible to the general public (e.g., cleaning agents for restrooms). According to Article 10(1) of the Consumer Chemical Products and Biocides Safety Act (K-BPR), manufacturers or importers of consumer chemical products must obtain verification from accredited testing institutions that their products meet the safety standards. Both testing and issuance of test reports are conducted based on the *finished product*, and the CHEMP (Chemical Management Platform) system also requires reporting of all ingredient concentrations in the finished product.

While separate safety standards exist for concentrated forms of antifreeze under the “Standards for Designation, Safety, and Labeling of Consumer Chemical Products Requiring Safety Confirmation,” such provisions are not extended to other product categories like industrial cleaners. This creates difficulties for industry when introducing products necessary for professional use.

The industrial sector is increasingly investing in concentrated products that minimize packaging, save storage space, reduce transportation costs, and decrease environmental impact. As a result, high-concentration, multi-purpose products are continuously being developed and launched both domestically and internationally. However, concentrated products often require dilution prior to use. In the final use form, the product may fall below regulatory concentration limits, but because testing and safety reporting are conducted on the undiluted finished product, registration can become impossible. To align with global market trends and facilitate the introduction of innovative, environmentally friendly, and efficient products, the regulatory framework needs to allow for safety reporting and compliance based on the *final use concentration* of concentrated products.

- **Issue**
Current safety confirmation and reporting requirements do not account for concentrated industrial products that are diluted during use, creating obstacles for market adoption and compliance.
- **Relevant Regulations**
Consumer Chemical Products and Biocides Safety Act (Article 10, Paragraph 1)

Designation and Safety/Labeling Standards for Consumer Chemical Products Requiring Safety Confirmation

- **Relevant Agencies**

Ministry of Climate, Environment and Energy (MCEE)

- **Recommendation**

AMCHAM recommends revising regulatory guidelines to allow concentrated products, including cleaning agents and other industrial chemicals, to be reported and evaluated based on their final use concentration. This adjustment would facilitate environmental protection, reduce operational burden on workers through smaller and lighter packaging, and support global competitiveness. Consideration could also be given to creating a new “concentrated” product category within the current formulation classifications, using the existing “Other (specify)” option as a temporary measure.

Clarifying Registration Requirements for Ingredients in Hygiene Products under the Hygiene Products Standards ^{NEW}

Under the *Standards and Specifications for Hygiene Products*, only certain ingredients are permitted for use in cleaning agents. Ingredients may be registered if they are recognized as food additives or food ingredients under the *Food Sanitation Act*, or if supporting documentation such as overseas usage references, relevant literature, and safety data is submitted to and reviewed by the Ministry of Food and Drug Safety (MFDS).

In practice, ingredient registration often encounters challenges. Overseas sales certificates and ingredient declarations, even when apostilled or notarized, may be deemed insufficient by MFDS, which frequently requests publicly accessible ingredient information. However, many B2B products lack public sales pages, and non-hazardous ingredients are often treated as confidential business information. Safety data sheets (MSDS) also may not list these ingredients, as mandatory disclosure applies only to hazardous substances. These practical constraints make ingredient registration difficult.

- **Issue**
Registration often encounters challenges due to MFDS requesting publicly accessible ingredient information.
- **Relevant Regulations**
Cleansing and Hygiene Products Control Act
- **Relevant Agencies**
Ministry of Food and Drug Safety (MFDS)
- **Recommendation**
AMCHAM recommends that documentation officially issued by the manufacturer or importer, such as ingredient declarations, be accepted as sufficient for registration, recognizing that such documents reflect the same information as publicly listed sources. This would create a practical framework for compliance.

Additionally, MFDS should clarify the anticipated timeline for the planned transition to a negative list-based management system, as discussed during the 2025 Hygiene Products Industry Meeting, to allow industry to prepare accordingly.



DIGITAL ECONOMY

TABLE OF CONTENTS

NO.	ISSUE	STATUS
	Overview	
01	Digital Infrastructure & Network Interconnection	NEW
02	Online Platform Regulations and KFTC Enforcement	
03	Application of the Cloud Security Assurance Program (CSAP)	
04	Artificial Intelligence	
05	Designation of a Local Representative	
06	Legislative Bill on Safety Management of Digital Disasters and Failures	
07	Personal Information Protection Act (PIPA)	

OVERVIEW

The free flow of data across borders and the nondiscriminatory treatment of digital service providers play an increasingly important role in global commerce and the development of artificial intelligence and other emerging technologies. As Korea advances its goal of becoming a Global Top Three AI powerhouse, the structure and predictability of its digital regulatory framework will be an important factor in shaping investment, innovation, and international competitiveness.

Korea has undertaken policy initiatives to strengthen its digital and AI ecosystem, including the implementation of the AI Basic Act, which seeks to promote responsible AI development and provide greater regulatory clarity. As AI systems depend on large-scale data processing and globally integrated cloud infrastructure, policies affecting cross-border data transfers, cloud services, and digital platforms have become increasingly significant for businesses operating in Korea.

At the same time, several digital regulatory developments have been discussed in bilateral contexts, including in the U.S.–Korea Joint Fact Sheet. Areas referenced in these discussions include cross-border data transfer frameworks, cloud security certification requirements such as the CSAP regime in public procurement, proposed network usage fee structures, and proposed online platform regulations.

As digital trade and AI-related services continue to expand, regulatory clarity, consistency, and coordination with global standards will remain relevant considerations for policymakers and stakeholders.

AMCHAM continues to engage with the Korean government, the U.S. government, and industry stakeholders to monitor digital policy developments and to contribute to discussions aimed at supporting innovation, competitiveness, and a balanced digital trade environment.

INDUSTRY ISSUES

Digital Infrastructure & Network Interconnection ^{NEW}

South Korea enforces a unique regulatory framework regarding internet interconnection, specifically under the “Notice on Interconnection Standards for Telecommunication Facilities” amended in 2016. Unlike the global standard of “Settlement-Free Peering” (SFP), where networks exchange traffic without monetary settlement for mutual benefit, Korea mandates a “Sender-Pays” (SPNP) system. This regulation compels Internet Service Providers (ISPs) to charge one another for traffic exchange, creating a structural “cost floor” that effectively eliminates price competition among ISPs and prevents them from offering competitive rates to content and cloud providers.

Consequently, network usage fees in Korea are disproportionately high, estimated to be up to 100 times higher than in major markets like the U.S., Europe, or Japan. This prohibitive cost structure acts as a significant non-tariff trade barrier for U.S. digital service providers. The adverse impact is tangible: for instance, in 2024, a major U.S. streaming platform was forced to exit the Korean market, explicitly citing network costs that were ten times higher than in other countries. Furthermore, this regime serves as a major disincentive for U.S. firms to invest in local digital infrastructure, such as cloud regions and data centers, which are foundational for Korea’s ambition to become a “Global AI G3” leader.

AMCHAM notes that the U.S. and Korean governments recently reaffirmed their commitment to removing unnecessary barriers to digital trade, specifically mentioning “network usage fees,” in the Joint Fact Sheet. Maintaining the current 2016 SPNP regime would contradict this high-level commitment. While AMCHAM supports a sustainable telecommunications ecosystem, the current cost structure runs the risk of stifling innovation and limits the availability of advanced digital services for Korean consumers and businesses.

- **Issue**
The unique "Sender-Pays" interconnection regime creates exorbitantly high network costs that act as a barrier to market access, risking the exit of global services and discouraging critical investment in Korea’s digital and AI infrastructure.
- **Relevant Regulations**
Notice on Interconnection Standards for Telecommunication Facilities (specifically the mandatory settlement provisions for

internet interconnection introduced in 2016), Telecommunications Business Act.

- **Relevant Agencies**

Ministry of Science and ICT (MSIT)

- **Relevant KORUS Provisions**

Chapter 14 (Electronic Commerce), Chapter 15 (Telecommunications)

- **Recommendation**

AMCHAM urges the Korean government to eliminate the 2016 “Sender-Pays” settlement framework and align Korea’s interconnection regime with the global standard of Settlement-Free Peering. Removing this structural barrier will lower costs, restore market competition, and attract the essential infrastructure investment needed to accelerate Korea’s AI innovation and digital transformation.

Online Platform Regulations and KFTC Enforcement

Digital platform innovation has contributed meaningfully to Korea's economic growth, including by expanding opportunities for SMEs and enhancing the consumer experience for millions of users. At the same time, a growing number of regulatory actions and legislative proposals, including those advanced from some policymakers and the Korea Fair Trade Commission (KFTC), have focused specifically on digital platform businesses.

Combined, these developments have raised concerns regarding the potential for disproportionately stringent regulation of certain platform companies, which could result in an uneven regulatory landscape. They may also raise questions in relation to Korea's commitments under the Korea Strategic Trade and Investment framework agreed last year, including commitments to ensure that U.S. companies are not subject to discriminatory treatment or unnecessary regulatory barriers.

Leading U.S. technology companies have continued to voice concern about the KFTC's enforcement posture which includes frequent dawn office raids, intrusive investigations, and threats of criminal prosecution. Such actions lead to significant compliance costs and act as barriers for U.S. companies seeking to compete in the Korean market.

Adding to this, most recently the Bill on the Fairness of Online Platform Intermediary Transactions (Fairness Act) was reintroduced in December 2025.

Leading U.S. online platform companies have also expressed concern that this legislative proposal may create further barriers and have a disproportionate impact on U.S. firms. In particular, concerns have centered on: (1) sector specific scoping that could disproportionately affect major U.S. digital services providers, which are among the leading participants in Korea's online platform market; (2) burdensome compliance requirements that could constrain innovation including strict contract and advance notice obligations, as well as the application of highly prescriptive rules more commonly found in financial services regulation than in competition law in peer jurisdictions; (3) the expanded authority granted to the KFTC to intervene between parties under fair transaction practice provisions that remain broadly defined; (4) increased liability exposure, including penalties of up to 10% of sales revenues for violations identified by the KFTC; (5) statutory protections for collective merchant organizations that may diverge from prevailing global norms and; (6) the possibility that the proposed bills could prove duplicative in light of existing enforcement authority under current law.

Leading U.S. digital service providers and technology industry associations have also emphasized that such measures could have unintended consequences for Korean consumers and SME's, including potential effects on pricing, innovation, and broader

economic growth. More broadly, this approach could contribute to additional friction in the U.S. – Korea economic relationship, particularly as U.S. officials and members of Congress have already expressed concerns regarding Korea’s direction in this area.

- **Issue**

Overall, the proposed regulatory criteria, compliance burdens, and sector-specific scope of the digital platform measures, as well as the existing enforcement posture, could disproportionately affect certain U.S. companies and may be perceived as discriminatory in application. Senior U.S. officials have indicated that such an approach could raise concerns under Korea’s international trade commitments. These measures could disadvantage U.S. digital service providers and function as non-tariff barriers, potentially adding strain to the U.S.-Korea trade relationship.

- **Relevant Regulations**

Monopoly Regulation and Fair Trade Act (MRFTA)
Online Platform Monopoly Regulation Act (OPMRA)
Bill on the Fairness of Online Platform Intermediary Transactions (Fairness Act) and related proposals in the National Assembly

- **Relevant Agencies**

Korea Fair Trade Commission (KFTC)
Ministry of Trade, Industry and Resources (MOTIR)
Ministry of Science and ICT (MSIT)
Korea Media and Communications Commission (KMCC)

- **Relevant KORUS Provisions**

Chapter 12 (Cross-border trade in services) and Most Favored Nation, Chapter 16 (Competition-related matters)

- **Recommendation**

Given the potential risk of significant trade friction arising from this regulatory approach, AMCHAM urges the Korean government to moderate its existing enforcement approach as well as discontinue the legislative discussions, and instead engage in robust consultation with the US Government, Korean consumers, civil society, academia, and industry to ensure harmonized approaches to technology regulation between Korea and the U.S.

Application of the Cloud Security Assurance Program (CSAP)

Korea's unique data protection standards for public cloud services, enforced by the Ministry of Science and ICT (MSIT) and the National Intelligence Service (NIS), require public agencies to only use cloud services certified under the Cloud Security Assurance Program (CSAP) operated by the Korea Internet & Security Agency (KISA), which is a public entity subsidiary of MSIT.

As of April 2025, leading U.S. cloud service providers all have obtained CSAP Low-tier certification (Group C) from the KISA. AMCHAM anticipated that these certifications will enable U.S. cloud service providers to actively contribute to innovation within the public sector, and we foresaw enhanced collaboration with public institutions and agencies. However, despite obtaining the CSAP Low-tier certification, NIS has not included U.S. cloud service providers on the list of approved cloud providers for serving the public sector. Furthermore, due to the Low-tier restrictions that limit services to handling only publicly available information without personal information, U.S. cloud service providers are effectively unable to provide services to the public sector.

Nevertheless, as highlighted in the introduction, the entire public sector market continues to be governed by strict data residency requirements under the CSAP framework across all impact level categories – High, Moderate, and Low. This data localization requirement significantly hinders the adoption of AI and various cloud-based SaaS applications, even when dealing with non-critical government data used to deliver citizen services through cloud computing.

In addition, due to the NIS's Security Verification Scheme for Public Sector IT Security Products, even the U.S. cloud service providers who obtained CSAP-Low tier certification can serve only Group C public sector customers such as local governments and K-12 institutions (including privately owned).

Recent reports suggest that the Korean government may be considering changes to the CSAP framework that could significantly alter its scope and governance structure. These discussions reportedly include reframing CSAP as a “voluntary” certification mechanism for private-sector cloud procurement while consolidating authority over public-sector cloud security approvals under the National Intelligence Service (NIS). Industry observers have noted that such changes could potentially expand the practical influence of CSAP-related requirements beyond the public sector and introduce additional uncertainty for global cloud service providers that have already invested in compliance with the existing framework.

Considering that most cloud service providers offer sophisticated data control mechanisms irrespective of data storage location, public institutions could focus on delivering more innovative and efficient public services while maintaining full oversight of data hosted in cloud environments. As Korea reviews its cloud security framework, policies that allow greater flexibility in cloud deployment while maintaining strong security safeguards would better support public sector innovation and digital transformation.

- **Issue**
Data residency requirements and Security Verification Scheme for Public Sector IT Security Products for public cloud hinder the wider adoption of AI and SaaS services in the public sector
- **Relevant Regulations**
Cloud Security Assurance Program (CSAP) certification
- **Relevant Agencies**
Ministry of Science and ICT (MSIT)
National Intelligence Service (NIS)
- **Relevant KORUS Provisions**
Chapter 12 (Cross-Border Trade in Services), Chapter 15 (Electronic Commerce) & Chapter 17 (Government Procurement)
- **Recommendation**
AMCHAM urges the Korean government to extend logical separation to the Moderate tier, broaden the range of non-sensitive public sector information, and revise Korea-specific requirements, including the strict data residency rule, to align with global technological standards. This would promote regulatory reform in the cloud computing sector.

Artificial Intelligence

On January 22, 2026, the Framework Act on the Development of Artificial Intelligence and the Creation of a Foundation for Trust (the "AI Basic Act") officially entered into force, alongside its Enforcement Decree and five related guidelines. This marks a pivotal shift in Korea's regulatory landscape, moving from legislative debate to the practical implementation of governance. Following the Act's passage in late 2024, the Ministry of Science and ICT (MSIT) led a task force to draft subordinate statutes, finalizing the Enforcement Decree after a public comment period in late 2025 to reflect stakeholder feedback.

Recognizing the nascent stage of global AI governance, the Korean government has exercised administrative discretion to implement a one-year grace period. During this time, administrative investigations and fines regarding specific compliance duties will be suspended to ensure a "soft landing" for the industry. However, civil liability remains active for disputes between businesses or with users. While the immediate regulatory pressure is alleviated, the duty to comply exists, and the precedents set during this period, via government Support Desks and Q&A sessions, will define future compliance risks.

Despite the progress with the AI Act, friction remains regarding data usage. The intersection of the AI Act and the Personal Information Protection Act (PIPA) continues to be a bottleneck. The strict requirements for processing personal information for AI training—specifically the ambiguity around "original collection purpose" and the bureaucratic burden of obtaining approval from the Personal Information Protection Committee (PIPC)—pose a risk of hindering the AI innovation that the AI Act seeks to promote.

In addition to privacy concerns, the copyright status of Generative AI training data has emerged as a critical conflict. Korean copyright associations and rights-holder groups are currently maintaining a hardline stance, asserting strict claims over data used for model training and demanding robust compensation models. This rigid approach creates significant legal uncertainty for AI developers. To ensure the competitiveness of Korea's AI sector, copyright disputes must be resolved in a direction that supports AI industry growth, such as establishing clear Text and Data Mining (TDM) exemptions, rather than imposing prohibitive costs that stifle innovation.

AMCHAM welcomes the MSIT's balanced approach in prioritizing industry promotion and the "soft landing" policy. However, operating under a grace period requires active engagement. Still of concern is that without clear, practical interpretations of "High-

Impact AI" and greater alignment with privacy and copyright regulations, companies will continue to face legal uncertainties that serve as non-tariff barriers to trade.

- **Issue**

Operational uncertainty during the initial enforcement phase of the AI Act. The need to shape the interpretation of the Enforcement Decree during the grace period. Critical need to resolve conflicts regarding copyright for training data and data privacy enforcement to ensure they do not hamper industry growth.

- **Relevant Regulations**

AI Basic Act (Enforced as of Jan 22, 2026)
Enforcement Decree of the AI Basic Act
Guidelines on High-Impact AI
Personal Information Protection Act (PIPA)
Copyright Act

- **Relevant Agencies**

Ministry of Science and ICT (MSIT)
Personal Information Protection Commission (PIPC)
Korea Media and Communications Commission (KMCC)
Ministry of Culture, Sports and Tourism (MCST)
Presidential Council on National Artificial Intelligence Strategy
Committee

- **Relevant KORUS Provisions**

Chapter 12 (Cross-Border Trade in Services), Chapter 15 (Electronic Commerce).

- **Recommendation**

AMCHAM urges the Korean government to:

1. Leverage the Grace Period: Utilize the grace period to actively shape the regulatory landscape by accepting industry feedback on the practical application of the Guidelines.
2. Clarify High-Impact Definitions: Ensure that the specific criteria for "High-Impact AI" are interpreted narrowly and clearly.
3. Resolve Copyright Uncertainty: Proactively establish a legal framework for training data usage that prioritizes AI industry

promotion, preventing excessive copyright claims from becoming a barrier to innovation.

4. Harmonize Data Rules: Align PIPA enforcement with the AI Act's promotion goals, moving toward a risk-based accountability model.

Designation of a Local Representative

In May 2020, the National Assembly amended the Telecommunications Business Act (TBA) to require large content providers to ensure network stability and appoint local representatives. However, industry stakeholders have raised concerns that this regulation places an undue burden on content providers for network quality issue beyond their control. Meanwhile, the Korea Fair Trade Commission (KFTC) has proposed amendments to the Act on the Protection of Consumers in Electronic Commerce (E-Commerce Act) to introduce a local agent system, under which large overseas business operators without a domestic address or branch office must designate a local representative to handle consumer complaints, support dispute resolution, and submit information on their behalf under the E-Commerce Act.

Additionally, amendments to the Personal Information Protection Act (PIPA) have strengthened the domestic representative system for overseas businesses. Under the revised law, overseas businesses that have a Korean subsidiary over which they exercise significant influence are now required to designate that subsidiary as their domestic agent for PIPA compliance. This change has imposed additional burdens on foreign businesses with local subsidiaries, compelling them to manage user grievances and regulatory responses under PIPA regardless of the original purpose of their domestic presence and potentially reducing business flexibility for international companies operating in Korea.

AMCHAM understands the intent of the amended TBA and subsequent legislative proposals mandating the appointment of a local representative is to promote the development of domestic e-commerce and to protect the rights and benefits of Korean users of online services provided by global service providers. However, such a regulation would have the unintended consequence of making it practically impossible for certain U.S. service providers to operate in Korea, particularly smaller U.S. internet companies that cannot designate an agent in Korea.

The regulation runs the risk of contradicting 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 could yield results similar to requiring the establishment of a representative office.

- **Issue**

- Recent and proposed legislation that requires foreign online service providers to designate a domestic representative in Korea.

- **Relevant Regulations**
 - Act on Promotion of Information and Communications Network Utilization and Information Protection, Etc. (Network Act)
 - Telecommunication Business Act (TBA)
 - Personal Information Protection Act (PIPA)
 - Amendments to the E-Commerce Act (KFTC)

- **Relevant Agencies**
 - Ministry of Science and ICT (MSIT)
 - Korea Media and Communications Commission (KMCC)
 - Personal Information Protection Commission (PIPC)
 - Korea Fair Trade Commission (KFTC)

- **Relevant KORUS Provisions**
 - Chapter 12 (Cross-Border Trade in Services)

- **Recommendation**

We encourage the Korean government to refrain from expanding and, where possible, to roll back requirements that compel foreign service providers to designate a local agent or domestic representative in Korea, as such measures could impose disproportionate burdens on U.S. service providers, especially smaller and emerging firms and ultimately reduce choice and innovation in the domestic online service market

Legislative Bill on Safety Management of Digital Disasters and Failures

In the aftermath of the fire and service outage at the Pangyo data center in late 2022, the Legislative Bill on Safety Management of Digital Disasters and Failures was proposed in the National Assembly's Science, ICT, Broadcasting, and Communications Committee on December 31, 2024. More recently in early 2026, a separate but related bill has been introduced, reflecting continued legislative momentum in this area.

By consolidating dispersed safety management regulations into a single legislative framework, the proposed bills mandate major digital service providers to develop annual digital safety management plans, report incidents, and cooperate with investigations into the causes of digital disasters or failures upon request by the Ministry of Science and ICT.

However, AMCHAM raises concerns about the broad and uniform application of these obligations across all value-added telecommunications business operators, regardless of the distinct nature of their services. In particular, the current legislative drafts appear to adopt an overly expansive definition of “digital disaster or failure,” potentially encompassing routine technical fluctuations such as temporary latency or traffic variations. This raises the risk that even minor or transient disruptions could trigger disproportionate regulatory measures, including administrative penalties.

In addition, the criteria used to designate “major operators” rely heavily on quantitative thresholds such as user numbers, traffic volume, and revenue. This approach may inadvertently capture a wide range of digital services that differ significantly in terms of public impact and operational risk, resulting in overinclusive regulation.

This blanket and expansive approach is both impractical and disproportionate, as it fails to account for differences in service models, operational risks, and user impact across the digital ecosystem. Moreover, the proposed requirements could significantly increase compliance costs and complexity, while raising concerns regarding the potential exposure of trade secrets due to extensive documentation and reporting obligations.

- **Issue**

The bills do not sufficiently distinguish between the various services provided by value-added telecommunications operators, resulting in redundant and overlapping regulatory obligations. In

particular, ambiguities in the definitions of “digital disaster or failure” and “major operators” risk overbroad application of regulatory requirements beyond cases of material service disruption or public impact. This approach undermines principles of proportionality and risk-based regulation, increases compliance uncertainty and administrative burden, and raises concerns regarding the protection of confidential business information.

- **Relevant Regulations**

The proposed Legislative Bill on Safety Management of Digital Disasters and Failures, Digital Disaster Safety Bill

- **Relevant Agencies**

National Assembly’s Science, ICT, Broadcasting, and Communications Committee

Ministry of Science and ICT (MSIT)

- **Relevant KORUS Provisions**

Chapter 15 (Electronic Commerce) and Chapter 18 (Intellectual Property Right)

- **Recommendation**

AMCHAM urges the National Assembly to thoroughly reassess the scope and structure of the proposed legislation. Clarifying key definitions and refining the criteria for “major operators” will be critical to ensuring that regulatory obligations are proportionate and appropriately targeted.

More broadly, regulatory obligations should be proportionate and tailored to the specific characteristics and risk profiles of different service providers. A calibrated, risk-based approach would help minimize unnecessary compliance burdens, reduce legal uncertainty, and ensure that regulatory objectives are achieved without undermining innovation or exposing sensitive business information.

Personal Information Protection Act (PIPA)

Following the amendment of PIPA in 2023, the updated law introduces several significant implications for global companies, including: (1) the expansion of data subject rights, such as data portability and the right to refuse or request an explanation on automated decision-making, and (2) a shift towards economic sanctions, with increased administrative penalties and fines based on “total revenue” rather than “relevant revenue.”

PIPA imposes strict regulations on the overseas transfer of personal data. Data controllers must inform users of the destination, intended use by third parties, transfer method and timing, and retention period when obtaining consent for such transfers. Additionally, the amended law grants the Personal Information Protection Commission (PIPC) the authority to halt a company's cross-border data transfers in cases of significant violations or insufficient protection of transferred personal data, raising concerns among U.S. stakeholders.

The PIPC's current stance on providing personal information to overseas third parties requires separate consent for both “cross-border transfer” and “third-party provision of personal information.” AMCHAM understands that these items must also be separately specified in the privacy policy. Given that the principal distinction lies in the involvement of an overseas third party, this approach may create additional compliance burdens for businesses.

Furthermore, PIPA treats third-party processors the same as data controllers/data owners under the broad concept of a “personal information handler.” As a result, all types of data-processing delegates are subject to nearly the same legal obligations as data owners. CSPs, in particular, are included in this blanket rule despite having no access, visibility or control over customer's data.

These regulations create an uneven playing field for U.S. data storage and processing service providers and are inconsistent with the principle of the most-favored-nation treatment under the KORUS FTA and the World Trade Organization (WTO) General Agreement on Trade in Services (GATS). Requiring global content providers to install servers in Korea and offer services effectively mandates data localization.

Finally, the National Assembly recently adopted an additional amendment to PIPA, which would mandate Information Security Management System–Personal Information Protection (ISMS-P) certification for companies that meet certain revenue thresholds or hold personal information. This legislation infringes upon corporate autonomy and imposes excessive regulatory compliance costs. It is unreasonable to

determine mandatory certification requirements based solely on uniform criteria such as revenue and the number of personal information records held, without considering the type of business operator. Additionally, the bill includes punitive administrative fines of up to 10% of revenue in cases of repeated and intentional personal information breaches. A fine of 10% of revenue exceeds the fundamental purpose of administrative sanctions, which is to recover unjust gains from violations, and poses a risk of excessively infringing upon corporate property rights.

- **Issue**

Strict requirements on handling the collection, usage, disclosure, and other processing of personal information Mandatory ISMS-P certification and excessive administrative fines

- **Relevant Regulations**

Personal Information Protection Act (PIPA)

- **Relevant Agencies**

Ministry of Science and ICT (MSIT)

Personal Information Protection Commission (PIPC)

National Assembly's Political Affairs Committee

- **Relevant KORUS Provisions**

Chapter 12 (Cross-Border Trade in Services)

- **Recommendation**

We urge the Korean government to align its personal information protection regulations with global standards, allow companies to voluntarily choose personal information-related certifications, establish reasonable administrative fine levels, and explore more effective ways to facilitate cross-border transfer of data in line with international best practices.



ENERGY & ENVIRONMENT

TABLE OF CONTENTS

NO.	ISSUE	STATUS
	Overview	
01	Need for Fast-track System to Supply Power for Datacenters	NEW
02	Energy Supply and Renewable Procurement Constraints for AI and Digital Infrastructure	NEW
03	Bilateral Agreements for CO2 Transport and Storage and the Establishment of Common CO2 Storage Standards	
04	Need for Strengthening the Hydrogen Sector	
05	Policy Improvement for the Distributed Power Sector	
06	Enabling the Use of Supplier-Provided Technical Documentation for RoHS Substance Compliance under the Act on Resource Circulation of Electrical and Electronic Equipment and Vehicles	NEW

ENERGY & ENVIRONMENT

OVERVIEW

In 2026, South Korea's energy and environmental policy remains anchored in its commitment to carbon neutrality by 2050, with increased focus on policy coherence, energy security, and implementation. A major institutional change is the transfer of core energy policy functions from the Ministry of Trade, Industry and Resources (MOTIR) to the Ministry of Climate, Energy and Environment (MCEE), bringing climate, energy, and environmental responsibilities under a single authority to improve coordination.

The Lee Administration continues to pursue a pragmatic energy transition, maintaining a diversified energy mix that expands renewables while relying on nuclear power and LNG to support system reliability and affordability. Coal reduction remains a policy objective, with implementation reflecting grid constraints, electricity demand growth, and industrial competitiveness. In this context, efforts to support sustainable industry development and establish effective policy and regulatory frameworks are welcome.

Following submission of Korea's 2035 Nationally Determined Contribution (NDC), which targets a 53 to 61 percent reduction in greenhouse gas emissions from 2018 levels, policy focus has shifted to execution. Greater clarity on how these targets will be achieved in practice, including the role of key carbon abatement levers, will be essential for long-term planning and investment. There is strong interest in understanding the government's policy priorities, roadmap, and implementation approach to ensure alignment with industry needs.

The Emissions Trading System (ETS) remains a central policy tool for delivering emissions reductions. Stakeholders are closely monitoring how the ETS will evolve to support investment in lower carbon solutions, particularly as future phases and implementation settings are considered. Ensuring that ETS design appropriately recognizes such investments while balancing emissions reduction objectives with economic considerations will be critical.

At the same time, rising electricity demand driven by data centers supporting artificial intelligence and cloud services is increasing pressure on power systems. This underscores the importance of grid capacity, transmission infrastructure, and clear regulatory frameworks for electricity use and self-generation.

Policy certainty and cost predictability will be critical for globally exposed, energy-intensive industries to maintain competitiveness while advancing decarbonization. Against this backdrop, AMCHAM encourages continued collaboration between the government and the private sector to develop energy and climate policies that are predictable, cost-effective, and supportive of investment, while advancing carbon neutrality and sustainable economic growth.

INDUSTRY ISSUES

Need for Fast-track System to Supply Power for Datacenters ^{NEW}

Amid the global AI transition race and the government's push to become one of the top three AI powers, the relevant industries in Korea are rushing to build data centers, a core infrastructure. However, considering the locations of major AI service customers, securing operation/maintenance personnel, and communication network, data center sites often overlap with areas which are already experiencing power demand congestion. As seen in recent discussions like the Ministry of Climate, Energy and Environment (MCEE)'s “Desirable Energy Mix” forum, securing new power sources and transmission networks requires social consensus and lengthy construction periods, making it difficult to meet the AI industry's needs. Furthermore, the Power System Impact Assessment, which requires prior evaluation of grid effects for projects needing over 10MW of power, and the Special Act on the Promotion of Distributed Energy, which only recognizes electrical facilities for commercial use under 40MW as distributed energy, are making datacenter site selection even more difficult.

- **Issue**

The Special Act on the Promotion of Distributed Energy, which aims to establish a structure where locally produced energy is consumed locally by designating special distributed energy zones and the Power System Impact Assessment which is mandatory for large-scale power consumers—including most datacenters—fails to meet the power requirements of AI datacenters, which demand large capacity, high stability, and rapid installation. Consequently, it is suppressing the construction of new datacenters. For example, the Power System Impact Assessment considers only the traditional power supply, i.e. receiving power from the grid because its primary goal is to reduce the burden on the power grid. Therefore, businesses with power exceeding 10MW must undergo this assessment. In case of the Special Act on the Promotion of Distributed Energy, only power generators of 40MW or less or combined heat & power plants of 500MW or less are considered as distributed energy sources.

- **Relevant Regulations**

- Power System Impact Assessment
 - Special Act on the Promotion of Distributed Energy

- **Relevant Agencies**

- Ministry of Climate, Energy and Environment (MCEE)
 - Ministry of Trade, Industry and Resources (MOTIR)
 - Ministry of Science and ICT (MSIT)
 - Korea Power Exchange (KPX)

- **Recommendation**

- The U.S., a leader in the AI industry, also faces the same challenges of power shortages, aging power grids, and insufficient infrastructure. The U.S. AI industry is addressing these difficulties through on-site power generation using gas turbines, fuel cells, etc. Therefore, AMCHAM proposes establishing a fast-track system modeled after these advanced success stories which are tailored to the specific power requirements of AI datacenters. Specifically, if a separate pathway is established allowing datacenter businesses to become energy prosumers—producers and consumers of their own power—Korea’s AI industry can be expected to rapidly locate data centers on suitable sites aligned with their inherent needs. By requiring that a certain percentage or more of total power consumption be sourced through self-generation and setting limits on the capacity for feeding surplus power back into the grid, the intent of current legislation to reduce grid burden can also be maintained. Furthermore, if incentives are provided for fully off-grid systems independent of the grid, the AI industry could grow regardless of the current national power grid challenges. Specifically, adopting a one-stop approach that includes fire safety and environmental permissions within this fast track would increase the effectiveness.

Energy Supply and Renewable Procurement Constraints for AI and Digital Infrastructure ^{NEW}

As Korea advances its AI and digital transformation agenda, power availability has emerged as a critical constraint affecting the timely deployment of large-scale digital infrastructure, including datacenters and cloud facilities. While this challenge is most visible in AI-related investments, it reflects broader structural issues within the electricity supply and regulatory framework that are likely to affect other strategically important, energy-intensive sectors over time.

Regions with high concentrations of economic activity, most notably the Seoul Metropolitan Area, face increasing limitations on accommodating new large electricity loads. These constraints are not always apparent during early project planning stages, creating uncertainty and inefficiencies in the investment process.

- **Issue**

In practice, power supply constraints are often identified only at relatively late stages of the investment process, after companies have already completed site selection and initial permitting, which significantly increases project risk and can result in delayed commissioning, phased development, or reduced project scope despite clear demand and capital readiness. Where additional grid reinforcement is required—such as the construction of new substations or transmission upgrades—remediation timelines frequently extend over several years, timelines that are fundamentally misaligned with the rapid development cycles required for AI and digital infrastructure. These challenges are particularly pronounced in high-demand regions such as the Seoul Metropolitan Area, where datacenter development is naturally concentrated due to proximity to customers, skilled labor, and network connectivity, further narrowing feasible site options. Compounding these issues, existing corporate renewable energy procurement mechanisms, including Green Premiums, Renewable Energy Certificates (RECs), limited PPA-based arrangements, and K-RE100 programs, often lack sufficient long-term certainty with respect to pricing, contract duration, and physical delivery, making it difficult for companies to plan operations reliably while meeting global decarbonization commitments.

- **Relevant Regulations**
Electricity Business Act

Enforcement Decree and Enforcement Rules of the Electricity Business Act
Distributed Energy Act and related implementing regulations Basic Plan for Long-Term Electricity Supply and Demand
K-RE100 renewable energy procurement guidelines

- **Relevant Agencies**

Ministry of Climate, Energy and Environment (MCEE)
Korea Electric Power Corporation (KEPCO)
Korea Power Exchange (KPX)

- **Recommendation**

Addressing current power supply and investment constraints requires improving predictability and transparency within the existing electricity policy framework, rather than undertaking fundamental structural reforms. Earlier and clearer signaling of power availability, grid capacity constraints, and potential grid reinforcement requirements at the initial stages of project planning would allow investors to make informed decisions before committing significant capital. At the same time, closer coordination among electricity planning processes, permitting authorities, and broader industrial and digital policy objectives would help reduce misalignment between national competitiveness goals and project-level feasibility. Finally, strengthening the commercial viability and reliability of corporate renewable energy procurement options, through greater price predictability, longer contract durations, and clearer delivery arrangements, would support long-term investment planning while contributing to Korea's energy transition objectives. As a more practical approach to address the imminent surge of electricity demand from AI-related investments, bridge power solutions such as fuel cells can be widely adopted if onsite power generation is promoted via revisions of current related regulations. They are fast to deploy and highly reliable regardless of weather condition and grid congestion.

Bilateral Agreements for CO₂ Transport and Storage and the Establishment of Common CO₂ Storage Standards

Given South Korea's limited storage capacity, capturing CO₂ from local emitters, transporting it, and storing it in foreign facilities will be crucial for the country to meet its emissions reduction targets for 2030 and 2050. While South Korea has ratified the London Protocol, it has actively pursued bilateral agreements with various countries to enhance its carbon capture and storage (CCS) capabilities. Notable examples include the Green Economy Partnership Arrangement with Australia in December 2024 and collaboration initiatives with Malaysia in November 2024. To further advance its CCS efforts, the Korean government should continue to actively explore additional bilateral partnerships with other countries in this field.

Additionally, as South Korea looks to store CO₂ abroad, establishing a common set of standards and requirements is essential. This would expedite transport permits and approvals, as well as enable private companies to replicate projects across various regions or countries.

The Carbon Capture, Usage, and Storage (CCUS) Act represents a positive step toward establishing a viable CCS industry in South Korea. To further support both domestic deployment and emerging transboundary CO₂ transport and storage opportunities, continued refinement of the regulatory framework will be important. In particular, greater clarity on permitting processes, as well as legal and financial responsibilities associated with long-term CO₂ storage, would help reduce uncertainty and support investment.

- **Issue**
Need for bilateral agreements to enable timely CO₂ transport from South Korea and common standards to accelerate the issuance of CO₂ transboundary transport permits
- **Relevant Regulations**
Act on the Capture, Transportation, Storage, and Utilization of Carbon Dioxide Act (CCUS Act)
- **Relevant Agencies**
Ministry of Trade, Industry and Resources (MOTIR)
- **Recommendation**
Accelerate the proposed bilateral agreements and establish additional timely agreements with countries that have relevant

storage capacity, while aligning on CCUS standards to drive the market development in collaboration with Korean stakeholders.

Further development of a comprehensive CCUS legislative and regulatory framework, covering both domestic and transboundary aspects, will also be important to support long-term industry development and the achievement of emissions reduction objectives.

Need for Strengthening the Hydrogen Sector

South Korea aims to position hydrogen and hydrogen-derived fuels as strategic tools to decarbonize power generation and other hard-to-abate sectors. In support of this goal, Korea launched the world's first clean hydrogen power generation competitive bidding scheme (CHPS) in 2024.

However, the first CHPS round underperformed relative to policy expectations. Although the government sought to contract up to 6,500 GWh per year, only 750 GWh per year was awarded, with Korea Southern Power (KOSPO) selected as the sole preferred bidder. This outcome underscored persistent bankability challenges, including uncertainties around delivered fuel costs and project risk allocation, at a stage when clean hydrogen and hydrogen-carrier supply chains remain capital-intensive and infrastructure-constrained.

The cancellation of the second CHPS auction in October 2025 brought confusion to the market with increased uncertainty surrounding policies. Market participants may lose confidence in the persistence of the program, which could escalate the risk premium. Due to the lengthy lead times associated with hydrogen production, transportation, and conversion infrastructure, consistent auction schedules and stable policies are essential for mobilizing sustained private-sector investment.

To ensure the firm establishment of CHPS, it is essential to accelerate the commercialization of production technologies that can drastically lower the procurement cost of hydrogen fuel. The government must significantly ramp up its policy momentum to ensure that green hydrogen, based on renewable energy, and pink hydrogen, which utilizes the affordable electricity and heat from nuclear power can establish themselves as the mainstream of the market.

To expedite the commercialization of these technologies, it is necessary to proactively expand large-scale electrolysis projects. The scale of state-led demonstration programs must be increased to allow for operational experience with electrolysis facilities at a level applicable to actual power generation sites, moving beyond mere technical verification. Furthermore, regarding nuclear power, where regulations are exceptionally stringent, pan-governmental efforts are required to swiftly address the rigid regulatory framework currently facing the nuclear industry.

By ensuring policy consistency and securing a downward stabilization of hydrogen prices, CHPS will finally gain sustainable momentum.

- **Issue**
Need for sustaining and strengthening the industrial ecosystem
- **Relevant Regulations**
Act on the Hydrogen Economy Promotion and Hydrogen Safety Management
- **Relevant Agencies**
Ministry of Climate, Energy, and Environment (MCEE)
- **Recommendation**
Strengthen and stabilize the Clean Hydrogen Power System (CHPS) by keeping the policy consistency and lowering the cost of fuel, clean hydrogen, through earlier commercialization of electrolysis technologies.

Policy Improvement for the Distributed Power Sector

The Special Act on the Promotion of Distributed Energy, which aims to overcome the limitations of the centralized power system and expand renewable energy infrastructure by enhancing the efficiency of energy production, transportation, and utilization through distributed power sources, came into effect on June 14, 2024. However, several key areas still need improvement to ensure the policy's success.

For instance, KEPCO maintains a monopoly over power transmission, distribution, and sales, which makes it difficult for microgrids to operate independently. Additionally, KEPCO's prioritization of its existing power resources can hinder the widespread adoption of distributed power sources, such as renewable energy. Notably, the concentration of data on power demand, supply, and distribution—critical for the efficient operation of distributed power grids—within a company representing the existing centralized system could impede the development of the broader industrial ecosystem.

Moreover, the economic incentive for adopting decentralized power remains unclear, as it lacks detailed regional pricing regulations. While the Special Act provides a legal framework for differentiated electricity rates, the absence of specific guidelines for applying these differential rates has stalled progress on related projects. To address this, it is essential to develop a clear and specific standard for calculating differential tariffs, taking into account factors such as the distance from power plants, the actual costs of transmission and distribution, and regional variations between electricity production and demand.

- **Issue**
Grant greater independence to microgrids and implement clear regional pricing regulations for decentralized power
- **Relevant Regulations**
The Special Act on Activation of Distributed Energy
- **Relevant Agencies**
Ministry of Climate, Energy, and Environment (MCEE)
- **Recommendation**
AMCHAM recommends that KEPCO & KPX protocols ensure greater independence for microgrids and establish clear regional pricing regulations for decentralized power. Additionally, specific guidelines should be created to implement differential tariffs based on transmission costs and regional demand.

Enabling the Use of Supplier-Provided Technical Documentation for RoHS Substance Compliance under the Act on Resource Circulation of Electrical and Electronic Equipment and Vehicles NEW

Following the announcement by the Ministry of Climate, Environment and Energy (MCEE) in September 2025, restrictions on the use of ten hazardous substances regulated under the Act on Resource Circulation of Electrical and Electronic Equipment and Vehicles (the “Resource Circulation Act”) will apply to electrical and electronic equipment and vehicles imported into Korea on or after January 1, 2028. For imported products, compliance with the hazardous substance content limits must be verified and substantiated within three months after importation.

Under the Resource Circulation Act, test reports related to Restriction of Hazardous Substances(RoHS)-regulated substances are considered evidentiary documents for post-market surveillance by regulatory authorities. The authorities have explained that importers and manufacturers are required to independently commission testing through accredited laboratories and maintain such documentation for compliance purposes.

For importing companies operating within global supply chains, this requirement creates a significant burden. Even where identical products have already been evaluated and verified in accordance with the global compliance process such as the EU’s RoHS requirements, companies are still required to undergo additional and duplicative verification procedures to meet the Korean Resource Circulation Act standards.

Korea’s “Guidelines on the Verification of Compliance with Hazardous Substance Content Limits in Electrical and Electronic Equipment and Vehicles” stipulate that, for importers, only test reports issued by accredited testing laboratories are recognized as valid evidence to demonstrate compliance with hazardous substance limits. This approach differs from international compliance practices that generally allow companies to demonstrate conformity through technical documentation based on internal compliance systems, supplier declarations, material information, contractual data, and testing results, as appropriate.

As a result, importers may be required to conduct repeated testing through accredited laboratories even where compliance has already been verified through established global compliance processes such as EU RoHS requirements. This evidentiary requirement does not adequately reflect the realities of global supply chains and can

impose duplicative administrative procedures on companies by requiring the same verification processes to be repeated under different regulatory regimes.

- **Issue**

Rigid evidentiary requirements for RoHS substance compliance under the Resource Circulation Act, which fail to reflect global supply chain practices, resulting in duplicative testing, increased administrative burden, and regulatory inefficiencies for importers

- **Relevant Regulations**

Act on Resource Circulation of Electrical and Electronic Equipment and Vehicles

- **Relevant Agencies**

Ministry of Climate, Environment and Energy (MCEE)

- **Recommendation**

AMCHAM recommends that the Korean government take the following actions:

- Revise the provisions on acceptable evidentiary documents for importers to allow recognition of compliance documentation issued by foreign governmental authorities or accredited laboratories, as well as supplier-provided technical documentation, where products imported into Korea have already demonstrated compliance with internationally recognized standards such as EU RoHS.
- Extend the implementation timeline for hazardous substance use restrictions to enhance global suppliers' understanding of Korean RoHS requirements and facilitate smoother compliance across international supply chains.



FINANCIAL SERVICES

TABLE OF CONTENTS

NO.	ISSUE	STATUS
	Overview	
	GENERAL ISSUES	
01	Relaxation of Network Separation Standards	NEW
02	Update of the Verification Practices under the Real Name Act	NEW
	BANKING & SECURITIES	
03	Recognition of Head Office Capital	NEW
04	Macro-prudential Stability Levy	NEW
05	Relaxation of Foreign Exchange Position Limits	NEW
06	Increase in Cash Pooling Management Limit	NEW
07	Authorization - Approval of MSD Investment Dealing License	NEW
08	Consistency in the Application of License Requirements	NEW
09	IPO Underwriter Lock-Up and Retention Requirements	NEW
10	Enforcement for Breach of Short Selling Requirements	NEW
	INSURANCE & ALTERNATIVE INVESTMENT	
11	Scope 3 Implementation: The Need for Insurance-Specific Guidance for Foreign-Invested Companies	NEW
12	Uncertainty Around the Equity Repo Business in Korea	NEW
13	Excessive Regulatory Control on Financial Products	

OVERVIEW

Korea is one of Asia's most dynamic economies, home to world-class corporations, a highly educated workforce, and a strong track record of innovation and resilience. In step with its economic presence, Korea's financial markets are important to global financial firms. The Korea Exchange, the primary securities exchange in Korea, is ranked 9th among exchanges globally with a market capitalization of USD 2.53 trillion as of January 2026, according to the World Federation of Exchanges. The Korean banking sector is an important market for foreign banks, particularly for corporates and, increasingly, wealth management, combining systemic stability, digital innovation, and a solid corporate client base.

The Lee Jae-myung administration has set ambitious targets to bolster the Korean capital markets, which include driving the KOSPI to 5,000, addressing the persistent Korea discount in the valuation of Korean corporations, supporting wealth creation for all Koreans, and seeking Korea's inclusion in the Morgan Stanley Capital International Index (the "MSCI") Developed Markets Index. We welcome the government's ambitious initiatives. Achieving these goals will require not only leveraging Korea's inherent strengths but also strategically reshaping the financial sector to foster a more open, flexible, and business-friendly regulatory environment that can attract and sustain foreign capital.

At this critical juncture, Korea's financial sector requires further regulatory reform to harness its full potential and enable the nation to achieve its goals of inclusion in the MSCI Developed Market Index, cementing its position as a global financial market, and becoming an Asian financial hub. While the market is already home to outstanding domestic and multinational companies, regulatory barriers continue to constrain the ease of doing business for foreign financial services companies operating in the country.

In this context, the government recently announced a "Comprehensive Roadmap for Foreign Exchange and Capital Market Measures for Korea's Inclusion in the MSCI Developed Markets Index," where some of our suggestions have been included in the future plans. As concrete policy reforms are expected to follow from this comprehensive roadmap, AMCHAM hopes that

the Korean government work closely with international businesses and the U.S. government to enhance investor confidence in the Korean market and provide the necessary infrastructure for multinational companies to thrive in Korea.

GENERAL ISSUES

Relaxation of Network Separation Standards **NEW**

Most foreign financial institutions mainly target businesses facing domestic and foreign institutional investors and corporations, rather than individuals. They provide institutional investors and corporations with automated services such as transaction history generation (sometimes including remittance services) and direct market access (the “DMA”). In particular, DMA services are provided through leased lines and are blocked from connectivity to external networks.

Moreover, foreign financial institutions delegate the operation and management of IT systems to their global head office or overseas affiliates (the “Overseas Affiliate”) and apply the same infrastructure and IT and security policies (the “Policies”) adopted globally in order to effectively manage and maintain various security risks. Considering the scope and complexity of the tasks relating to IT resources and cyber security that the onshore IT department typically undertakes, it would be difficult for the onshore IT staff to carry out such tasks without considerable delegation to the Overseas Affiliate. To carry out the delegated tasks, the IT systems located in the onshore IT server room must be connected to the terminal of the Overseas Affiliate through a dedicated line.

As certain limited services that foreign financial institutions provide to customers constitute electronic financial business, these institutions are required to fulfill obligations to implement various security measures under the Electronic Financial Supervisory Regulations (the “EFSR”). These security measures include network separation requirements, an obligation that does not exist in other jurisdictions. To comply with the Korean network separation requirements, foreign financial institutions must implement IT infrastructure and policies that are completely different from those that the global head office applies. This Korean requirement not only imposes significant costs, but also impedes the Korean operation’s adoption and application of new technologies, given that it limits onshore access to the various IT security measures provided by the global head office.

Regarding the connection of the onshore IT system to the Overseas Affiliate’s terminal, the Financial Supervisory Service (the “FSS”) issued an interpretive ruling¹⁴ which held that (i) such connection is in violation of the physical network separation requirement under Article 15(1)5 of the EFSR if the terminal of the Overseas Affiliate

¹⁴ FSS No-action Letter, June 10, 2025 (No. 250019).

only has logical network separation applied to it and is connected to multiple foreign affiliates' servers; and (ii) the connection and access between the Overseas Affiliate's terminal and the onshore server for the performance of the outsourced IT system operation and management cannot be deemed to be "unavoidable" for business purposes, and as such it does not avail the exception set out in Article 2-3(2) of the Detailed Enforcement Rules of the EFSR. Due to the FSS's interpretation, foreign financial institutions face difficulties in outsourcing/delegating IT-related tasks in Korea to Overseas Affiliates.

The recent pre-announcement of amendments to the Enforcement Rules of the EFSR, recognizing software-as-a-service ("SaaS") provided by Cloud Service Providers (the "CSPs") as eligible for exemption from network separation requirements, is a constructive development in the modernization of Korea's IT regulatory framework. However, as the exemption remains limited where personal identification or credit information is processed and detailed, prescriptive information protection controls continue to apply, the practical scope of the reform may be constrained. Given current global cloud security standards, which emphasize multi-layered and continuously monitored controls rather than strict physical isolation, the continued rigid application of network separation requirements may warrant calibrated reassessment. Such reassessment would better align regulatory requirements with modern cloud architectures and Korea's broader digital transformation objectives in the financial sector.

- **Issue**

Korean network separation mandates impose high costs and impede the Korean operation's ability to adopt new technologies and integrate fully with global IT policies. A restrictive FSS interpretation prevents "unavoidable" business connections to Overseas Affiliates for outsourced IT management. While the recent amendments to the Enforcement Rules of the Electronic Financial Supervisory Regulations (EFSR) recognizes SaaS provided by cloud services providers (CSPs) as exempt from network separation requirements, the practical impact remains limited due to restrictions tied to the processing of personal information and the continued application of prescriptive control standards.

- **Relevant Agencies**

Financial Services Commission (FSC)
Financial Supervisory Service (FSS)

- **Relevant Regulation**

Electronic Financial Supervisory Regulations (EFSR): Article 15(1)5
Detailed Enforcement Rules of the EFSR; Article 2-3(2); Annex 7

- **Recommendation**
 - **Easing of the Network Separation Requirement:** We request that the regulations relating to network separation be eased in cases where (i) the onshore IT system is connected to the terminal of the Overseas Affiliate or institutional investors (for the use of DMA services) through secure networks such as leased lines, or (ii) internal business terminals can be designated as non-electronic financial networks as they do not access the information processing system related to electronic financial business. Furthermore, the network separation framework should be further refined on a risk-based basis, with exceptions permitted where appropriate information protection controls are in place.

 - **Exceptions to Network Separation Requirement:** Currently, even where there is a business necessity to connect the onshore IT system with the terminal of the Overseas Affiliate using a secure dedicated line for the delegation of the operation and management of the Korean entity's IT system to the Overseas Affiliate, it does not constitute an exception to the network separation obligation due to the FSS's restrictive interpretation discussed above. In line with the recent initiative to exempt certain SaaS arrangements from network separation requirements, similar exception treatment should be extended to connections between the onshore IT system and the terminal of the Overseas Affiliate, where such connections are established over secure private networks or dedicated communication lines. To this end, the relevant provisions of the EFSR Enforcement Rules and related interpretive guidance should be refined to provide greater clarity on the applicable criteria and procedural requirements. If such an exception is granted, foreign financial institutions will comply with the alternative information protection controls in lieu of network separation as required under Annex 7 of the Detailed

Enforcement Rules of the EFSR to ensure that application of the exception does not heighten IT security risks.

Update of the Verification Practices under the Real Name Act ^{NEW}

Under the Act on Real Name Financial Transactions and Confidentiality (the “Real Name Act”), in order to prevent customers from conducting transactions under fictitious or borrowed names, the real name verification system requires customers to use their real names in financial transactions. This involves verifying a person’s identity through photo identification, such as an ID card, to ensure transparency in financial transactions.

Financial institutions’ operational practices under the Real Name Act follow the Guidelines on Real Name Financial Transactions (the “Guidelines”) issued by the Korea Federation of Banks, which apply not only to the banking sector but also to the financial investment sector. The Guidelines set out, in detail, the documentation and procedures required for face-to-face real-name verification by customer type. Failure to obtain any of the specified documents is treated as a procedural violation, and administrative fines may be imposed on the financial institution and responsible personnel on a per-transaction and per-amount basis. However, for corporate customers, the corporation’s representative or agent must present identification and undergo cumbersome real-name verification either in person or through remote methods. In this process, the bank must request a power of attorney from the representative or agent representing the corporation or for notarization of documents from corporations, even from jurisdictions that do not have a notarization system. For foreign corporate customers, such real-name verification is even less practical and serves as a significant procedural hurdle when entering into financial transactions.

Foreign corporate customers continue to face significant practical burdens under the current real-name verification regime. Requirements for local bank staff to obtain powers of attorney and for customers from jurisdictions without notarization systems to provide notarized documents impose substantial procedural obstacles to financial transactions in Korea. Under the recently announced comprehensive foreign exchange and capital market roadmap, aimed at facilitating Korea’s inclusion in the MSCI Developed Markets Index, certain easing measures are contemplated for low-risk foreign corporate customers, including exemptions from notarization, waiving of the requirement to have in place domestic-resident proxies, and the introduction of non-face-to-face verification procedures. While these measures are welcomed, further adjustments will be necessary to ensure practical implementation – particularly in enabling practicable non-face-to-face verification procedures, easing verification at the account-opening stage, and permitting asset management companies to satisfy verification requirements on behalf of underlying investors. Continued alignment with international identification standards will be essential to enhance foreign investor access to the Korean market.

Since the enactment of the Act on Reporting and Using Specified Financial Transaction Information (the “Specified Financial Transaction Act”), all Korean financial institutions are

required to conduct rigorous customer due diligence (CDD) for corporate customers. Therefore, corporations whose identity is clearly established through these due diligence procedures pose little risk of conducting transactions under pseudonyms or borrowed names. Nevertheless, imposing an additional real name verification process separate from the CDD requirements is uncommon in other global markets and ultimately weakens the competitiveness of Korean financial institutions.¹⁵

- **Issue**

Despite the application of stringent Customer Due Diligence (CDD) requirements under the Specified Financial Transaction Act, a Korea-specific real-name verification framework remains in place under the Act on Real Name Financial Transactions and Confidentiality. The additional verification requirements imposed on foreign corporate customers are not aligned with international practice and impose disproportionate operational burdens.

- **Relevant Agencies**

Financial Services Commission (FSC)
Financial Supervisory Service (FSS)

- **Relevant Regulation**

Act on Real Name Financial Transactions and Confidentiality (“Real Name Act”): Article 3(1), 3(2)
Enforcement Decree of the Real Name Act; Article 3

- **Recommendation**

We respectfully request relaxation of the real name verification requirements under the Real Name Act. In addition, financial institutions should be allowed to adopt, at their discretion, real-name verification procedures aligned with international standards, in a manner that does not undermine the objectives of the Real Name Act and the Specified Financial Transaction Act.

- Domestic corporate customers: Allow verification either by the business registration document of the corporate customer or allow remote, non-face-to-face methods of real name verification

¹⁵ In particular, with the introduction of the RFI system, foreign corporate customers are now permitted to engage in foreign exchange transactions as RFIs. Since RFIs are foreign financial institutions not obligated to verify customers’ real names, foreign corporate customers are likely to prefer conducting foreign exchange transactions through RFIs, rather than domestic financial institutions. In this changing regulatory environment, the real name verification requirements under the Real Name Act may undermine the competitiveness of Korean financial institutions.

of the identity of a lawful representative or agent through a power of attorney and a person's ID or a certificate of employment issued by the corporate customer.

- Foreign corporate customers: Introduce practicable non-face-to-face real-name verification procedures for non-resident corporate customers, ease verification requirements at the account-opening stage, and permit asset management companies to satisfy verification requirements when acting on behalf of underlying investors so as to reduce unnecessary procedural burdens. In the longer term, consideration should be given to: (i) exemption from the real name verification requirements or (ii) deem the real name verification process to be satisfied if the CDD requirements under the Specified Financial Transaction Act are met.¹⁶

¹⁶ Article 3 of the Enforcement Decree of the Real Name Act explicitly prescribes for the necessary identification requirements for foreign individuals who are natural persons as "the name and registration number as stated in the registered alien record (or the name and number as stated in the passport or ID card if an alien registration card has not been issued)." The fact that requirements for corporates are not stipulated could provide the basis for a reasonable interpretation that the real name verification obligation does not apply to foreign corporations under the current laws and regulations.

BANKING & SECURITIES

Recognition of Head Office Capital ^{NEW}

Under the Bank Act and the Corporate Income Act Law, various prudential regulations and tax base applied to banks are calculated from a bank's capital. However, in the case of a foreign bank branch, the Bank Act does not recognize the capital of the head office. Rather, the operating fund of a foreign bank branch (Fund A and Fund B) is deemed to be the capital of a foreign bank branch.¹⁷ Regulation based on the operating fund rather than the capital of the bank significantly constrains the business capacity of a foreign bank branch. This result not only limits a foreign bank's business in Korea, but it also limits the development and expansion of the Korean financial market. A bank cannot extend credit to the same borrower in excess of 25% of its equity capital. In the case of a foreign bank branch, the same credit limit per borrower is set from the operating fund held in Korea, resulting in severe restrictions on the loan amount that can be extended to customers.

For reference, in the U.S., the regulation seeks to protect creditors of foreign bank branches by either recognizing the head office's capital of a foreign bank branch or by imposing an obligation to hold assets in excess of a certain amount in the US. Korea has a similar requirement for foreign bank branches to hold assets in size equivalent to the size of the operation fund as a measure to protect creditors. However, this requirement is in addition to recognizing only the branch's operating funds as capital of the bank.¹⁸

- **Issue**

The Banking Act only recognizes the foreign bank branch's domestic operating fund (Fund A/B) as capital, severely constraining the limit on credit extension to the same borrower (25% of equity capital).

- **Relevant Agencies**

Financial Services Commission (FSC)

- **Relevant Regulation**

Banking Act: Article 9, Article 62, Article 63

¹⁷ Articles 9 and 63 of the Bank Act and Article 26 of the Enforcement Decree of the Bank Act.

¹⁸ Article 62 of the Bank Act, Article 25 of the Enforcement Decree of the Bank Act.

- **Recommendation**

Considering the necessity to protect Korean creditors when liquidating a bank branch, we suggest that the requirement under the Bank Act for a foreign bank branch to retain a certain amount of assets in Korea be maintained or supplemented. However, we respectfully request that the Bank Act be amended to recognize all or a significant portion of the head office's capital as the capital of a foreign bank branch.

Macro-prudential Stability Levy ^{NEW}

The recently implemented regulatory relaxation measures to promote trading in KTBs and MSBs by foreign investors are expected to increase foreign investors' demand for the bonds. To accommodate this increased demand, foreign bank branches will need to maintain a higher inventory balance of Korean government bonds, which, in turn, will increase the need for short-term borrowings from their head offices or offshore affiliates. An increase in short-term borrowings will result in higher macro-prudential stability levies.¹⁹ For foreign bank branches that must compete with RFIs for foreign exchange businesses, the increase in macro-prudential stability levies is expected to adversely affect their competitive position.

We understand that the primary objective of macro-prudential stability levies is to curb excessive short-term foreign currency borrowings by financial institutions such as banks, thereby reducing foreign exchange liquidity risk. However, short-term borrowings by a foreign bank branch from its head office or offshore affiliates are intercompany transactions, where maturity profiles can be easily adjusted. This practical flexibility does not run afoul of the intended purpose of the macro-prudential stability levies, whose aim is to limit short-term foreign currency borrowings.

In addition, an alternative approach to achieve the regulatory purpose of the macro-prudential stability levy would be through a liquidity coverage ratio (LCR) threshold to respond to the short-term liquidity crisis and Net Stable Funding Ratio (NSFR) to finance foreign currencies in the mid- to long-term.

- **Issue**

Short-term borrowings from the head office or offshore affiliates – often necessary to maintain higher inventories of Korean government bonds – are included in the non-deposit foreign currency liabilities base for the levy, adversely affecting the competitive position of foreign bank branches against RFIs, despite such intercompany borrowings posing limited liquidity risk.

- **Relevant Agencies**

Ministry of Finance and Economy (MOFE)

- **Relevant Regulation**

Foreign Exchange Transactions Act (FETA) Article 11-2

¹⁹ Article 11-2 of the Foreign Exchange Transactions Act and Article 21-3 of the Enforcement Decree of the Foreign Exchange Transactions Act.

Enforcement Decree of the FETA Article 21-2 and 21-3

- **Recommendation**

Short-term borrowings from the head office or offshore affiliates of a foreign bank branch should be excluded from non-deposit foreign currency liabilities, based on which the macro-prudential stability levy is calculated. This adjustment would enable foreign bank branches to increase their business in Korea, including responding more effectively to the rising demand for Korean government bond transactions by foreign investors.

Relaxation of Foreign Exchange Position Limits ^{NEW}

Banks regulated in Korea are subject to foreign exchange position limits, comprised of comprehensive and forward exchange position limits.²⁰ On the other hand, RFIs are exempt from these foreign exchange position limits.²¹ As a result, foreign bank branches in Korea conducting primarily foreign exchange transactions with non-resident clients are subject to a stricter requirement for equity capital²²—which is the basis for establishing the foreign exchange position limits—in comparison to offshore peers. Unlike prevailing global standards, the equity capital of foreign bank branches in Korea is calculated only based on the branch’s “A fund” and “B fund”, reserves, and carried-over retained earnings. This results in significantly lower foreign exchange position limits for foreign bank branches, bringing down the permissible volume of foreign exchange transactions. The foreign exchange position limits that foreign bank branches in Korea are subject to place them at a competitive disadvantage for foreign exchange business when compared to offshore RFIs. Consequently, there is concern that many non-resident foreign customers are likely to switch their correspondent banks to RFIs from foreign bank branches operating in Korea.

- **Issue**

Foreign bank branches are subject to FX position limits based on the lower locally calculated equity capital (Fund A/B), placing them at a competitive disadvantage against offshore RFIs, which are not subject to such constraints.

- **Relevant Agencies**

Ministry of Finance and Economy (MOFE)
Financial Supervisory Service (FSS)

- **Relevant Regulation**

Foreign Exchange Transactions Act (FETA), Articles 2-1(2)(2), 7-15, and 11(2)
Enforcement Decree of the FETA, Article 21(2)

²⁰ Article 11-2 of the Foreign Exchange Transactions Act, Article 21-2 of the Enforcement Decree of the Foreign Exchange Transactions Act, and Article 2-9 and Article 2-9 (2) of the Foreign Exchange Transactions Regulation.

²¹ Article 5-2 of the Guidelines on Foreign Exchange Business of Foreign Financial Institutions provides for foreign exchange position limits, but further details are not provided.

²² Article 2-9-2(4) of the Foreign Exchange Transactions Regulation.

Foreign Exchange Transactions Regulation, Articles 2-9, 2-9(2), and 2-9(2)(4)

Guidelines on Foreign Exchange Business of Foreign Financial Institutions, Article 3-3(5)(2)

Foreign Exchange Guidelines for the Current Account Transactions and Other Transactions of RFI

- **Recommendation**

We respectfully request that the FSS proactively consider implementing measures to enable foreign bank branches and RFIs to compete on an equal footing. This could be achieved either by revising the methodology for the calculation of equity capital for foreign exchange position limits or by granting exemptions from the application of these limits specifically for foreign bank branches.

Increase in Cash Pooling Management Limit ^{NEW}

Under the current foreign exchange law, the cash pooling limit is capped at USD 50 million, which is too low to allow effective utilization of the cash pooling system by foreign-invested companies.

- **Issue**
The current cash pooling limit is capped at USD 50 million, which is too low to allow effective utilization of the cash pooling system by foreign-invested companies.
- **Relevant Agencies**
Ministry of Finance and Economy (MOFE)
- **Relevant Regulation**
Foreign Exchange Transactions Regulation, Article 7-2(6)
- **Recommendation**
Although efficient cash pooling has become a common practice globally, foreign companies face difficulties in setting up effective cash pooling arrangements in Korea due to strict foreign exchange regulations. This restriction hampers the entry and operation of foreign-invested companies in Korea. Therefore, we respectfully request that the FSS actively consider raising the cash pooling limit from the current USD 50 million to USD 100 million.

Authorization – Approval of MSB Investment Dealing License ^{NEW}

The iCSD accounts are expected to facilitate trading not only KTBs but also MSBs by foreign investors in the future, resulting in increased trading of MSBs through licensed investment dealers. However, under the current licensing framework, foreign bank branches require an additional investment dealing business license for MSBs because the license to deal in KTBs and MSBs is differentiated. Most foreign bank branches hold the investment dealing license for KTBs but not for MSBs.

From the perspective of foreign investors, both KTBs and MSBs generate similar exposures to Korean sovereign risk and are thus viewed similarly. However, the fact that foreign bank branches generally hold investment dealing licenses for KTBs and not for MSBs creates confusion and inconvenience in trading MSBs in Korea.

- **Issue**

Foreign bank branches typically hold KTB dealing licenses but are restricted from dealing in MSBs (Monetary Stabilization Bonds), causing confusion and inconvenience for foreign investors who view both securities as having similar sovereign risk exposure.

- **Relevant Agencies**

Financial Services Commission (FSC)

- **Relevant Regulation**

Financial Investment Services and Capital Markets Act (FSCMA), Article 12
Enforcement Decree of the FSCMA
Regulation on Financial Investment Business

- **Recommendation**

To actively address foreign investors' demand for trading MSBs, we recommend considering the granting of an investment dealing business license for MSBs to domestic banks, including foreign bank branches. If there are concerns that granting such a license for cross-border bond dealing may infringe on the existing business scope of Korean securities firms, limiting the scope of the license to transactions exclusively with foreign investors would help to some extent to address this concern. Under this arrangement, foreign bank branches could source cross-border bond trades with foreign investors and trade with Korean securities firms, thereby minimizing any conflict with the business interests of Korean securities firms.

Consistency in the Application of License Requirements ^{NEW}

Foreign financial investment firms have shown continued interest in entering the Korean market, and the regulators have relaxed the licensing regime over the years. Nevertheless, certain aspects of the licensing regime continue to present difficulties for foreign firms in entering the Korean market or in restructuring an existing Korean business entity operating in Korea.

While certain exemptions from the head office qualification requirements apply when a branch changes its head office to an entity within the same group, there remains ambiguity on whether the same exemptions would extend to the ongoing “maintenance requirements” upon completion of the restructuring. One example of a lack of clarity is the application of the requirement that the proposed new head office must not have received a criminal penalty exceeding KRW 500 million in the preceding three years. This “no-sanctions” requirement is exempted when applied to change the head office of an existing branch, but it is unclear if the same exemption would apply to the maintenance requirement once the restructuring is completed.

Additionally, the ongoing maintenance requirement for the head office of a foreign branch (that it must not have received a criminal penalty exceeding KRW 500 million in its home jurisdiction in the last three years) is itself an excessively strict standard.

- **Issue**
Gaps and inconsistencies in applying special exemptions and post-restructuring maintenance requirements remain ambiguous.
- **Relevant Agencies**
Ministry of Finance and Economy (MOFE)
- **Relevant Regulation**
Enforcement Decree of the Financial Investment Services and Capital Markets Act (FSCMA), Article 19-4
- **Recommendation**
To address gaps in the divergent application of the same regulatory exemption to post-restructuring of the entity, we request that the relevant legal framework be amended or clarified through an interpretive ruling so that exemptions can be applied consistently and fairly.

IPO Underwriter Lock-Up and Retention Requirements ^{NEW}

(1) 30-Day Lock-Up Requirement for Underwriter in Cases of Undersubscription

Investment dealers or brokers that act as a lead underwriter in an initial public offering or unlisted public offering of the company whose securities they or their interested party held for two years prior to the initial public offering of the company are subject to a 30-day lock-up.²³

The FSC issued an interpretive ruling²⁴ stating that the lock-up applies equally to those securities taken up by the underwriters due to undersubscription of the public offering, and on this basis, the FSS imposes sanctions on underwriters who violate the lock-up.

Where a foreign securities company underwrites an IPO in Korea, it may have to subscribe to some of the shares due to circumstances beyond its control, such as undersubscription. However, since foreign securities firms mainly engage in the brokerage of transactions between domestic investors and offshore affiliates, there is significant difficulty for the foreign securities companies to have the capital in Korea to acquire and hold newly issued shares for a long duration.

- **Issue**

The 30-day lock-up applies to securities acquired by underwriters due to undersubscription. This poses difficulties for foreign securities companies, whose primary role is brokerage, and who lack the capital capacity in Korea to hold shares for an extended duration.

- **Relevant Agencies**

Financial Services Commission (FSC)

- **Relevant Regulation**

Financial Investment Services and Capital Markets Act (FSCMA), Article 71(7)

Enforcement Decree of the Financial Investment Services and Capital Markets Act (FSCMA), Article 68(5)4(ma)

²³ Article 71(7) of the FSCMA, Article 68(5)4(e) of the Enforcement Decree of the FSCMA, Article 4-19(5) of the Financial Investment Business Regulation.

²⁴ FSC Interpretive Ruling, October 12, 2017 (No. 170265).

- **Recommendation**

To address gaps in the divergent application of the same regulatory exemption to post-restructuring of the entity, we request that the relevant legal framework be amended or clarified through an interpretive ruling so that exemptions can be applied consistently and fairly.

(2) Underwriter Mandatory Retention Requirement in Cases of Lock-Up Allocation Shortfall

In an IPO, 40% or more of the shares that can be allocated to institutional investors must be pre-allocated to those institutional investors with lock-up commitments.²⁵

Moreover, institutional investors with longer lock-up commitments are to be granted preferential allocation of the shares depending on the lock-up period.²⁶

If the underwriter fails to allocate all of the shares to institutional investors with lock commitments, the underwriter is required to acquire either 1% or KRW 3 billion of notional value of the publicly offered shares and hold such shares for at least 6 months from the date of listing.²⁷

This requirement diverges from global market practice. The preferential allocation by lock-up commitments makes it challenging to attract investment from leading foreign institutional investors in Korean domestic IPOs. The obligation imposed on foreign securities firms in Korea to hold a certain minimum amount of securities is a significant burden to the foreign securities companies whose main business is brokerage.

- **Issue**

Requirements mandate preferential allocation of institutional investor shares based on lock-up commitments (40% or more). This diverges from global market practice and makes it challenging

²⁵ Article 9(1)7(a) of the Regulations on Securities Underwriting.

²⁶ Best Practices for Underwriters Part 3 "Demand Forecast for IPO", 5-2.

²⁷ Article 9(14)3 of the Regulations on Securities Underwriting Business.

to attract leading foreign institutional investors, placing a significant burden on foreign underwriters.

- **Relevant Agencies**

Financial Services Commission (FSC)

Korea Financial Investment Association (KOFIA)

- **Relevant Regulation**

Regulations on Securities Underwriting Business, Articles 9(1)7(*ga*) and 14

- **Recommendation**

Foreign institutional investors participating in Korean IPOs rarely agree to voluntary lock-up commitments and often have an internal approval process, which makes it practically impossible to agree to lock-up commitments. Notwithstanding this challenge, a solid investment track record by foreign institutional investors participating in Korean domestic IPOs has been maintained, as many of the foreign institutional investors have long established relationships with global investment banks on the group level. However, foreign institutional investors would find it difficult to accept the recently amended requirement for underwriters to preferentially allocate shares to those investors who agree to voluntary lock-up commitments. Furthermore, if the Korean supervisory agencies were to impose regulatory disadvantages on underwriters who fail to comply with the foregoing provisions, such a decision would be contrary to global market practices. We respectfully request that exceptions to the application of the new IPO preferential allocation requirements be granted to foreign underwriters of domestic IPOs that allocate shares to foreign investors in light of global market practices and to ensure that Korean domestic IPOs remain attractive to foreign institutional investors.

Enforcement for Breach of Short Selling Requirements ^{NEW}

Foreign financial institutions that engage in cash short sale trades of Korean listed stocks understand and appreciate the importance of preventing illegal naked short sales in order to preserve the integrity and transparency of stock markets. Moreover, they are of the view that there should be strict monitoring of intentional illegal naked short sales intended to manipulate stock prices or to engage in other market abuse conduct, and imposition of significant penalties on parties that engage in such conduct.

However, they view short sale regulatory breaches that occur due to inadvertent error or mistake should be clearly distinguished from intentional illegal naked short sales and be subject to a much less stringent enforcement process and penalties. The positive impact of short sales on the market, such as promoting liquidity and improving price discovery (by having both positive and negative information promptly reflected in market prices), should also be recognized.

Also, we note that the recently announced MSCI-related initiative includes an item on the rationalization of short-selling regulations. In light of the introduction of measures such as short-selling ID issuance through the supervisory authority and daily transaction and balance reporting via the Korea Exchange's Naked Short Selling Detection System (NSDS), there may be scope to streamline certain existing reporting and compliance requirements. As there does not currently appear to be a formal process for gathering industry perspectives, we would welcome the establishment of an appropriate channel for industry consultation.

- **Issue**
Short sale regulatory breaches occurring due to inadvertent error or mistake are not clearly distinguished from intentional illegal naked short sales, leading to overly stringent enforcement and penalties.
- **Relevant Agencies**
Financial Services Commission (FSC)
- **Relevant Regulation**
New short sale regulatory requirements effective from March 31, 2025

- **Recommendation**

We request that the short sale regulatory regime be amended to provide the basis for a more equitable level of sanctions for those short sale breaches that occur due to inadvertent error or mistake and do not involve any intentional market abuse. Furthermore, in connection with the ongoing rationalization of short-selling regulations and enhancements to the reporting requirements under the NSDS, we recommend establishing an appropriate channel for industry consultation to ensure that industry perspectives are reflected in the reform process.

INSURANCE & ALTERNATIVE INVESTMENT

Scope 3 Implementation: The Need for Insurance-Specific Guidance for Foreign-Invested Companies ^{NEW}

As global climate-related regulatory frameworks become increasingly stringent, foreign-invested companies operating in Korea are already subject at the group level to international disclosure regimes, including the EU's Corporate Sustainability Reporting Directive (CSRD), standards issued by the International Sustainability Standards Board (ISSB), and the framework developed by the Task Force on Climate-related Financial Disclosures (TCFD). If Korea adopts Scope 3 standards that differ from those applied in other major jurisdictions, companies may face duplicative reporting requirements, leading to additional administrative burden and compliance costs.

The insurance sector differs from manufacturing and other asset-intensive industries. Insurers provide intangible financial products and operate through long-term contractual arrangements centered on risk transfer. Applying Scope 3 standards in the same manner as manufacturing industries does not adequately reflect these structural differences. Scope 3 emissions may extend to investment activities, underwriting, and the full sales and servicing process, many of which are not directly controlled by insurers. In practice, obtaining reliable, measured emissions data across these areas can be challenging. Accordingly, guidance tailored to the insurance sector should be developed.

For essential partners such as general agencies (GAs), call centers, and IT outsourcing providers, differences in size and operational capacity should be taken into account, with proportionate application or threshold-based exemptions where data collection is not reasonably feasible.

- **Issue**

If Scope 3 requirements do not adequately reflect the business characteristics of the insurance sector, they may impose disproportionate regulatory burdens. The insurance industry provides intangible products and is built on long-term contractual structures and risk transfer through underwriting and reinsurance, resulting in an emissions profile fundamentally different from that of manufacturing. Scope 3 may also require insurers to obtain reliable data from partners involved in sales and servicing processes, including general agencies (GAs), call centers, and IT outsourcing providers. Given practical constraints in data collection, a uniform, early mandatory or enforcement-driven approach may undermine the framework's overall

effectiveness and industry acceptance.

- **Relevant Agencies**

Financial Services Commission (FSC)

Financial Supervisory Service (FSS)

- **Relevant Regulation**

Financial Investment Services and Capital Markets Act (FSCMA)

- **Recommendation**

We recommend that Korea's Scope 3 framework be designed in alignment with internationally recognized disclosure standards to avoid unnecessary divergence. In addition, insurance-specific Scope 3 guidance should be developed, allowing for flexible calculation methodologies that reflect the structural characteristics of the insurance sector.

Uncertainty around the Equity Repo Business in Korea ^{NEW}

Equity repo remains a relatively nascent segment of Korea's financial market. While the business is legally permissible under the Financial Investment Services and Capital Markets Act, market participants have faced significant headwinds over the past several years.

Despite efforts to ensure full compliance with existing legal frameworks – including review by leading law firms and engagement with relevant authorities such as the Financial Services Commission (FSC) and the Prosecution Service – the sector has been affected by informal supervisory “window guidance.” This non-transparent approach has created a chilling effect, discouraging local broker-dealers from engaging in equity repo transactions without reference to specific regulatory breaches.

At the core of the issue is a lack of transparency. Specific supervisory concerns were not clearly communicated through formal channels, limiting the ability of market participants to address them in a timely manner. In practice, obtaining clarity often requires reliance on external advisors to interpret discussions held outside formal processes, effectively raising the cost of entry for this line of business.

- **Issue**

While equity repo transactions are legally permissible under the Financial Investment Services and Capital Markets Act, the market has been subject to sustained uncertainty arising from informal supervisory “window guidance” and the absence of clearly articulated, written regulatory standards. The resulting lack of transparency has discouraged market participation without reference to specific regulatory breaches and has materially increased barriers to entry in this segment of Korea's capital markets.

- **Relevant Agencies**

Financial Services Commission (FSC)
Financial Supervisory Service (FSS)

- **Relevant Regulation**

Financial Investment Services and Capital Markets Act (FSCMA)

- **Recommendation**

Regulatory transparency is a prerequisite for the continued maturation of the Korean capital markets. For foreign institutions, the current environment presents a structural risk where business

viability is dictated by invisible barriers rather than codified law. Resolving this lack of visibility is critical not only for those interested in this business but for the broader appeal of Korea as a global financial hub. For equity repo business, which is entirely legal according to the Financial Services and Capital Markets Act, the FSS should provide clear best practice guidelines to ensure that market participants can operate within clear legal and regulatory boundaries without fear of unintended regulatory breaches.

Excessive Regulatory Control on Financial Products

While regulatory oversight on financial products is essential to ensure customer protection, particularly in light of recent incidents in Korea, the current level of regulation has made it increasingly difficult to differentiate products in certain categories. As a result, financial institutions are forced to offer nearly identical products, which limits consumer choice.

This regulatory environment poses a challenge for foreign financial institutions, as it significantly limits their ability to introduce diverse product designs developed through international experience into the Korean market. Moreover, financial products denominated in USD – a global currency and one of the most stable investment assets – face disproportionate regulatory treatment compared to KRW-denominated products. This excessive control hampers product innovation and reduces market competitiveness.

- **Issue**
Excessive and inflexible product-level regulation limits differentiation and innovation in financial products, constrains consumer choice, and creates disproportionate regulatory burdens on foreign financial institutions – particularly with respect to USD-denominated products.
- **Relevant Agencies**
Financial Services Commission (FSC)
Financial Supervisory Service (FSS)
- **Relevant KORUS Provision**
Chapter 13 (Financial Services)
- **Recommendation**
To create a balanced regulatory environment that both protects consumers and encourages product innovation, financial regulatory authorities should adopt a more principles-based approach to product regulation. This would grant financial institutions greater flexibility in product design while ensuring essential consumer protection measures are maintained. Additionally, regulators must ensure that USD-denominated financial products, recognized globally for their stability, receive fair and balanced regulatory treatment comparable to KRW-denominated products. This approach would enhance customer choice and promote market efficiency.



LABOR

TABLE OF CONTENTS

NO.	ISSUE	STATUS
	Overview	
01	Interpretation Guidelines for the Amended Trade Union and Labor Relations Adjustment Act (“Yellow Envelope Act”)	NEW
02	Expansion of the Deemed Working Hours System for Discretionary Work	NEW
03	Ensuring Inclusive Representation in Labor Management Councils	NEW

OVERVIEW

In 2026, South Korea's labor policy landscape is shaped by significant regulatory transition and evolving labor-management dynamics. While recent reforms have sought to strengthen worker protections and reinforce collective labor rights, businesses are facing growing concerns regarding legal predictability, operational flexibility, and institutional balance within the labor framework.

As global competition intensifies and employment structures become more diverse, companies operating in Korea require a labor environment that provides both regulatory clarity and practical adaptability. Uncertainty surrounding newly amended labor legislation, continued rigidity in working hour regulations, and structural imbalances in labor-management consultation mechanisms have collectively heightened compliance risks and increased operational complexity for businesses across industries.

In particular, clearer standards governing labor relations in multi-layered subcontracting structures, greater flexibility for highly skilled and project-based professions, and more inclusive mechanisms for employee representation are essential to fostering stable and constructive labor-management relations. Without thoughtful refinement, regulatory ambiguity and structural rigidity may undermine Korea's competitiveness as a stable and attractive investment destination.

Moving forward, a balanced approach that strengthens legal certainty, modernizes working hour systems, and promotes inclusive workplace governance will be critical to supporting sustainable economic growth. Establishing a predictable and forward-looking labor framework will reinforce Korea's position as a competitive, innovation-driven economy while maintaining robust worker protections.

Interpretation Guidelines for the Amended Trade Union and Labor Relations Adjustment Act (“Yellow Envelope Act”) NEW

The Ministry of Employment and Labor (MOEL) issued interpretation guidelines for the amended Trade Union and Labor Relations Adjustment Act (commonly referred to as the “Yellow Envelope Act”) in February 2026. With enforcement in effect since March 2026, substantial uncertainty remains regarding the scope, application, and legal effect of both the amended Act and its interpretation guidelines.

In particular, businesses continue to express concerns over employer status, collective bargaining obligations, and liability for alleged violations of collective agreements. In the absence of sufficiently clear and detailed guidance, companies face ongoing challenges in aligning their labor relations practices with the new regulatory framework, increasing the risk of disputes, operational disruptions, and uncertainty across complex contracting and subcontracting structures.

Accordingly, the government should proactively review and refine the interpretation guidelines based on industry feedback early in the implementation phase, with a view to enhancing legal clarity, consistency, and predictability. Clearer guidance on key concepts, particularly employer status and bargaining obligations, would help reduce uncertainty, prevent unnecessary disputes, and support stable labor-management relations.

- **Issue**
Unclear interpretation of the amended Trade Union and Labor Relations Adjustment Act may create legal uncertainty regarding employer status, collective bargaining obligations, and liability for collective agreement violations, potentially undermining stable labor relations and business continuity.
- **Relevant Regulations**
Trade Union and Labor Relations Adjustment Act
- **Relevant Agencies**
Ministry of Employment and Labor (MOEL)
- **Recommendation**
AMCHAM encourages the government to enhance legal clarity and predictability by refining the interpretation guidelines and by allowing sufficient transition time for businesses to adapt. In particular, the following considerations should be reflected:

- **Clarification of Employer Status in Contractual Relationships:**

Employer responsibility should be clearly limited to the existence and duration of a valid subcontracting relationship. Once a subcontract has been terminated, the principal company should no longer be deemed an employer under the Act, even if collective bargaining is ongoing, as the factual basis for structural control ceases to exist upon termination of the contract. Clear guidance on this point is essential to avoid prolonged and unjustified exposure to bargaining obligations after contractual relationships have ended.

Furthermore, with respect to second- and third-tier subcontractors operating within a principal company's worksite, employer status should rest with the direct (first-tier) subcontractor. While lower-tier subcontractors may perform work influenced by production schedules or work volumes set at the principal level, their structural control is exercised by their immediate contractor, not the principal company. Accordingly, extending employer status to the principal company in such cases would be inconsistent with the actual control structure of subcontracting arrangements.

- **Balanced Interpretation of Industrial Safety Responsibilities:**

The principal company's proactive efforts, as a contractor, to ensure workplace safety and health should be clearly distinguished from recognition as an employer for collective bargaining purposes. Interpreting safety and health measures as evidence of employer status risks discouraging companies from voluntarily adopting robust safety practices. A clear separation between industrial safety obligations and labor relations responsibilities is therefore necessary to avoid unintended negative effects on workplace safety initiatives.

- **Clear Standards for Collective Agreement Violations:**

Final determinations regarding violations of collective agreements should be made through judicial review rather than by administrative bodies such as labor offices or labor relations commissions. Entrusting such determinations to the judiciary

would help ensure due process, legal consistency, and predictability, thereby reducing the risk of inconsistent or premature administrative interpretations.

- **Streamlined Bargaining Channel Unification:**

With respect to subcontractor unions, stricter standards should be applied when allowing the separation of bargaining units. Enabling multiple subcontractor unions to negotiate through a single bargaining channel would promote more efficient negotiations, reduce fragmentation in labor relations, and support greater stability in collective bargaining processes. Excessive fragmentation of bargaining units may otherwise increase administrative burdens and complicate dispute resolution.

AMCHAM believes that a more predictable, balanced, and clearly articulated regulatory framework will contribute to constructive labor-management relations while preserving Korea's competitiveness as a stable and attractive investment environment.

Expansion of the Deemed Working Hours System for Discretionary Work ^{NEW}

South Korea's labor market continues to face structural challenges under the rigid application of the 52-hour work week framework, particularly in knowledge-intensive and project-based industries. One key issue is the limited scope of the deemed working hours system for discretionary work, which allows an employee to be regarded as having worked "the number of hours agreed in writing by the employer and the employee representative." While this system is designed for roles that require substantial discretion in both the performance of duties and the allocation of working hours, its eligibility is narrowly restricted to specific job categories prescribed under the Enforcement Decree of the Labor Standards Act.

Currently, activities involving consultation, advice, appraisal, or acting on behalf of others in relation to financial investment analysis and asset management qualify for the deemed working hours system. As a result, research analysts at securities firms and certain asset management professionals are eligible. In addition, employees or executives of a general partner of a private equity fund meeting certain conditions may also qualify pursuant to interpretive rulings of the Ministry of Employment and Labor. However, employees in the investment banking (IB) divisions of securities firms, who perform comparable discretionary, transaction-driven, and time-sensitive work, are excluded from the system.

This inconsistency creates inefficiencies and competitive disadvantages within the financial services sector. Investment banking professionals frequently engage in complex deal structuring, cross-border transactions, and client advisory services that require extended and irregular working hours driven by market conditions rather than fixed schedules. The current regulatory framework does not sufficiently reflect the practical realities of such roles.

Moreover, in many advanced economies such as the United States and Japan, highly compensated professionals are subject to more flexible working hour regimes or exemptions from strict overtime restrictions. As global competition intensifies, aligning Korea's labor regulations with international standards is increasingly important to attract investment, support high-skilled employment, and maintain competitiveness in global financial markets.

- **Issue**

- Limited scope of the deemed working hours system for discretionary work under the Enforcement Decree of the Labor

Standards Act, excluding investment banking professionals performing comparable discretionary duties.

- **Relevant Regulations**

Enforcement Decree of the Labor Standards Act (Article 31; Article 58(3))

- **Relevant Agencies**

Ministry of Employment and Labor (MOEL)

- **Recommendation**

AMCHAM recommends that the government broaden the scope of work eligible for the deemed working hours system for discretionary work under the Enforcement Decree of the Labor Standards Act to include employees in the investment banking divisions of securities firms whose roles require substantial discretion in performing their duties.

Furthermore, AMCHAM urges regulators to proactively consider amending relevant laws and regulations to introduce greater flexibility in working hour restrictions for highly compensated professionals, consistent with international best practices, thereby enhancing labor market competitiveness while maintaining appropriate worker protections.

Ensuring Inclusive Representation in Labor Management Councils ^{NEW}

South Korea's labor-management consultation framework plays a critical role in fostering dialogue, workplace stability, and cooperative industrial relations. Under Article 6 of the Act on the Promotion of Employees' Participation and Cooperation (the "Workers' Participation Act"), when a majority labor union exists, the representative of that union and individuals appointed by the union automatically become employee-members of the Labor Management Council (LMC). While this structure was designed to streamline representation, it has, in practice, resulted in all employee-members of the LMC being drawn exclusively from the majority labor union.

This arrangement can limit representation of non-union employees and diverse segments of the workforce, including contract workers, dispatched workers, and in-house subcontracted workers. Even in workplaces where a majority labor union exists, it remains important that the LMC reflect the full spectrum of employee perspectives to ensure balanced consultation on workplace policies, working conditions, and corporate decisions. Without broader representation, certain employee groups may lack an effective voice in key labor-management discussions.

The need for more inclusive representation aligns with the President's policy pledge ("Respect for Labor and Guarantee of Rights 03"), which emphasizes pro-rata election of employee representatives to reflect the interests of non-regular workers and other underrepresented groups. Ensuring that employee-members of the LMC represent all employees, rather than exclusively union members, would strengthen transparency, fairness, and trust in workplace governance structures. It would also promote more constructive and sustainable labor-management dialogue in an evolving labor market characterized by diverse employment arrangements.

- **Issue**
Lack of inclusive representation of non-union employees in Labor Management Councils where a majority labor union automatically appoints employee-members under the current legal framework.
- **Relevant Regulations**
Act on the Promotion of Employees' Participation and Cooperation (Article 6)
- **Relevant Agencies**
Ministry of Employment and Labor (MOEL)

- **Recommendation**

AMCHAM recommends amending the Act on the Promotion of Employees' Participation and Cooperation to ensure that employee-members of the Labor Management Council represent all employees, including non-union members, even when a majority labor union serves as the employee representative.

Specifically, AMCHAM urges the introduction of a more inclusive and proportionate election mechanism that reflects the diversity of the workforce, including non-regular and indirectly employed workers. Such reform would enhance balanced representation, promote diverse viewpoints in workplace decision-making, and strengthen cooperative labor-management relations in line with national policy objectives.



MEDICAL DEVICES

TABLE OF CONTENTS

NO.	ISSUE	STATUS
	Overview	
01	Improvement of Diagnosis-Related Group (DRG) System	
02	Needs for Improvement of New Healthcare Technology Assessment (nHTA) System	
03	Necessity of Reforming and Introducing Greater Flexibility in the nHTA Process for Technologies Targeting Severe and Critical Diseases	NEW
04	Policy Support for Medical Devices Necessary for Cancer Diagnosis and Treatment	
05	Necessity of Expanding Support for Suppliers to Ensure the Stable Supply of Pediatric Medical Devices and Therapeutic Materials	NEW
06	Establishing a Foundation for Improving Home-Based and Telemedicine Systems and Expanding the Use of Digital Health	
07	Regulatory Overlap in Digital Medical Device GMP Audits	

OVERVIEW

Korean society continues to face significant healthcare challenges driven by a rapidly aging population, escalating healthcare costs, and the growing demand for more efficient and equitable care delivery systems. In this evolving landscape, the medical device industry remains a cornerstone for improving patient outcomes, reducing long-term healthcare expenditures, and advancing cutting-edge medical technologies. With increasing emphasis on digital health, AI applications, and personalized care, the sector supports both public health objectives and Korea's ambition to strengthen its position as a global medical technology hub.

The Korean government has designated healthcare as a national strategic industry and is promoting medical devices, AI, and digital healthcare as core policy priorities. The introduction of the Market Immediate Entry Medical Technology System (effective January 26, 2026) significantly shortens the market entry period for innovative devices, from up to 490 days to as few as 80 days. In addition, certain digital medical devices, medical robots, and in vitro diagnostic products that have undergone internationally recognized clinical evaluations and received approval from the Ministry of Food and Drug Safety may be introduced into clinical settings without a separate new medical technology assessment, enhancing early commercialization and patient access.

To further support digital transformation, the government is advancing legislative efforts, including the proposed Digital Healthcare Act, aimed at strengthening the institutional framework for data utilization and innovation in digital health.

Despite these improvements, U.S. companies continue to face challenges related to reimbursement approval and regulatory complexity. Ongoing public-private dialogue will be essential to ensure predictable pathways and timely patient access to advanced medical technologies. AMCHAM and its members remain committed to fostering innovation, supporting patient access, and contributing to South Korea's healthcare advancement.

INDUSTRY ISSUES

Improvement of Diagnosis-Related Group (DRG) System

Korea's current Diagnosis-Related Group (DRG) system has played a role in enhancing predictability in system operation and improving fiscal efficiency. However, in certain surgical areas, it does not fully reflect clinical needs and the diversity of patient recovery processes.

For example, in cesarean section procedures, although post-surgical wound care and recovery are critical components of treatment, the current structure may limit the use of clinically necessary medical materials within the bundled payment framework. This goes beyond a simple cost issue and may constrain the ability of patients and healthcare providers to select appropriate treatment options based on clinical judgment. Given that cesarean section patients must simultaneously manage post-surgical recovery and newborn care, the convenience and safety of wound management should be viewed not merely as a matter of comfort, but as an issue of effective treatment access and recovery support.

However, the current system remains largely focused on procedures and hospitalization-based reimbursement, and does not sufficiently reflect the importance of selecting appropriate medical materials during the recovery process. Accordingly, greater flexibility within the existing DRG framework should be considered for medical materials whose clinical necessity and safety have been established.

Such reforms do not imply unrestricted expansion of non-reimbursed services or broad exceptions, but rather a targeted and balanced approach that allows for limited exceptions or separate reimbursement based on clinical necessity, patient benefit, and healthcare system needs.

In addition, discussions on improving the DRG system should take into account patient choice, predictability in system operation, and the practical acceptability within clinical settings in a balanced manner.

- **Issue**

The current DRG system does not adequately reflect the diversity of patient recovery processes and the need for appropriate selection of medical materials. Clinically necessary materials may not be sufficiently utilized under the existing framework, limiting treatment options based on clinical judgment. For example, in cesarean section cases, necessary wound care materials may not

be adequately reflected within the system, constraining both patient and provider decision-making. A more balanced system design is needed that incorporates patient choice, predictability, and sound fiscal management principles.

- **Relevant Regulations**

National Health Insurance Act

- **Relevant Agencies**

Ministry of Health and Welfare (MOHW)

Health Insurance Review & Assessment Service (HIRA)

National Health Insurance Service (NHIS)

- **Relevant KORUS Provisions**

Chapter 5 (Pharmaceutical Products and Medical Devices)

Article 1 (General Provisions), Article 2 (Access to Innovation)

- **Recommendation**

- **Consider allowing limited patient choice:** Allow patient selection of clinically necessary and safe medical materials under defined criteria
- **Establish criteria for exceptions or separate reimbursement:** Develop a review framework that reflects clinical necessity, availability of alternatives, patient benefit, and healthcare system demand
- **Strengthen stakeholder engagement:** Establish consultation mechanisms involving clinicians, patient groups, industry, and policymakers
- **Pilot or phased implementation:** Consider pilot programs or phased approaches to assess feasibility at specific indications or institutional levels

Needs for Improvement of New Healthcare Technology Assessment (nHTA) System

Korea's New Health Technology Assessment (nHTA) system applies rigid classification criteria whereby a technology is deemed "new" and subject to evaluation if even one of three elements - intended purpose, target population, or method of use - differs from existing technologies. Conversely, if no difference is recognized in these elements, even clinically innovative technologies may not qualify for new reimbursement categories.

This structure is relatively unique compared to international practices and places a disproportionate procedural burden on the nHTA system as the primary gateway for reimbursement recognition. In practice, minor modifications frequently trigger duplicative reviews of identical safety and clinical evidence, creating administrative inefficiencies. Moreover, even after successfully completing nHTA, technologies are often assigned existing procedure codes or reimbursement levels aligned with legacy technologies, limiting meaningful recognition of clinical differentiation.

Because nHTA effectively serves as the primary pathway for establishing new reimbursement fees, the system bears excessive structural burden. This dynamic reduces predictability, increases administrative duplication, and weakens incentives for innovation within the healthcare system.

- **Issue**
The current nHTA system creates inefficiencies and delays by requiring duplicative evaluations for technologies with minor modifications, while limiting meaningful reimbursement differentiation for clinically validated innovations. This structure increases administrative burden and slows timely patient access.
- **Relevant Regulations**
National Health Insurance Act
Medical Service Act
- **Relevant Agencies**
Ministry of Health and Welfare (MOHW)
Health Insurance Review & Assessment Service (HIRA)
National Health Insurance Service (NHIS)
- **Relevant KORUS Provisions**
Chapter 5 (Pharmaceutical Products and Medical Devices)
Article 1 (General Provisions), Article 2 (Access to Innovation)

- **Recommendation**

AMCHAM recommends making the nHTA and new procedure fee review processes more efficient, predictable, and patient-centered so that they can better and more consistently reflect the innovation, clinical differentiation, and international alignment of medical technologies. Specifically, AMCHAM recommends:

- New fee setting should not rely solely on nHTA but allow flexible procedure reclassification based on meaningful differences in clinical effectiveness and safety.
- nHTA should shift from formal "purpose-target-method" criteria to real value - innovation, therapeutic impact, and patient benefits - while eliminating redundant assessments of identical technologies as practiced in major countries and introducing existing fee revision models to accelerate adoption of clinically meaningful technologies and enhance system efficiency.

Necessity of Reforming and Introducing Greater Flexibility in the nHTA Process for Technologies Targeting Severe and Critical Diseases NEW

While the Korean government is pursuing institutional reforms to facilitate the adoption of innovative medical technologies, industry perception remains that market entry barriers are still high, particularly for technologies targeting severe and life-threatening conditions.

In Korea, the introduction of new medical devices requires sequential regulatory approval, safety and effectiveness assessment, and reimbursement negotiation, often resulting in extended timelines before clinical adoption. Although this framework is designed to ensure safety and quality, its uniform application may disproportionately affect technologies addressing severe and critical conditions.

For such technologies, evidentiary requirements are frequently applied at an exceptionally stringent level, including expectations for large-scale randomized controlled trials (RCTs), meta-analyses, and cost-effectiveness data. In some cases, mortality reduction is treated as a de facto primary endpoint, even when other clinically meaningful endpoints demonstrate significant patient benefit. These heightened standards, combined with limited flexibility in evaluation criteria, contribute to perceived barriers to market entry for urgently needed technologies.

However, for severe and emergency conditions, large-scale RCTs are often impractical due to ethical constraints, patient heterogeneity, and urgent treatment timelines. Real-world evidence (RWE) may be more appropriate and reflective of actual clinical practice, yet current assessment frameworks do not sufficiently accommodate these realities.

There is therefore a need to establish a differentiated review track within the nHTA framework that reflects disease severity and unmet medical need. Evaluation criteria should incorporate flexible evidentiary standards and recognize a broader range of clinically meaningful endpoints to facilitate timely access for patients with severe and critical conditions.

- **Issue**

Excessively stringent and inflexible evidentiary requirements within the current nHTA framework create high market entry barriers for technologies targeting severe and life-threatening conditions, delaying timely patient access.

- **Relevant Regulations**
 - Medical Service Act
 - National Health Insurance Act
- **Relevant Agencies**
 - Ministry of Health and Welfare (MOHW)
 - Health Insurance Review & Assessment Service (HIRA)
 - National Evidence-based Healthcare Collaborating Agency (NECA)
- **Relevant KORUS Provisions**
 - Chapter 5 (Pharmaceutical Products and Medical Devices)
 - Article 1 (General Provisions);
 - Article 2 (Access to Innovation);
 - Article 5 (Transparency and Procedural Fairness)
- **Recommendation**

AMCHAM recommends introducing greater flexibility and differentiation within the nHTA framework for technologies addressing severe and critical diseases. Specifically, AMCHAM recommends:

 - Establishing a dedicated or expedited review track reflecting disease severity and unmet medical need.
 - Adopting proportionate evidentiary requirements that account for the practical and ethical limitations of conducting large-scale RCTs in severe and emergency settings.
 - Recognizing a broader range of clinically meaningful endpoints beyond mortality reduction, including improvements in functional outcomes and quality of life.
 - Expanding the appropriate use of real-world evidence (RWE) in evaluation and reimbursement decision-making to better reflect actual clinical practice.

Policy Support for Medical Devices Necessary for Cancer Diagnosis and Treatment

The Ministry of Health and Welfare held a public hearing in January 2026 on the draft "5th Comprehensive Cancer Management Plan (2026-2030)" and announced plans to reduce regional disparities in cancer care by raising the self-sufficiency rate for surgeries on the top 10 cancers from 63.6% to 65% by 2030. The plan centers on expanding support for cutting-edge diagnostic and treatment equipment, improving early detection rates, strengthening survivor care, and building AI-based research infrastructure.

Cancer is the leading cause of death in Korea, making early diagnosis and optimal treatment essential amid a super-aging society where incidence rises with age. According to the 2023 National Cancer Registry Statistics, the top cancers overall were thyroid, lung, colorectal, breast, prostate, and liver cancers, with prostate cancer topping the list for men for the first time. However, PSA (Prostate-Specific Antigen) testing is not included in national cancer screening programs, and robot-assisted surgery, the standard for prostate cancer, remains ineligible for insurance reimbursement.

Cancer outcomes are highly dependent on early detection and timely access to appropriate treatment technologies. For instance, lung cancer has an 80% 5-year survival rate when detected early (2017–2021), but this drops sharply to 12.1% in metastatic stages, underscoring the critical importance of early diagnosis. In early-stage cancers, minimally invasive surgery and precision radiation therapy play a key role in preserving patients' quality of life.

Despite rapid advancements in innovative medical technologies, constraints in the current fee schedule hinder their adoption. Even improved technologies are often grouped under existing reimbursement categories, or new fee codes are not established following new medical technology evaluations, creating operational challenges for healthcare providers. While reimbursement for high-cost anticancer drugs has expanded, high-end medical devices and advanced companion diagnostics required for these targeted therapies remain subject to relatively limited policy support, shifting a greater financial burden onto patients. This contrasts with countries such as Japan and Taiwan, where robot-assisted surgeries are reimbursed across a broader range of indications.

- **Issue**

Despite the government's commitment to strengthening cancer

care under the 5th Comprehensive Cancer Management Plan (2026–2030), limited reimbursement and inadequate fee recognition for advanced diagnostic and treatment medical devices, such as PSA testing, advanced precision diagnostics performed in overseas central laboratories, and robot-assisted surgery, restrict patient access and hinder timely adoption of innovative technologies.

- **Relevant Regulations**

Medical Service Act
National Health Insurance Act
In Vitro Diagnostic Medical Devices Act
Bioethics and Safety Act

- **Relevant Agencies**

Ministry of Health and Welfare (MOHW);
Health Insurance Review & Assessment Service (HIRA);
National Health Insurance Service (NHIS)
Ministry of Food and Drug Safety (MFDS)
Korea Disease Control and Prevention Agency (KDCA)

- **Relevant KORUS Provisions**

Chapter 5 (Pharmaceutical Products and Medical Devices)
Article 1 (General Provisions), Article 2 (Access to Innovation),
Article 6 (Regulatory Cooperation)

- **Recommendation**

AMCHAM recommends establishing appropriate reimbursement levels and coverage policies for advanced medical devices used in cancer diagnosis and treatment, particularly those with demonstrated safety and clinical effectiveness.

For high-cost innovative medical technologies, alternative payment models should be considered to appropriately balance fiscal sustainability and patient affordability while ensuring timely access. The “New Conditional Selective Reimbursement (Reference Pricing System),” legislated in 2021, could be more actively operationalized by drawing on international best practices, such as the U.S. Coverage with Evidence Development (CED) framework and Taiwan’s balance billing model, to facilitate early and equitable access to innovative medical technologies.

Particularly for advanced precision diagnostics, regulatory flexibility is urgently needed to recognize the clinical validity of test results from globally accredited overseas central laboratories (e.g., CAP/CLIA). Furthermore, a framework should be established to ensure that even if patients bear the full cost of these overseas tests, they do not face reimbursement cuts for the subsequently prescribed targeted therapies.

Necessity of Expanding Support for Suppliers to Ensure the Stable Supply of Pediatric Medical Devices and Therapeutic Materials NEW

Even amid accelerating trends of declining birth rates and rapid population aging, improving treatment options and securing healthcare infrastructure for essential pediatric and adolescent care remain critical national priorities. Strengthening the pediatric healthcare system constitutes a core pillar of the current government's policy agenda to reinforce essential, severe, and public healthcare services. In particular, for pediatric patients requiring intensive care, those with congenital conditions, or those suffering from rare and intractable diseases, therapeutic alternatives are often extremely limited or nonexistent. As such, a stable supply of pediatric medical devices and therapeutic materials is directly linked to patient survival.

However, pediatric therapeutic materials are characterized by significantly smaller patient populations and limited usage volumes compared to adult products, while being subject to the same, or even more stringent, quality and safety standards. As a result, manufacturers, importers, and suppliers must bear high fixed costs and substantial regulatory burden. Under the current reimbursement and compensation framework, it is structurally difficult to recover these costs, leading to inherent challenges in maintaining a stable supply. Recent external pressures, including rising raw material costs, increased logistics expenses, and exchange rate volatility, have further exacerbated these burdens, raising concerns over reduced supply or even market withdrawal for certain essential pediatric products.

Supply instability may undermine efforts to strengthen essential and regional healthcare systems, potentially disrupting continuity of care and increasing burden on patients and healthcare providers.

Accordingly, targeted and sustainable policy support is needed to ensure a stable supply of essential pediatric therapeutic materials and safeguard the resilience of pediatric healthcare services.

- **Issue**

Structural reimbursement limitations and rising cost pressures make it economically challenging for suppliers to maintain a stable supply of essential pediatric medical devices and therapeutic materials, posing risks to the continuity of pediatric and regional essential healthcare services.

- **Relevant Regulations**
 - National Health Insurance Act
 - Medical Service Act
 - Medical Devices Act

- **Relevant Agencies**
 - Ministry of Health and Welfare (MOHW)
 - Health Insurance Review & Assessment Service (HIRA)
 - National Health Insurance Service (NHIS)
 - Ministry of Food and Drug Safety (MFDS)

- **Relevant KORUS Provisions**
 - Chapter 5 (Pharmaceutical Products and Medical Devices)
 - Article 1 (General Provisions), Article 2 (Access to Innovation),
 - Article 5 (Transparency and Procedural Fairness)

- **Recommendation**

AMCHAM recommends establishing targeted policy mechanisms to safeguard a stable and sustainable supply of essential pediatric medical devices and therapeutic materials. Specifically, AMCHAM recommends:

 - Introducing priority cost-recovery and enhanced reimbursement mechanisms for essential pediatric therapeutic materials.
 - Implementing flexible pricing adjustment or exceptional compensation arrangements that reflect fluctuations in production and procurement costs.
 - Strengthening cross-agency coordination to monitor supply risks and establish a protective framework for designated essential pediatric products.

Establishing a Foundation for Improving Home-Based and Telemedicine Systems and Expanding the Use of Digital Health

With the acceleration of population aging and the growing number of patients with chronic diseases, the importance of home-based care and telemedicine is rapidly increasing. In particular, ahead of the enforcement of the amended Medical Service Act related to telemedicine, scheduled for 2026, expectations are rising for the institutionalization and stable settlement of home-based and remote healthcare systems. The industry likewise views these changes as highly meaningful, as they contribute to strengthening essential regional public healthcare systems and securing infrastructure to respond to a super-aged society.

Home-based and telemedicine services enable continuous health management for elderly patients and those with chronic conditions, improve access to healthcare, and help reduce unnecessary medical utilization. Digital health technologies, including remote patient monitoring, allow for continuous oversight of patient conditions and early detection of abnormal signs, thereby preventing disease progression and supporting the efficient use of healthcare expenditures. Consequently, they have become a key policy priority in many countries. These technologies are also closely aligned with the goal of reducing disparities in healthcare access for medically underserved regions.

To expand the use of these technologies in clinical settings, an institutional framework centered on reimbursement must be firmly established. While partial and temporary reimbursement schemes have been introduced in certain areas domestically, most digital remote monitoring technologies remain subject to limited compensation structures yet, with insufficient permanent and independent reimbursement. This results in underutilization of the full value of these technologies, such as their clinical effectiveness, operational efficiency, and improvements in patient access, across the healthcare system.

There is a need to enhance acceptance in clinical settings and improve the quality of patient management by introducing reimbursement on a phased basis, starting with areas such as chronic disease management and home-based monitoring, where clinical value is clearly demonstrated and operational readiness is high. Through the establishment and refinement of a systematic and dedicated reimbursement framework, the sustainability of a patient-centered care system can be strengthened, while also contributing to enhancing the competitiveness of the domestic digital health industry.

- **Issue**
The absence of a stable and dedicated reimbursement framework for digital health and remote patient monitoring limits clinical adoption and sustainable expansion of these services.
- **Relevant Regulations**
Medical Service Act (including amended provisions on telemedicine)
National Health Insurance Act
- **Relevant Agencies**
Ministry of Health and Welfare (MOHW)
Health Insurance Review & Assessment Service (HIRA)
National Health Insurance Service (NHIS)
- **Relevant KORUS Provisions**
Chapter 5 (Pharmaceutical Products and Medical Devices)
Article 1 (General Provisions)
Article 2 (Access to Innovation)
Article 5 (Transparency and Procedural Fairness)
- **Recommendation**
AMCHAM recommends establishing a robust and sustainable institutional framework to support the expansion of home-based and telemedicine services and digital health technologies. Specifically, AMCHAM recommends:
 - Introducing permanent and independent reimbursement codes for clinically validated digital health and remote patient monitoring technologies.
 - Implementing phased reimbursement expansion, beginning with high-impact areas such as chronic disease management and home-based monitoring.

Regulatory Overlap in Digital Medical Device GMP Audits

As the digital healthcare industry undergoes rapid transformation, the need for fundamental restructuring of medical device regulations has become imperative. While the "Digital Medical Device Act," which took effect on February 21, 2025, has accelerated the approval of new digital medical devices and transition of traditional devices into digital medical devices, regulatory bottlenecks continue to stifle industry growth. In particular, the "Digital Medical Device Good Manufacturing Practice (GMP) Guideline" released by the Ministry of Food and Drug Safety (MFDS) in November 2025 has provided necessary clarity but simultaneously burdened manufacturers with redundant audit requirements for the same manufacturing site.

Under current guidelines, a manufacturing site that has already received Good Manufacturing Practice (GMP) approval for conventional medical devices must obtain separate GMP certifications for conventional and digital medical devices, even if they share the same contract giver and manufacturer.

The GMP audit scope for digital medical devices is structured by adding software-specific items (Annex 3 and Annex 4) to the standard medical device review items (Annex 2). The core issue lies in the auditing bodies: while conventional medical devices are audited by various private certification agencies, digital medical devices are currently handled exclusively by a single entity, the National Institute of Medical Device Safety Information (NIDS). Consequently, companies are unable to undergo an integrated audit. Instead, they must bear the financial and administrative burden of submitting redundant Annex 2 documentation to two different institutions. Furthermore, as NIDS is tasked with auditing Annex 2 along with Annex 3 and/or 4, it has led to the extension of the audit period.

- **Issue**

Despite the Digital Medical Device Act's progress, overlapping GMP audit requirements by separate authorities create unnecessary burdens and delays for manufacturers.

- **Relevant Regulations**

Digital Medical Device Act
Digital Medical Device GMP Guideline

- **Relevant Agencies**

Ministry of Food and Drug Safety (MFDS)

- **Relevant KORUS Provisions**

Chapter 5 (Pharmaceutical Products and Medical Devices)

Article 1 (General Provisions), Article 6 (Regulatory Cooperation)

- **Recommendation**

To enhance regulatory efficiency, Korea should establish a mutual recognition system allowing GMP audit results for conventional medical devices (Annex 2) to be accepted for digital medical devices manufactured at the same site, enabling NIDS to focus only on digital-specific items (Annex 3 and 4). Additionally, expanding the number of authorized digital medical device audit bodies beyond NIDS to include qualified private agencies will prevent audit delays, reduce administrative burdens, and accelerate market entry while maintaining robust quality standards.



PHARMACEUTICAL

TABLE OF CONTENTS

NO.	ISSUE	STATUS
	Overview	
	INNOVATIVE MEDICINES: VALUE AND PATIENT ACCESS	
01	Pricing Innovative Medicines Based on True Value (Enhancing ICER Thresholds for Innovation)	
02	Expedited Listing and Reimbursement Pathways for New Medicines	
03	Expansion of Flexible Price Contract System	
04	Introduction of Indication-Based Pricing	
05	Ensuring Predictable Off-patent and Gx Pricing Reform	NEW
	OPEN PARTNERSHIP FOR THE BIOPHARMACEUTICAL ECOSYSTEM	
06	Enhancing the Innovative Pharmaceutical Company (IPC) Designation Framework to Ensure Fair Recognition and Meaningful Incentives	
	REGULATORY FRAMEWORK FOR VACCINES AND IMMUNIZATION POLICIES	
07	Improving the Predictability of the National Immunization Program (NIP) to Ensure Effective Infectious Disease Management	
	INTELLECTUAL PROPERTY PROTECTION FOR PHARMACEUTICALS	
08	Intellectual Protection Challenged by the Amendment to the Patent Act	

OVERVIEW

South Korea's transition into a super-aged society presents both pressing challenges and significant opportunities for its healthcare system and biopharmaceutical industry. As healthcare demand rises amid demographic shifts, ensuring timely patient access to innovative medicines while maintaining the sustainability of the National Health Insurance (NHI) system has become increasingly critical. In this context, the structure of Korea's drug pricing and reimbursement system plays a central role.

Compared to other advanced economies, public investment in innovative medicines remains relatively limited in Korea, constraining patient access and the long-term growth potential of the biopharmaceutical sector. Reports of delayed market entry, cautious launch strategies by global pharmaceutical companies, and concerns about Korea's competitiveness as a clinical research hub underscore the need to strengthen predictability and value recognition within the ecosystem.

The pharmaceutical industry recognizes the government's ongoing efforts to address these structural challenges. In particular, the drug pricing reform, first announced in November 2025 and finalized in March 2026, represents a meaningful step toward improving the pricing and reimbursement environment by signaling greater recognition of innovation. As the reform moves into the implementation phase, its ultimate impact will depend on the timely finalization of detailed measures, along with consistent execution and sustained policy alignment.

In this regard, ensuring that detailed measures are developed in close consultation with industry stakeholders will be essential to support smooth and practical implementation. Continued engagement, along with transparent communication and alignment with global best practices, will help ensure that the reform delivers its intended benefits for both patients and the biopharmaceutical sector.

AMCHAM remains committed to working closely with the Korean government and relevant stakeholders to support a policy environment that balances fiscal sustainability with innovation. By fostering a more predictable and innovation-friendly system, Korea can strengthen its biopharmaceutical ecosystem, attract global investment, and ensure timely patient access to life-changing therapies.

INDUSTRY ISSUES

Innovative Medicines: Value and Patient Access

Pricing Innovative Medicines Based on True Value (Enhancing ICER Thresholds for Innovation)

The pharmaceutical industry seeks to improve patient outcomes through the development of innovative medicines, an inherently high-risk and investment-intensive process that depends on appropriate reward to sustain continued R&D. However, despite Korea's stated ambition to foster the biopharmaceutical sector as a future growth engine, the current pricing and reimbursement framework continues to undervalue innovation. Public spending on innovative medicines accounts for only 0.09% of GDP, significantly lower than the United States (0.78%) and Japan (0.40%), placing Korea among the lowest in the OECD.²⁸ Drug prices in Korea are also estimated to be well below OECD averages and substantially lower than U.S. levels.²⁹

< Low Investment in Innovative Medicines in Korea >

- ⇒ Spending on new medicines accounts for approximately **4% of total NHI pharmaceutical expenditure** in Korea.³⁰
 - ▶ U.S.A. (26%), Germany (19%), U.K. (18%), Australia (18%), Italy (17%), Canada (16%), Japan (14%)
- ⇒ **Expenditure on new innovative medicines** as a percentage of GDP per capita stands at **0.09% in Korea**.¹
 - ▶ U.S.A. (0.78%), Spain (0.53%), Italy (0.46%), Japan (0.40%), Germany (0.36%), Canada (0.32%), France (0.29%), U.K. (0.28%), Australia (0.26%)

A strong emphasis on short-term cost containment within the NHI system has led to comparatively low initial listing prices and repeated post-listing reductions, contributing to delayed launches and more cautious market entry strategies. As a result, patient access to innovative therapies remains limited, and uncertainty

²⁸ PhRMA. *Key Statistics: Access, Spending and R&D Pipelines for New Innovative Medicines in High-Income Countries*. 2025.

²⁹ 2021 RAND report (International Prescription Drug Price Comparisons: Estimates Using 2018 Data

³⁰ Jonghyuk Lee. *An Analysis of New Drug Expenditure in Korea and a Study on Rationalization Measures*. 2023, PHARMA Joint Research.

surrounding reimbursement has also weakened Korea's competitiveness as a global clinical trial destination.

The industry welcomes the MOHW's November 2025 drug pricing reform plan, which signals greater recognition of innovation through proposed ICER threshold adjustments reflecting disease severity, therapeutic benefit, and budget impact, as well as consideration of a dedicated pricing pathway for innovative medicines. In particular, enhancing value recognition for rare disease treatments, already identified as a national policy priority, will be critical to reducing the burden on patients and improving access.

Global experience demonstrates that value-based pricing frameworks can balance fiscal sustainability with innovation when implemented predictably. For example, the UK's NICE applies the High Specialized Technologies (HST) program to eligible rare disease treatments, allowing the ICER threshold to increase from the standard £20,000 per QALY to as high as £300,000, reflecting disease severity and unmet need.³¹ To ensure effective reform, Korea's ICER framework should likewise be strengthened through earlier and more consistent application of enhanced thresholds, clear operational criteria, transparent methodologies, and predictable decision-making.

Although the 2025 reform plan envisions introducing an improved ICER framework in 2027 following research in 2026, more proactive implementation would be appropriate. Broad consensus exists on the need to raise current ICER thresholds, and advancing practical application of enhanced flexibility would help translate policy intent into measurable improvements in reimbursement outcomes.

AMCHAM encourages the government to reinforce a value-based pricing environment for innovative medicines through a clear long-term commitment to patient access and a more forward-looking refinement of the ICER framework.

First, AMCHAM recommends that the government articulate a concrete medium- to long-term commitment to expanding NHI spending on new innovative medicines, aligned with Korea's rising GDP per capita and level of economic development.

Second, AMCHAM calls for more specific reforms to the ICER framework. This could include raising ICER thresholds in line with international best practices, introducing a tiered ICER evaluation system that reflects disease severity and the degree of

³¹ www.nice.org.uk/process/pmg36; *Int J Technol Assess Healthcare*. 2023;39(1):e19.

<http://www.yhec.co.uk/glossary-term/highly-specialised-technologies-uk-nice/>

therapeutic innovation, and incorporating additional value elements beyond QALYs to better capture broader societal benefits.

Third, AMCHAM recommends a reassessment of the appropriateness of comparator selection in reimbursement evaluations. The current reliance on outdated or excessively low-priced comparators may undervalue innovative therapies and constrain fair assessment. Reviewing and modernizing comparator standards would help address structural limitations in the system and enable more balanced and innovation-supportive evaluation outcomes.

- **Issue**
Limited predictability and transparency in value recognition for innovative medicines, combined with persistently low NHI spending on new innovative medicines
- **Relevant Regulations**
Pricing & Reimbursement (P&R) regulations
- **Relevant Agencies**
Ministry of Health and Welfare (MOHW)
National Health Insurance Service (NHIS)
Health Insurance Review and Assessment Service (HIRA)
- **Relevant KORUS Provisions**
Chapter 5 (Pharmaceutical Products and Medical Devices) Article 2 (Access to Innovation) & Article 3 (Transparency)
- **Recommendation**
AMCHAM urges the Korean government to reinforce a value-based pricing environment for innovative medicines by committing to a long-term expansion of NHI spending in line with Korea's rising GDP per capita and by advancing targeted ICER reforms. These should include raising thresholds in line with global best practices, adopting a tiered approach reflecting disease severity and innovation, incorporating broader societal value beyond QALYs, and modernizing comparator standards to ensure fair and balanced evaluations.

Expedited Listing and Reimbursement Pathways for New Medicines

Historically, the time from global launch to public reimbursement in Korea has averaged 46 months, substantially longer than in other reference countries. As a result, Korean patients often wait nearly four years to access new therapies, which significantly delays clinical benefits and reduces alignment with global standards.

< Delayed Patient Access to Innovative Medicines in Korea ³²>

- ⇒ The average time from global launch to public reimbursement in Korea is approximately **40 months**.
 - ▶ U.S.A. (4 months), Japan (15 months), U.K. (26 months), France (25 months)
- ⇒ Over the past decade, **20% of the 500 new medicines** launched globally have been reimbursed under Korea's NHI system.
 - ▶ U.S.A. (87%), Japan (50%), U.K. (43%), OECD Average (43%)

Recognizing this challenge, the Ministry's November 2025 drug pricing reform plan introduced expedited listing and reimbursement pathways, particularly for therapies addressing rare and severe diseases, with plans to shorten the cost-effectiveness assessment and price negotiation period from 240 days to under 100 days.

According to the Ministry, a pilot program applying the 100-day pathway to rare disease treatments will be launched in 2026, alongside a mid- to long-term roadmap to expand expedited listing to all innovative medicines. Clearly articulating and advancing this broader expansion plan will be essential to institutionalizing faster access.

While the initiative represents meaningful progress, effective implementation will be critical. In practice, although the MOHW launched the first phase of the regulatory–evaluation–pricing linkage pilot program in June 2023 and selected two medicines, those products required 14 and 24 months, respectively, to achieve reimbursement listing. The second phase of the pilot program is currently underway, but as of April 2026, no reimbursement decisions have been finalized, making it difficult to identify tangible improvements. Ensuring that compressed timelines remain feasible and are not undermined by procedural bottlenecks or additional evidence requirements will therefore be essential to realizing the intended impact of the reform.

AMCHAM urges the government to ensure the effective and timely implementation of expedited listing and reimbursement pilot programs, with a clear focus on

³² PhRMA. *Key Statistics: Access, Spending and R&D Pipelines for New Innovative Medicines in High-Income Countries*. 2025.

delivering tangible reductions in the total time to patient access, not merely administrative targets, but the full duration until patients can initiate treatment, including periods for data supplementation and resubmission. In this context, as discussions advance on the detailed operational design of the 100-day expedited pathway, it will be important to avoid overly burdensome post-management requirements or restrictive conditions, such as mandatory Korean real-world data or clawback that could undermine the practical usability and policy intent of the expedited system. In parallel, the government should advance medium- to long-term reforms to institutionalize expedited pathways for all innovative medicines through streamlined procedures, clear timelines, and reduced duplication across regulatory, assessment, and negotiation stages.

To support effective operation, detailed guidelines and operational rules should be developed and regularly reviewed in close collaboration with industry stakeholders, including structured dialogue mechanisms from the early stages of policy design. Such collaboration will enhance predictability and transparency, strengthen Korea's attractiveness as a launch market, and ensure that faster access to innovative medicines is achieved in a sustainable and fiscally responsible manner.

- **Issue**
Prolonged time from regulatory approval to public reimbursement for new innovative medicines, reflecting limited effectiveness, predictability, and transparency of existing pathways
- **Relevant Regulations**
Pricing & Reimbursement (P&R) regulations
- **Relevant Agencies**
Ministry of Health and Welfare (MOHW)
Ministry of Food and Drugs Safety (MSDS)
National Health Insurance Service (NHIS)
Health Insurance Review and Assessment Service (HIRA)
- **Relevant KORUS Provisions**
Chapter 5 (Pharmaceutical Products and Medical Devices) Article 2(Access to Innovation)
- **Recommendation**
AMCHAM urges the government to ensure timely and effective implementation of the planned expedited reimbursement pilot program in the near term, while advancing structural reforms toward

a permanent fast-track system for innovative medicines, developed through early and continuous dialogue with industry stakeholders.

Expansion of Flexible Price Contract System

A dual pricing system, also referred to as a flexible pricing or separate-contract mechanism, plays a critical role in ensuring equitable patient access to innovative medicines while maintaining a sustainable supply in Korea. Under this system, the publicly listed price of a medicine can differ from the actual, confidential price agreed upon with the National Health Insurance Service (NHIS). This separation prevents Korea's comparatively lower official drug prices from being referenced internationally, which could otherwise undermine the perceived value of innovative medicines globally.

In March 2025, Korea introduced a dual pricing system primarily for domestically developed drugs. This system has helped mitigate the risk of market withdrawal or delayed launches caused by the low public prices of innovative therapies. However, eligibility criteria remain restrictive, and most foreign-developed drugs, including many global innovations, are largely excluded. This limited application restricts patient access to cutting-edge therapies and poses a potential barrier to Korea's competitiveness as a launch market.

The November 2025 drug pricing reform package included the introduction of the "Flexible Pricing Contract System", further advancing the dual pricing concept. AMCHAM welcomes this policy development as a meaningful step toward improving pricing flexibility and addressing long-standing structural constraints in Korea's reimbursement framework.

- The listed price will be publicly announced at levels comparable to major overseas markets.
- Separate contracts with NHIS will set the actual, confidential price, allowing flexibility in negotiations without affecting international reference prices.
- The system is intended to cover not only innovative new drugs but also newly listed medicines, refund-based Risk-Sharing Agreement drugs, off-patent originator products, and certain biosimilars.

By expanding pricing flexibility beyond the previously limited risk-sharing arrangements (RSA), the reform is expected to lower barriers to market entry and improve launch conditions for new medicines in Korea. AMCHAM supports this policy direction, while emphasizing that negotiated prices should continue to reflect the value of innovation within a strengthened value-based pricing framework.

Industry stakeholders note that the first medicines eligible under the Flexible Pricing Contract System are expected in the second quarter of the year. To fully realize the reform's intended benefits, timely and effective implementation should be clearly prioritized. While the government has confirmed that refund-based RSA medicines will transition into the new system, greater clarity is needed regarding other RSA medicines, including newly listed or existing products not structured as refund-only agreements.

To maximize policy impact, AMCHAM recommends expanding the Flexible Pricing Contract System to all RSA medicines that include a refund component, regardless of contract structure. This could be achieved either by extending eligibility to all such RSA products or by allowing existing RSA contracts to adopt an equivalent refund operation mechanism under the flexible pricing framework.

A comprehensive and simultaneous transition for all eligible RSA medicines would reduce patient out-of-pocket inconvenience, eliminate issues such as double VAT charging, ease administrative burdens on NHIS, and enhance predictability and efficiency in the reimbursement system in line with the original policy intent. To ensure that existing products can fully benefit from the dual pricing framework, the administrative transition should occur seamlessly, without requiring a separate termination process, so as to avoid delays, reduce unnecessary burdens, and safeguard continuous patient access.

In addition, to preserve the integrity of the dual-pricing model, strengthened operational safeguards should be put in place to prevent unintended disclosure of actual, confidential prices, ensuring that confidential pricing arrangements are not exposed in practice. In cases requiring a high level of confidentiality, companies could be provided with the option to choose between distribution at the actual confidential price or distribution at the listed price followed by a refund. To preserve the integrity of the dual-pricing model, stronger operational safeguards are needed to prevent unintended disclosure of actual confidential prices and to ensure that such pricing arrangements remain protected in practice.

- **Issue**
Uncertainty surrounding the timely implementation and operational details of the newly announced Flexible Pricing Contract System, potentially limiting its early effectiveness despite positive policy intent
- **Relevant Regulations**
Pricing & Reimbursement (P&R) regulations

- **Relevant Agencies**

Ministry of Health and Welfare (MOHW)

National Health Insurance Service (NHIS)

Health Insurance Review and Assessment Service (HIRA)

- **Relevant KORUS Provisions**

Chapter 5 (Pharmaceutical Products and Medical Devices) Article 2(Access to Innovation)

- **Recommendation**

AMCHAM urges the government to ensure the prompt and effective rollout of the Flexible Pricing Contract System as planned, supported by clear operational guidance developed through early and continuous dialogue with industry stakeholders.

In parallel, a phased transition should be enabled, for example by allowing all RSA medicines with a refund component to move into the system, to deliver predictable improvements in patient experience and administrative efficiency, while maintaining flexibility in operational distribution models where a high level of confidentiality is required.

Introduction of Indication-Based Pricing

The growing prevalence of multi-indication innovative medicines presents structural challenges under Korea's current single-price drug pricing system. Many modern therapies, particularly in oncology and other advanced treatment areas, are approved for multiple distinct indications with varying levels of clinical benefit and budget impact. However, prices are typically set based on the initial indication and subsequently adjusted downward when additional indications are approved, rather than reflecting the incremental value of each new use. This approach can weaken incentives to pursue additional indications and may delay or limit patient access, while applying a uniform price that does not adequately reflect indication-specific clinical value.

In addition, the increasing use of combination therapies involving products from multiple companies has exposed further limitations of the current framework. In certain cases, reimbursement expansion linked to combination use has led to price reductions applied across all indications of an existing product, creating supply and sustainability challenges.

Recognizing these issues, the MOHW's November 2025 drug pricing reform plan includes plans to assess the feasibility of introducing an indication-based pricing system that evaluates each approved indication separately. While this signals a positive direction, detailed methodologies, eligibility criteria, and implementation timelines have yet to be defined.

Several advanced markets have adopted differentiated pricing models that better align price with indication-specific value. For example, Switzerland assigns reimbursement codes by indication, enabling differentiated reimbursement levels, while Australia applies indication-based pricing that allows multiple actual prices depending on approved use.³³

AMCHAM urges the government to establish a system and assessment procedure that enables differentiated pricing by indication, allowing prices to reflect the distinct clinical value and budget impact of each approved indication. Establishing such a system would recognize the additional R&D and evidence-generation investment required to expand medicines into multiple indications, and ensure that pricing more

³³ Ringger et al. Review of indication-based pricing practice in Switzerland, 2022. Available at https://www.ispor.org/docs/default-source/intl2023/review-of-indication-based-pricing-practice-in-switzerland-pdf.pdf?sfvrsn=41d333_0

Cole et al. Payment Models for Multi-indication Therapies, OHE consulting report. 2021. Available at <https://www.ohe.org/publications/payment-models-multi-indication-therapies/>

accurately reflects differences in clinical outcomes and eligible patient populations across indications. AMCHAM further encourages piloting this approach, with clear operational rules, to assess its impact on coverage, and patient access prior to broader implementation.

- **Issue**
Inability of the current single-price system to adequately reflect differences in value across multiple indications, limiting incentives for additional R&D and timely patient access to new indications.
- **Relevant Regulations**
Pricing & Reimbursement (P&R) regulations
- **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 (Pharmaceutical Products and Medical Devices) Article 2 (Access to Innovation)
- **Recommendation**
AMCHAM urges the government to establish a system that enables differentiated pricing by indication, allowing prices to reflect indication-specific value, and to pilot this approach to support innovation and patient access.

Ensuring Predictable Off-patent and Gx Pricing Reform ^{NEW}

The November 2025 drug pricing reform plan represents a significant structural adjustment to Korea's pharmaceutical pricing system. As implementation moves forward, predictability and a well-managed transition will be essential to maintaining supply stability and supporting sustainable business operations across the pharmaceutical sector.

While the industry supports the overall concept, the scale and pace of implementation may present practical challenges during the transition period. Although the government has incorporated a phased implementation approach, spreading adjustments over multiple years to mitigate industry impact, ensuring consistency and predictability throughout this process will be critical in practice.

For multinational companies, the challenge is compounded by fixed budget cycles and long-term planning requirements. Even under a phased framework, uncertainty around timing and magnitude of price adjustments may affect financial planning and alignment with global headquarters, potentially limiting investment decisions.

To ensure effective implementation, continued efforts will be needed to maintain clear timelines, transparent communication, and ongoing dialogue with industry stakeholders. This will be important to ensure that the phased approach delivers its intended objectives while safeguarding supply stability and sustaining long-term investment.

- **Issue**
Rapid and significant drug price reductions are undermining predictability and creating operational, supply, and investment challenges.
- **Relevant Regulations**
Pricing & Reimbursement (P&R) regulations
- **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 (Pharmaceutical Products and Medical Devices) Article 1 (General Provisions), Article 2 (Access to Innovation) & Article 3 (Transparency)

- **Recommendation**

AMCHAM welcomes the government's adoption of a phased implementation approach for drug pricing reform. To maximize its effectiveness, we recommend ensuring that implementation remains predictable and transparent, with clear timelines and consistent communication. Strengthening ongoing engagement with industry stakeholders will be essential to support business planning, maintain supply stability, and encourage sustained investment throughout the transition period.

Open Partnership for the Biopharmaceutical Ecosystem

Enhancing the Innovative Pharmaceutical Company (IPC) Designation Framework to Ensure Fair Recognition and Meaningful Incentives

The Innovation Pharmaceutical Company (IPC) designation system has been a central policy tool in Korea since 2012 to recognize and support pharmaceutical innovation. IPC-designated companies benefit from tax incentives, R&D support, and preferential pricing opportunities. The aim is to foster a virtuous cycle in which successful innovation drives continued investment in research and development.

Despite these intentions, as of February 2026, only four out of 48 IPCs were multinational companies, indicating that the current evaluation criteria may disproportionately favor domestic companies. Moreover, the benefits conferred to multinational companies have been limited, highlighting the need for a more balanced and meaningful incentive structure that encourages both global and domestic innovation.

In this context, on March 26, 2026, the Korean government announced a proposed amendment to the Enforcement Rule of the Pharmaceutical Industry Promotion and Support Act, introducing concrete changes to the IPC designation framework. The proposed revision establishes a dedicated global track for multinational companies, allowing them to apply under criteria better aligned with their operating structure. It also simplifies the evaluation framework by reducing assessment indicators and strengthening the use of quantitative metrics.

These developments are a welcome step toward enhancing the inclusiveness and relevance of the IPC framework for multinational companies. Continued alignment with broader drug pricing reforms, along with transparent and consistent implementation, will be important to ensure that the intended policy benefits are fully realized in practice.

To further strengthen the effectiveness of the IPC system, it will be important to link designation more clearly to tangible and value-based incentives, such as preferential pricing and expedited review, within the broader pricing and reimbursement framework. In addition, the IPC criteria could be further refined to better reflect the global operating structure of multinational companies by recognizing R&D investments made at the headquarters level that contribute to activities in Korea, while also capturing structured partnership efforts.

- **Issue**
Limited effectiveness of the IPC designation framework in recognizing multinational innovation contributions and providing meaningful incentives, resulting in constrained global participation.
- **Relevant Regulations**
Special Act on Fostering and Support of Pharmaceutical Industry
MOHW Regulations on Innovative Pharmaceutical Company (IPC) Designation
- **Relevant Agencies**
Ministry of Health and Welfare (MOHW)
Korea Health Industry Development Institute (KHIDI)
- **Relevant KORUS Provisions**
Chapter 5 (Pharmaceutical Products and Medical Devices) Article 1 (General Provisions) & Article 2 (Access to Innovation)
- **Recommendation**
AMCHAM urges the Korean government to enhance the IPC framework by ensuring fair recognition of multinational R&D and partnership contributions and by strengthening the link between designation and value-based, predictable incentives within the broader pricing and reimbursement framework.

Regulatory Framework for Vaccines and Immunization Policies

Improving the Predictability of the National Immunization Program (NIP) to Ensure Effective Infectious Disease Management

In the wake of recent pandemic experiences, the importance of a robust national infectious disease prevention and management system, as well as a stable global supply chain, has become even more evident. As the National Immunization Program (NIP) represents the cornerstone of Korea's infectious disease prevention framework, continuous improvement of the current NIP system is essential to ensure the timely introduction and reliable supply of appropriate vaccines.

Given Korea's demographic shifts and the rise of emerging infectious diseases, the KDCA's decision-making process for including new and innovative vaccines in the NIP must be predictable and expedited. Establishing a comprehensive National Immunization System (NIS) would support efficient and equitable vaccine distribution, improve coverage, streamline logistics, and enable timely access, particularly in underserved or remote areas. In addition, as the disease burden among adults and the elderly increases due to population aging and the rise in chronic conditions, adult immunization programs remain insufficient in terms of having a comprehensive, medium- to long-term roadmap. A well-structured system would also strengthen immunization tracking, optimize supply management, and enhance rapid response capacity to future public health risks.

In parallel, a comprehensive review and enhancement of NIP policies is needed. This includes regularly updating vaccination schedules, expanding vaccine inclusion based on evolving medical evidence, and strengthening public awareness initiatives to improve vaccination rates. Effective reform will require enhanced training for healthcare providers, stronger communication strategies, and improved coordination between national and local health systems.

To achieve these goals, three key recommendations are proposed:

- **Enhancing Transparency and Governance of the NIP Framework:** A clearer and more predictable process for NIP inclusion and vaccine tender standards should be established, supported by defined timelines and transparent evaluation criteria. Regular consultative advisory meetings should be institutionalized, with meaningful participation from pharmaceutical companies and relevant stakeholders, particularly in decision-making on the introduction of new vaccines. Closer coordination

among the KDCA, MOHW, and the Ministry of Finance and Economy (MOFE) is also essential to ensure policy coherence, budget stability, and long-term sustainability of the program.

- **Accelerating and Modernizing NIP Inclusion for Innovative Vaccines:** To expedite patient access, pharmaceutical companies, medical societies, and other stakeholders should be permitted to formally apply for NIP listing of MFDS-approved vaccines. In addition, adult immunization should be established as a central pillar of a life-course approach, with clearly defined principles for expansion focused on high-risk groups and a structured medium- to long-term introduction roadmap. Furthermore, a data-driven policy feedback mechanism should be strengthened to regularly assess outcomes, such as disease prevention and healthcare cost savings, and to ensure that these results are systematically reflected in decisions on adoption and expansion. At the same time, the system should appropriately recognize the value of innovative vaccines, including consideration of flexible pricing approaches - such as dual-pricing mechanisms where necessary - to better reflect clinical value, support sustainable supply, and encourage continued vaccine.
- **Securing Stable and Adequate Budget Support for NIP:** As a core pillar of Korea's national infectious disease prevention system, the NIP requires sufficient and stable financial support to ensure timely introduction and reliable supply of vaccines. Therefore, it is necessary to consider diversifying the payment structure, taking into account vaccine characteristics and disease burden. This would help alleviate bottlenecks in adoption while enhancing medium- to long-term predictability and supply stability. In light of industry concerns over recent recurring annual budget reductions, greater budget predictability and the establishment of sustainable long-term funding mechanisms are critical to safeguarding public health preparedness and maintaining a stable global vaccine supply chain.

These improvements will help build a more robust and responsive immunization framework, ensuring Korea is well-prepared to address current and future public health challenges.

- **Issue**
Limited predictability in the expansion and review timelines of the National Immunization Program (NIP) has led to delays in the inclusion of innovative new vaccines. In addition, adult

immunization lacks performance management and a clear expansion roadmap, while constraints on budget expansion and reduced predictability have created bottlenecks in the introduction of innovative vaccines and the expansion of coverage.

- **Relevant Regulations**

Infectious Disease Control and Prevention Act and Enforcement Regulation of the Act

- **Relevant Agencies**

Korea Disease Control and Prevention Agency (KDCA)

- **Relevant KORUS Provisions**

Chapter 5 (Pharmaceutical Products and Medical Devices) Article 2(Access to Innovation) & Article 3 (Transparency)

- **Recommendation**

- **Strengthen the transparency and governance of the National Immunization Program (NIP)** by establishing clear timelines and evaluation criteria, institutionalizing structured stakeholder consultation, and enhancing coordination among relevant ministries to improve the predictability of system operations;
- **Accelerate the inclusion of innovative vaccines** by introducing a formal NIP application pathway, while establishing clear expansion principles, a roadmap, performance management, and a policy feedback mechanism for adult immunization;
- **Ensure that the value of innovative vaccines is appropriately reflected** through diversified payment structures, where appropriate, to establish an institutional framework that supports supply stability; and
- **Secure stable and adequate medium- to long-term budget support** to sustain timely vaccine introduction, reliable supply, and national infectious disease preparedness.

Intellectual Property Protection for Pharmaceuticals

Intellectual Protection Challenged by the Amendment to the Patent Act

The recent amendment to the Patent Act in December 2024 introduces a cap on the extension of patent terms and limits the number of patents that can be extended per approval to a single patent, which has a significant impact on pharmaceutical companies holding patented drugs.

- **Patent Term Extension (PTE):** The additional restriction of limiting the extension period to a maximum of 14 years from the approval date and restricting the number of extendable patents to one per approval is expected to create a more unfavorable environment for new drug patent holders.
- **Insufficient Compensation for Patent Infringement:** Recent rulings by the Korean Supreme Court have resulted in inadequate compensation for global pharmaceutical companies' innovative new drugs when patents are infringed. The forced price reduction of innovative products due to the market entry of generic products reduces incentives for R&D investment and weakens patent rights.

Industry stakeholders have also noted concerns regarding the legislative process, particularly in relation to the extent of stakeholder consultation, given the potential impact of the amendment on the pharmaceutical sector.

In parallel, a proposed amendment to the Patent Act related to compulsory licensing has been introduced to establish a clearer legal basis for government intervention in public health emergencies, including in response to infectious disease outbreaks such as COVID-19.

Given the nature of the pharmaceutical industry, where medicines undergo lengthy regulatory review even after patent filing, the patent term extension system remains an important mechanism to support innovation. Ensuring that the system appropriately reflects the time required for regulatory approval will be important to sustaining continued investment in the development of innovative medicines. In this context, continued dialogue with stakeholders will be important to ensure that the Patent Act framework remains aligned with global practices. In particular, consideration could be given to ensuring that Patent Term Extension (PTE) granted to the first patent appropriately covers subsequent indications approved prior to the expiration of the granted extension.

In addition, a comprehensive review of the compulsory licensing framework may be beneficial to ensure that public health objectives are balanced with the need to maintain a stable and innovation-supportive intellectual property environment.

- **Issue**

- IP Challenges with the Patent Act Amendment Bill & Proposed Amendment to Patent Act on Compulsory Licensing

- **Relevant Regulations**

- The Patent Act
 - Patent Regulations
 - Pricing & Post-Management System

- **Relevant Agencies**

- Ministry of Health and Welfare (MOHW)
 - Ministry of Intellectual Property (MOIP)

- **Relevant KORUS Provisions**

- Chapter 5 (Pharmaceutical Products and Medical Devices) Article 1 (General Provisions) & Article 2 (Access to Innovation)

- **Recommendation**

- AMCHAM urges the Korean government to collaborate with key stakeholders to either halt or amend the Patent Act Amendment Bill to align with U.S. practices, ensuring that PTE granted to the first patent covers all future indications approved before PTE expiration. Additionally, a comprehensive review of the IP compulsory issue is needed for effective pandemic preparedness.

- **Recommendation**

- AMCHAM encourages the Korean government to engage closely with key stakeholders to review the Patent Act Amendment Bill and consider adjustments to enhance alignment with international practices, including those of the United States. In particular, consideration could be given to ensuring that Patent Term Extension (PTE) granted to the first patent appropriately covers subsequent indications approved prior to the expiration of the granted extension.

In addition, a comprehensive review of the compulsory licensing framework would help balance public health objectives with a stable and innovation-supportive intellectual property environment.



TAXATION

TABLE OF CONTENTS

NO.	ISSUE	STATUS
	Overview	
01	Education Tax	NEW
02	Exemption from Withholding Tax on KTBs and MSBs	NEW
03	Pre-Payment Requirement for Tax Disputes	NEW
04	Ensuring Tax Neutrality and Competitiveness for the Beer Industry	NEW
05	Enhancing Predictability and Proportionality in Tax Audits and Enforcement	

OVERVIEW

South Korea's tax system continues to be perceived as complex and, in certain areas, unpredictable, which can present challenges for businesses, particularly foreign investors. Frequent changes in tax rules and evolving enforcement practices may create uncertainty that can affect business planning and long-term investment decisions. For global companies operating across multiple jurisdictions, differences in tax treatment and administrative procedures can also contribute to increased compliance efforts and operational complexity.

At the same time, certain structural and procedural aspects of the tax system may warrant further consideration. In some cases, the design of tax rules and administrative requirements can lead to additional compliance or financial burdens for taxpayers, particularly in cross-border transactions or dispute resolution processes. Variations in tax treatment across industries and evolving audit practices may also give rise to questions regarding consistency and predictability in tax administration.

To further strengthen Korea's attractiveness as an investment destination, continued efforts to enhance clarity, consistency, and predictability in tax policy and administration would be beneficial. Measures that help streamline administrative procedures, promote balanced tax treatment, and support alignment with international practices could provide businesses with greater certainty and facilitate cross-border investment and sustainable growth.

INDUSTRY ISSUES

Education Tax ^{NEW}

The Education Tax Act was enacted in December 1981 with a five-year statute of limitations for securing financial resources required for the improvement of school facilities and the welfare of teachers. The statute of limitations was extended by another five years in December 1986, but was converted into a perpetual tax in December 1990, and has been effective to date.

Under the current Education Tax Act, taxpayers fall into two categories: (i) taxpayers of individual consumption tax, traffic, energy, and environment tax, and liquor tax, and (ii) financial companies and insurance companies such as banks, insurance, securities, and asset management companies. For the first category, it is a surtax added to individual consumption tax, traffic, energy and environment tax, and liquor tax, which can ultimately be passed on to consumers of the relevant goods. However, for financial companies and insurance companies, it is difficult to pass on to consumers the cost of the education tax, as the tax base is not only interest income and commission income charged to customers, but also dividend income and gains on sale and purchase of securities, foreign exchange, derivatives transaction and disposal of fixed assets. In other words, the education tax is an additional cost to be borne by the financial companies and insurance companies.

In addition, the tax base for education tax on financial companies and insurance companies is revenues, while only certain items, such as foreign exchange, derivatives transactions, and government bond transactions (to apply from 2026) are exceptionally permitted to be offset against profits and losses. Furthermore, in principle, relevant expenses are not allowed to be deducted. For example, interest expenses and losses from the disposal of securities are not deducted from interest income and gains from the disposal of securities, and thus, education tax may be imposed even if no income is generated from the relevant transaction. Also, education tax may be imposed even if net losses are incurred by the tax payer because expenses such as labor and SG&A expenses cannot be deducted.

- **Issue**

Under the current Education Tax Act, financial institutions bear the education tax as a direct cost, as it cannot be passed on to consumers, unlike other categories of taxpayers. Moreover, because the tax base is calculated on gross revenues with limited loss offset and expense deductibility, the education tax may be

imposed even in the absence of net income, raising concerns regarding tax equity and neutrality.

- **Relevant Regulations**

Education Tax Act

- **Relevant Agencies**

National Tax Service (NTS)

Ministry of Finance and Economy (MOFE)

- **Recommendation**

AMCHAM believes it is unreasonable (i) to impose the education tax only on financial companies and insurance companies despite the fact that the education tax is intended to secure funds for the nation's education, and (ii) for the education tax to be imposed even when there is no income to the taxpayer due to revenue representing the tax base. Therefore, we hope that the education tax regime can either be abolished or reformed to ensure greater equity.

Exemption from Withholding Tax on KTBs and MSBs ^{NEW}

Non-residents or foreign entities without a permanent establishment in Korea (“Tax Exempt Foreign Investors”) are exempt from withholding tax on interest income and capital gains from investing and trading in KTBs (Korea Treasury Bonds) and MSBs (Monetary Stabilization Bonds) pursuant to the Income Tax Law and Corporate Tax Law, as applicable. Tax Exempt Foreign Investors trading KTBs and MSBs through a recognized international central securities depository are also waived of the requirement to submit documentations for withholding tax exemption. However, the same exemption does not apply when the Tax Exempt Foreign Investors trade KTBs and MSBs through an onshore financial institution in Korea which includes foreign banks and securities companies.

In the case of offshore funds, operational issues often make it difficult to submit the required withholding tax documentation. The Korean financial institution must then withhold tax from the Tax Exempt Foreign Investor, and such investor must then file for a tax refund. In other markets, it would be unusual for the broker to be obligated to withhold tax; this responsibility typically rests with the custodian which has a record of all the transaction history information. Moreover, this process creates additional burden for the broker to collect information to withhold tax which the beneficiary will ultimately seek to have refunded.

- **Issue**
Tax Exempt Foreign Investors trading through onshore Korean financial institutions are required to submit documentation, which often leads to tax withholding followed by a burdensome refund process, unlike those trading through a recognized iCSD.
- **Relevant Regulations**
Income Tax Act
Corporate Tax Act
- **Relevant Agencies**
National Tax Service (NTS)
Ministry of Finance and Economy (MOFE)
- **Recommendation**
AMCHAM requests the exemption of Tax Exempt Foreign Investors from the requirement to submit documents for exemption from withholding tax, regardless of whether they are trading through a recognized iCSD or a Korean financial institution, given that the foreign status of the Tax Exempt Foreign Investors can be

confirmed through the Investment Registration Certificate (IRC) or Legal Entity Identifier (LEI). Maintaining this differential treatment based upon whether the Tax Exempt Foreign Investors traded KTBs or MSBs through an iCSD from offshore or through an onshore financial institution in Korea will place the latter at a competitive disadvantage to iCSDs.

Pre-Payment Requirement for Tax Disputes ^{NEW}

South Korea's current tax dispute framework effectively operates on a strict "pay-first, litigate-later" basis, requiring taxpayers to remit the full amount of an assessed tax liability before pursuing administrative appeals or litigation under the Framework Act on National Taxes and its Enforcement Decree. While this approach supports timely revenue collection, it can create significant practical barriers to dispute resolution - particularly in complex cases where the assessment amount is substantial and the final outcome may not be determined for several years.

For multinational enterprises (MNEs), large and technical assessments (e.g., transfer pricing, withholding tax, or permanent establishment matters) can trigger immediate, material cash outflows long before the merits of the case are reviewed by an independent appeals body or court. This pre-payment obligation can constrain liquidity, delay investment and hiring decisions in Korea, and discourage taxpayers from pursuing legitimate challenges even where strong contemporaneous documentation and legal grounds exist. In effect, the absence of a meaningful suspension or deferral mechanism during the dispute period places disproportionate financial risk on taxpayers and undermines Korea's competitiveness as a predictable and investment-friendly jurisdiction.

- **Issue**
Korea's "pay-now, argue-later" practice requires full pre-payment of disputed tax assessments before meaningful appeals or litigation can proceed, creating significant cash-flow burdens, deterring legitimate dispute resolution, and weakening confidence in procedural fairness, particularly for large and long-running MNE disputes.
- **Relevant Regulations**
Framework Act on National Taxes
Enforcement Decree of the Framework Act on National Taxes
- **Relevant Agencies**
National Tax Service (NTS)
Ministry of Finance and Economy (MOFE)
- **Recommendation**
AMCHAM recommends adopting a more balanced dispute framework by introducing a formal "stay of collection" or deferral mechanism that allows suspension of payment for disputed assessments where taxpayers demonstrate reasonable legal

grounds and cooperate in good faith. Objective criteria could include interpretative uncertainty, OECD-aligned transfer pricing issues, or cases subject to Mutual Agreement Procedures (MAP). Korea should also consider safeguards commonly used across OECD jurisdictions, such as permitting guarantees or bank bonds in lieu of cash deposits and limiting interest accrual during bona fide disputes, to secure government revenue while reducing unnecessary disruption to legitimate business operations and investment decisions.

Ensuring Tax Neutrality and Competitiveness for the Beer Industry ^{NEW}

Korea's manufacturing sector is facing mounting pressure amid a prolonged global economic slowdown, weakened domestic consumption, rising inflation, and heightened exchange rate volatility. Within this environment, the alcoholic beverage industry has experienced particularly acute strain due to rising input costs and declining consumer demand.

In response to these conditions, the Korean government has implemented targeted tax relief measures to support domestic manufacturers. Since January 2024, reduced excise tax burdens have been applied to domestically produced distilled spirits through the introduction of a "standard sales ratio," with further tax reductions extended to additional categories. Moreover, beginning in April 2026, the excise tax rate on low-alcohol mixed beverages, such as highballs, is scheduled to be reduced by approximately 50 percent. These measures reflect the government's recognition of the need for tax policy flexibility to support affected industries during a period of economic stress.

However, beer, despite being a direct substitute and competitor to these products, has been excluded from comparable tax relief measures. This differential treatment raises concerns regarding tax neutrality across alcoholic beverage categories. The beer industry is structurally disadvantaged due to its heavy reliance on imported raw materials, such as malt, making it especially vulnerable to exchange rate fluctuations and global commodity price increases. As a result, beer producers, including small and medium-sized brewers, are absorbing significant cost pressures without corresponding policy support, placing them at a relative disadvantage compared to other segments of the alcoholic beverage market.

Notably, the current legal framework provides flexibility for adjusting beer excise tax rates. Under Article 8(2) of the Liquor Tax Act, the government is authorized to adjust excise tax rates by up to 30 percent by presidential decree, taking into account factors such as price levels, consumption trends, and industry conditions. This statutory authority offers a clear legal basis for targeted and proportionate tax relief measures to address the challenges facing the beer industry.

- **Issue**

Beer producers remain excluded from recent excise tax relief measures despite facing significant cost pressures, raising concerns over tax neutrality and competitive imbalance among alcoholic beverage categories.

- **Relevant Regulations**

 - Liquor Tax Act

 - Enforcement Decree of the Liquor Tax Act

- **Relevant Agencies**

 - National Tax Service (NTS)

 - Ministry of Finance and Economy (MOFE)

- **Recommendation**

 - AMCHAM recommends that the Korean government consider a partial reduction of the excise tax applied to beer, consistent with the flexibility permitted under the Liquor Tax Act. A measured adjustment would help restore tax neutrality across alcoholic beverage categories, alleviate cost pressures on beer producers, including small-scale brewers, and support the sustainability of the broader manufacturing and distribution ecosystem. Such an approach would align tax policy with current economic realities while maintaining the integrity of the existing excise tax framework.

Enhancing Predictability and Proportionality in Tax Audits and Enforcement

In recent years, multinational enterprises (MNEs) operating in Korea have observed increasingly assertive positions taken by the National Tax Service (NTS) during tax audits, particularly in technically complex areas such as transfer pricing, permanent establishment attribution, withholding tax obligations, and the characterization of cross-border transactions. In some cases, audit positions appear to place limited weight on contemporaneous documentation, arm's-length analyses, or the underlying commercial substance of transactions, resulting in reassessments that diverge from established OECD guidance or prior administrative practice.

Compounding these concerns, taxpayers have also reported instances where unresolved interpretational disputes at the audit stage are accompanied by the potential referral to criminal proceedings under the Punishment of Tax Offenses Act. While criminal enforcement is an important tool to address clear and intentional tax evasion, generally where alleged evasion exceeds statutory thresholds (approximately KRW 500 million), its application prior to the final administrative or judicial determination of tax liability can create a coercive environment. In practice, such referrals may be accompanied by investigative measures, including dawn raids and immediate travel restrictions on corporate executives, even in cases involving good-faith interpretational differences rather than fraudulent intent. The early invocation of criminal exposure in unresolved civil tax disputes significantly heightens procedural and reputational risks for companies.

This dynamic risks undermining predictability, proportionality, and trust in Korea's tax administration. Where taxpayers perceive that disputing an assessment may escalate routine civil tax matters into criminal investigations, they may feel compelled to accept aggressive adjustments irrespective of their legal merits. Such practices can weaken confidence in the neutrality of tax enforcement and may adversely affect Korea's attractiveness as a stable and rules-based jurisdiction for global investment.

- **Issue**
In complex international tax matters, assertive audit interpretations and the early use of criminal enforcement measures may create uncertainty and procedural imbalance for taxpayers, discouraging legitimate dispute resolution and weakening confidence in fair tax administration.
- **Relevant Regulations**
Corporate Income Tax Act

International Tax Coordination Act
Punishment of Tax Evaders Act
Framework Act on National Taxes

- **Relevant Agencies**

National Tax Service (NTS)
Ministry of Finance and Economy (MOFE)

- **Recommendation**

AMCHAM recommends enhancing predictability, proportionality, and procedural clarity in tax audit and enforcement practices. In particular, audit interpretations in complex cross-border matters should be applied in a manner consistent with OECD guidance, established administrative practice, and contemporaneous documentation. In parallel, clearer standards should be introduced to ensure that criminal enforcement measures are reserved for cases involving clear and demonstrable intent to evade tax, and are not applied during unresolved civil tax disputes. These measures would support balanced tax administration, reduce unnecessary disputes, and strengthen Korea's position as a transparent and investment-friendly jurisdiction.

Table of Abbreviations

ABBR.	EXPANDED
AMCHAM	American Chamber of Commerce in Korea
CAFE	Corporate Average Fuel Economy
CBI	Confidential Business Information
CC	Common Criteria
CCA	Chemical Control Act
CED	Coverage with Evidence Development
CMS	Center for Medicare and Medicaid Services
COVID	Coronavirus Disease-19
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CSAP	Cloud Security Assurance Program
DAPA	Defense Acquisition Program Administration
ECHA	European Chemicals Agency
ELV	End-of-life Vehicle
EMA	European Medicines Agency
EPR	Extended Producers' Responsibility
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FSC	Financial Services Commission
FSS	Financial Supervisory Service
FTA	Free Trade Agreement
GHG	Greenhouse Gas
HIRA	Health Insurance Review and Assessment Service
HVAC	Heating, Ventilation & Air Conditioning
IaaS	Infrastructure-as-a-Service
ICT	Information Communication Technology
IPC	Innovative Pharmaceutical Company
JECFA	Joint FAO/WHO Expert Committee on Food Additives
K-BPR	Safety Control Act of Household Chemical Products and Biocidal Products
KCC	Korea Communications Commission

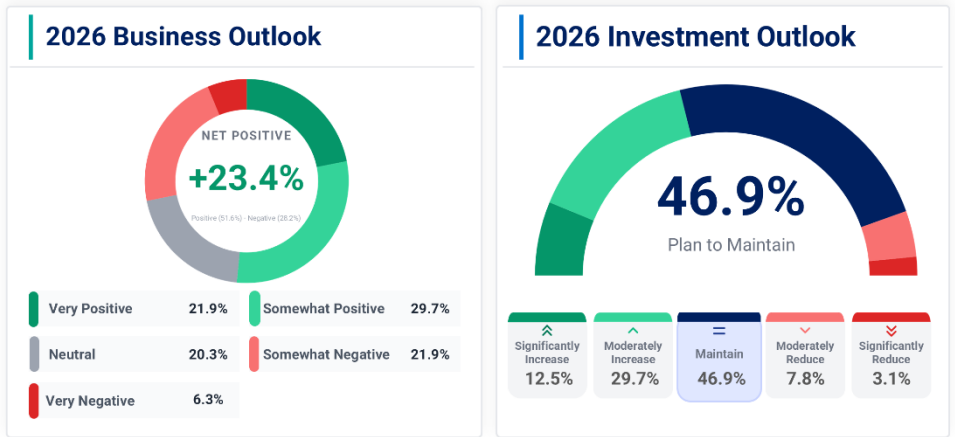
KDCPA	Korea Disease Control and Prevention Agency
KEA	Korea Energy Agency
KFTC	Korea Fair Trade Commission
KISA	Korea Internet Security Agency
KORUS	Free Trade Agreement between the United States of America and the Republic of Korea
K-REACH	Act on the Registration and Evaluation of Chemicals
KTB	Korea Treasury Bond
LMO	Living Modified Organism
MAFRA	Ministry of Agriculture, Food and Rural Affairs
ME	Ministry of Environment
MFDS	Ministry of Food and Drug Safety
MOA	Memorandum of Agreement
MOEL	Ministry of Employment and Labor
MOHW	Ministry of Health and Welfare
MOLIT	Ministry of Land, Infrastructure and Transportation
MOTIR	Ministry of Trade, Industry and Resources
MRFTA	Monopoly Regulation and Fair Trade Act
MSDS	Material Safety Data Sheet
MSIT	Ministry of Science and ICT
MVCA	Motor Vehicle Control Act
NDC	Nationally Determined Contribution
NECA	National Evidence-based Healthcare Collaborating Agency
NHIS	National Health Insurance Service
NHPA	National Health Promotion Act
nHTA	New Health Technology Assessment
NIE	National Institute of Ecology
NTS	National Tax Service
OECD	Organization for Economic Cooperation and Development
OEM	Original Equipment Manufacturer
OR	Only Representative
OSHA	Occupational Safety and Health Act
PIPA	Personal Information Protection Act
PIPC	Personal Information Protection Committee

PR	Parallel Review
P&R	Pricing & Reimbursement
RDA	Rural Development Agency
R&D	Research & Development
REC	Renewable Energy Certificate
RFP	Request for Proposals
RFQ	Request for Quotation
RIFM	Research Institute for Fragrance Materials
SMEs	Small and Medium-Sized Enterprises
TAA	Technical Assistance Agreement
TBA	Telecommunication Business Act
WHO	World Health Organization
WTO	World Trade Organization

AMCHAM Business Survey 2026



Outlook for Korea's Business and Investment Environment

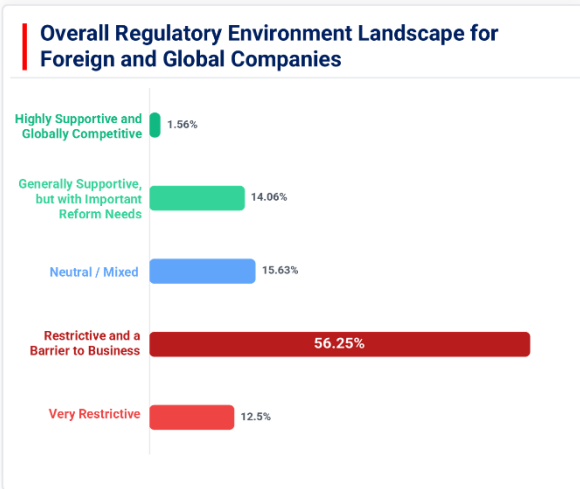


Expected Workforce Adjustments in Korea



* Note: Percentages may not sum to 100 due to rounding and multiple selections.

Korea's Business Climate and Regulatory Environment



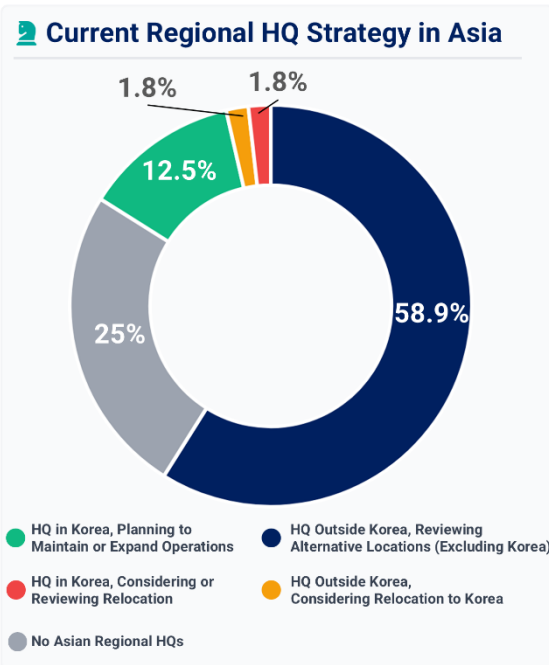
Key Finding

68.8%

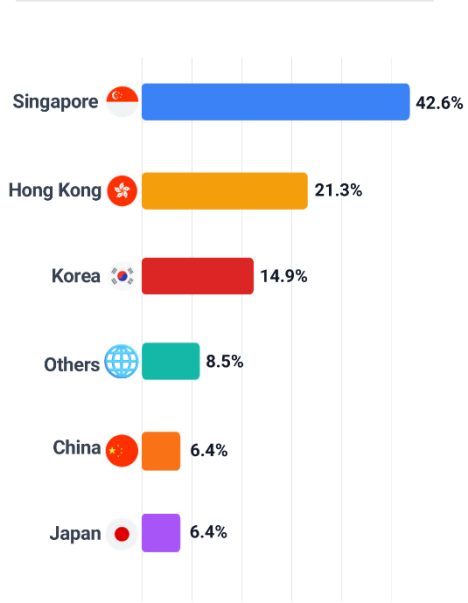
of respondents assess the environment as **Restrictive** or **Very Restrictive**, highlighting significant regulatory challenges.

- Major reform needed to improve global competitiveness

Korea as a Regional Business Hub



Location of Current Regional HQ



* Note: Percentages may not sum to 100 due to rounding and multiple selections.

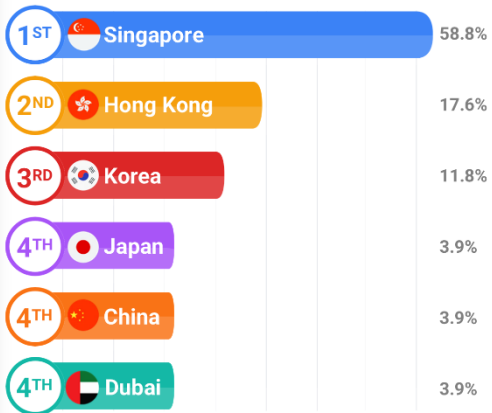
AMCHAM Business Survey 2026



Korea as a Regional Business Hub



Most Preferred Regional HQ Location



Key Regulatory Challenges and Reform Priorities

Key Policy Factors Undermining RHQ Potential



Other Factors



Urgent AI-related Policy Reforms



Other Reforms

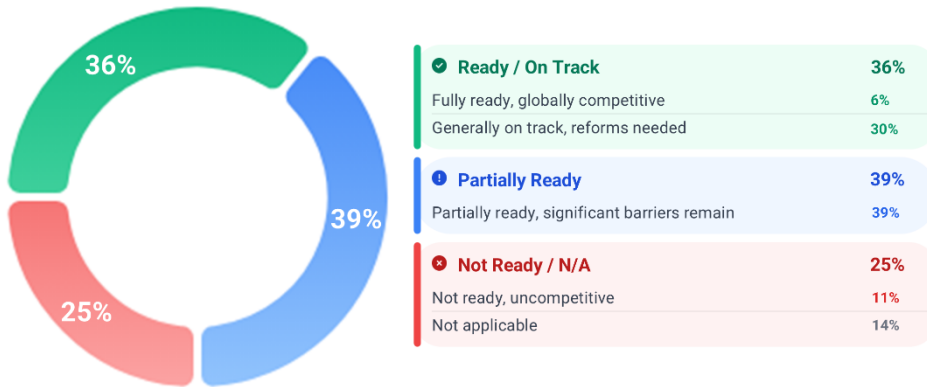


* Note: Percentages may not sum to 100 due to rounding and multiple selections.

AMCHAM Business Survey 2026

Korea's Financial Market Competitiveness and MSCI Inclusion Readiness

MSCI Inclusion Readiness Assessment



Key Reforms for MSCI Developed Market Status and Financial Hub Competitiveness

- 1 Regulatory transparency, consistency, and predictability **39%**
- 2 Alignment with global business and market standards **22%**
- 3 Fair and open market access for international firms and investors **20%**
- 4 Efficient legal systems and institutional systems protecting investors and companies **7%**
- 5 Ease of cross-border transactions and movement of capital **6%**

OTHER CRITICAL FACTORS

- Stable tax and compliance environment **2%**
- Public-private sector communication **2%**
- Reduction of foreign ownership restrictions **2%**

* Note: Percentages may not sum to 100 due to rounding and multiple selections.