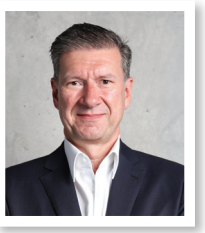
EUROPEAN CHAMBER OF COMMERCE IN KOREA

ECCK White Paper 2022

Message from Chairperson



Dirk Lukat
Chairperson,
European Chamber of Commerce in Korea

Dear Valued Members and Friends,

It is my pleasure to present you the 2022 ECCK White Paper, the most important publication of the chamber focusing on key industrial issues and recommendations of the European business community in Korea. The White Paper has been acting as an important and unique communication platform, bridging the ECCK, its members and the Korean government since the launch in 2015.

On 10th of May, 2022, I had the honour of participating in President Yoon's inauguration ceremony. The messages he portrayed and discussions in subsequent meetings with the new government provide an optimistic outlook on improvements for businesses operating in Korea over the next 5 years. I am hopeful for constructive discussions toward deregulation, which remains a key agenda item for us but also for Korean business. I have confidence in the intensive and dedicated work of our committees, and industry experts from our member companies and I am sure that we will succeed in providing continuously valuable input to the new government. Adding to the success of our committees, we have this year added a new committee, namely the Sustainability Committee which shall promote sustainability across all industries and therewith help all our member companies' transition to a sustainable way of doing business.

The importance of ECCK's advocacy activities continues to grow with the increase of foreign direct investment (FDI) in Korea amid the post-pandemic. According to the Ministry of Trade, Industry, and Energy (MOTIE), FDI pledges made to Korea amounted to $29.5 billion in 2021, showing a significant growth compared to the year before, which was $20.7 billion. Additionally, investment from the EU reached $12.8 billion in the previous year, nearly tripling the figure from 2020. I believe this growth in investment by the European business community in Korea will enable the chamber to provide our members with even better business support and valuable communication channels with the Korean authorities.

I am proud to say that this year the ECCK celebrates its 10th anniversary – which means that we have been representing European business successfully for the past 10 years towards the Korean government. The reputation and recognition the ECCK receives is also attributable to your commitment and support! This is evident in our growth, having started the chamber in 2012 with 166 member companies and now representing almost 400 member companies (as of August 2022).

In closing, I would like to send special thanks to our members for their dedication and input into this publication. I am positive that open and effective dialogues with the government will be sparked by the White Paper 2022. Thank you for your unceasing support!

Thank you.

Dirk Lukat
European Chamber of Commerce in Korea (ECCK) Chairperson

Executive Summary

Christoph Heider
President,
European Chamber of Commerce in Korea

The European Chamber of Commerce in Korea (ECCK) has published its White Paper since 2015. It is the key publication of the ECCK and shall be considered as a publication containing recommendations to the Korean government. In fact, since 2015 more than 1,000 recommendations have been delivered to the Korean administration, some of them accepted and some of them not.

All recommendations have been received by the ECCK from representatives hailing from its member companies who are active in one (1) of our twenty-one (21) advocacy platforms known as committees. These committees are the real contributors of these recommendations, and I am proud to say that this year, the energy and the effort in creating all these recommendations and the White Paper 2022 as a whole has exceeded that of previous years.

The compilation of all these issues and recommendation is only half of the work that goes into to making the White Paper a meaningful publication. The ECCK wishes to extend its sincere gratitude to the Korean administration, especially the Office of the Foreign Investment Ombudsman led by Ombudsman Kim Sung Jin, for all its openness in reviewing these recommendations, thoroughly following up with experts in the Korean administration, and sharing the resulting feedback with the ECCK. The positive feedback received at the beginning of 2022 on about 33 (29%) out of the 114 recommendations submitted in 2021 has proven that collaboration and cooperation can deliver meaningful results.

European businesses are convinced that these recommendations are always worth sharing as they are provided by a different group of stakeholders – namely by European companies. European companies and their business representatives have a different and diverse range of views on how to run their businesses. This is primarily due to the corporate governance of their European headquarters and the experiences CEOs and other executives have had in different countries. Naturally not all of our recommendations can be accepted as the Korean government has to choose a balancing approach, balancing Korean interest with, for example, internationally accepted standards.

The White Paper 2022 with its 96 recommendations – as in every year – will be shared with Korean ministries but also with the European Commission in Brussels, the European Free Trade Association Secretariat in Geneva, and the British government in London. Additionally, we will share it with other organisations and associations with whom we have developed close relations with due to their strong interest in European-Korean trade.

Korea since 10th of May, 2022, has a new president; President Yoon Suk-Yeol. The ECCK has observed the forming of the new government with avid interest and has also noted with pleasure a more open approach towards business, including foreign business. For many years, the ECCK has advocated for Korea to take on a stronger role and have a stronger voice in international policy making, reflecting not only its economic strength, but also its innovative power. As one of the ten leading economies, I believe that now, more than ever, is a time from which it will be heard more often.

Challenges for countries and companies alike remain. The hope that COVID-19 will have disappeared this year has vanished. It still has – although luckily to a lesser extent – a certain impact on our lives and work. Problems in supply chain still remain and the resulting freight costs continue to be high. The latest addition to these problems has been caused by the Russian invasion of the Ukraine which has led to skyrocketing energy and food prices. Interest rates have been hiked by various central banks, making it more expensive to finance necessary investment.

In such difficult times, stronger alliances among like-minded countries must be made. Korea and Europe share the same principles and values in respect to trade and it must be our mission to ensure that trade can be conducted smoothly and without friction. Therefore, the work for Korea shall be to ensure compliance with fully implemented international standards.

It is our belief that a full implementation of international standards will foster trade between Europe and Korea in both ways. There is huge potential in Europe and Korea as far as SMEs are considered. In fact, for many SMEs, exporting is still too complex due to all the different rules and regulations. Another point is that innovation cycles have become shorter and shorter, making it more difficult for country specific regulations to have an effect. In fact, many products in Europe are not available due to differences in European and Korean standards – products that are essential for the health of Korean citizens or for fighting climate change.

In 2023, Korea and the European Union will celebrate its 60th year anniversary of diplomatic relations at the same time as Korea will do with Switzerland. It will also be 140 years of bilateral ties between Korean and Germany that same year. Thus, it is the belief of the ECCK that 2023 will be a good opportunity to demonstrate that collaboration really is the key for success for Korea, for Korean companies and for European companies operating in and with Korea, following receipt of the final feedback on our White Paper recommendations in the first quarter of the year.

Christoph Heider
European Chamber of Commerce in Korea (ECCK) President

EUROPEAN CHAMBER OF COMMERCE IN KOREA

ECCK White Paper 2022

Table of Contents

ECCK Introduction

ECCK Introduction

Established in 2012, the European Chamber of Commerce in Korea (ECCK) is a business association of European companies operating in and with Korea, representing the common voice of the European business community. The ECCK provides its members with information, communication, and access pertaining to the business and regulatory environment of Korea. As of August 2022, the Chamber consists of almost 400 member companies and approximately 50,000 employees in Korea.

While European firms form the largest membership base of the organisation, the ECCK welcomes companies of all nationalities to join and share their experience together. Entrusted with a member's mandate, the Board of Directors presides over the organisation. The Advisory Board embodies business representatives nominated by national chambers or embassies, providing general guidance and advice. The Secretariat functions to execute the Chamber's day-to-day activities and operations.

The ECCK strives to cultivate an optimal business environment and community for European companies. Furthermore, the Chamber aims to promote a sustainable relationship between European corporations and the Korean government by working hand-in-hand with both parties. This annual White Paper is a perfect example of bridging European businesses and the Korean government together toward creating a better business environment.

In line with connectivity, the Chamber has worked to have a positive influence on Korean society, connecting local and global CSR partners and our members to further grow and contribute to meaningful actions.

The ECCK has built cooperative ties with the European Commission and the Secretariat of the European Free Trade Association. The ECCK is also a member of the European Business Organisation Worldwide Network (EBO WWN).

ECCK Vision & Mission

The ECCK is committed to advancing the interests of companies from Europe operating in Korea. We cooperate with organisations that share mutual interests to fairly represent the European business community and promote an optimal business environment in Korea. To achieve these objectives, the ECCK focuses on:

- Ensuring a fair and open business environment by facilitating dialogue with the government
- Collecting and disseminating information on business as well as economic and regulatory developments in Korea and Europe
- Creating networking opportunities for members and partners
- Contributing to Korean society by supporting corporate social responsibility activities and promoting good corporate governance practices
- Becoming a commercial and cultural ambassador to Korea

Board of Directors

Dirk Lukat (Germany)
Chairperson of the Board
CEO
Schenker Korea

Dirk Lukat is a German citizen and is the CEO of Schenker Korea Ltd in Seoul since January 2015. Dirk Lukat started his career at the former Schenker & Co. GmbH in Frankfurt and held a number of management positions at DB Schenker in Singapore, Vietnam, and India. Before coming to Korea, he served as General Manager of Schenker-Seino Co., Ltd in Japan and was active in the Logistics & Transport Committee of the EBC. He has comprehensive experience in the logistics industry including Contract Logistics, Air & Ocean Freight, Fairs & Exhibitions, and Projects for over 20 years. Dirk joined the ECCK as a member from January 2015 and was elected in February 2017 to the ECCK Board. He then was appointed as a Chairperson of the ECCK in July 2020. Previously from 2017 to 2019 he served as the Chairperson of ECCK's Logistics & Transport Committee of which he still is a member today.

Jan Benggaard (Denmark)
Vice Chairperson of the Board
Country President
Oerlikon Korea

Jan Benggaard is a Danish citizen and is the Managing Director of Oerlikon Korea since November 2016. In Busan, he has been the Managing Director and Chief Executive Officer of Wärtsilä Marine Systems (previously L-3 Marine Systems) since 2002. Before moving to Busan in 1998, he worked as a project engineer and later as Sales Manager in charge of regional operations in the Americas and Europe. Jan's honorary assignments include being a Board Member and Treasurer of Busan International Foreign School since 2005 as well as a Vice Chairman of the ECCK since February 2015.

Younhee Kim (Korea)
Vice Chairperson of the Board
General Manager
Galderma Korea

Younhee Kim is a Korean citizen and is the General Manager of Galderma Korea since October 2020. She has extensive experience in the pharmaceutical, vaccines, skincare & medical device business industry for over 20 years. Her understanding of Korean business and culture is based on, not only the local experience but also the working experience in Asia Pacific region, Europe, and US. Before joining Galderma, she has worked with global companies including L'oreal Korea, MERZ Korea and MSD (MERCK & Co.,INC.) leading sales & marketing, other business and communications strategy. Younhee joined the ECCK as a member in October 2020, was elected as Vice Chairperson in May 2022.

Thomas Klein (Germany)
Vice Chairperson of the Board
President and CEO
Mercedes-Benz Korea

Thomas Klein is a German citizen and has been appointed as President and CEO of Mercedes-Benz Korea from January 1, 2021. Since beginning his career with Daimler AG in 1999, Thomas built his career as a member of Daimler AG's Management Trainee program, various functions in the German organisation on both wholesale and

retail level, Managing Director of Mercedes-Benz Passenger Cars at Sandown Motors Holding Pty, South Africa, and the President and CEO of Mercedes-Benz Cars Middle East in Dubai. He has successfully led the sales and services performance in the region based on his diverse experience in sales and marketing. He has significantly contributed to the overall success of the brand and built excellent relationships with partners as well.

Fredrik C Johansson (Sweden)
Director of the Board
CEO
IKEA Korea

Fredrik is a Swedish citizen and has been CEO of IKEA Korea since July 2019. He first joined IKEA in Älmhult, Sweden in 1987. After earning his Master's degree, he gained extensive exposure in the global home furnishing industry in various positions within IKEA in several countries spanning from Asia to Europe including Managing Director of IKEA Components. He moved to IKEA Retail in 2010, where he extended his experience as Deputy Store Manager and Store Manager for XuHui and Daxing stores in China. He was also the Deputy Country Manager for IKEA France for almost 3 years before joining IKEA Korea in 2017 as CEO.

Donghwan Kim (Korea)
Director of the Board
General Manger
Finnair Oyj.

Donghwan Kim is a Korean citizen and has been General Manager of Finnair since 2012. In 2008, he joined as a Sales Manager and until 2011, he mainly took care of regulatory matters as well as corporate & trade sales. In 2011, he has worked in Finnair HQ as a Corporate Sales Manager in global corporate sales team having a role of corporate sales in whole Europe to Korea. Then, he was appointed as a General Manager from 2012 taking responsibility of whole Finnair business in Korea.

Board of Directors

Melanie Lorsery-Chamaux (France)
Director of the Board
General Manager
Servier Korea

Melanie Lorsery-Chamaux is a French citizen and is the General Manager of Servier Korea appointed since October 2020. She has been in the pharmaceutical industry for about 20 years working from several multinational companies such as AstraZeneca, Novartis and Servier occupying different responsibilities across European countries before arriving in Korea.

Elizabeth Kyunghee Nam (Korea)
Treasurer of the Board
CEO
Windsor Global

Elizabeth Kyunghee Nam is a Korean citizen and is CEO at Windsor Global. She has 20+ years of progressive experience in Finance and General management within the business units in the developed & emerging markets, global organisation and start-up business. Before joining Windsor Global, Elizabeth worked with Diageo, LG Telecom, Shepard, Schwartz & Harris and Philippine Airlines.

Johan Vandromme (Belgium)
Trustee of the Board
Senior Advisor
Kim & Chang

Johan is a Belgian citizen and has been a senior advisor with Kim & Chang since October 2020, as well as from 2007 to 2009. He started his career in Brussels in 2001 as a case-handler at the European Commission's Competition Directorate-General, before moving to Korea in 2007. He left private practice in 2009 to return to the service of the European Commission at the Delegation in Beijing, covering trade and competition matters, later coming back to Korea in 2013 to the Seoul Delegation. Prior to returning to Kim & Chang as a senior advisor in 2020, he was serving at the Beijing Delegation since 2018, covering matters of competition and justice policies for the Commission.

ECCK Secretariat

Christoph Heider
President

Christoph Heider has been the President of the European Chamber of Commerce in Korea (ECCK) since 2013. He is the former Chief Financial Officer for Bayer Korea Ltd. in Seoul and Regional Manager of Bayer AG Legal Entity Accounting Asia Pacific Division in Germany. Christoph had worked for Bayer Ltd. in Tokyo since 1997 having arrived in Japan as a teacher shortly before.

Christoph graduated with an Intermediate Diploma in Economics from the Technical University of Braunschweig, Germany in 1988 before going on to complete his Diploma in Business Economics from the University of Mannheim in 1991. He then went on to finish a Postgraduate Program in Japanese from the University of Tuebingen in Germany and Doshisha University in Japan in 1996.

In 2016, Christoph received an Honorary Citizenship of Seoul. His other honorary assignments include being a board member of Heider-Kober Foundation in Munich, Germany as well as being a member of the European Union Domestic Advisory Group and the Korea-EU Civil Society Forum. He further holds a position as board member of the European Business Organisation Worldwide Network (EBO WWN).

Andrew Millard
Busan Chapter Representative, Marine & Shipbuilding Committee

Ansook Park
Director, Cosmetics/Healthcare Committees

Bo Sun Kim
Vice President, Government Relations

Cassandra Talbot
Manager, L&T/Sustainability/Tourism Committees

ECCK Secretariat

Changhoon Rim
Senior Manager, Aerospace & Defence/Automotive Committees

Eunsung Na
Manager, Fashion & Retail/IPR Committees

Hyeeun Cho
Senior Manager, Membership & Management Support

Hyewon Shim
Senior Manager, Marketing & Event Management

Hyoeun Choe
Manager, Finance & Administration

Hyokyung Suh
Director, Head of Committee Operations
Beer, Wine & Spirits/Food/Kitchen & Home Appliances Committees

Hyowon Moon
Assistant Manager, Committees Support

Jihyun Shin
Assistant Manager, PR & Communications

Siyoon Kim
Manager, ICT/Insurance/Taxation Committees

Taeyang Kim
Manager, Chemical/Energy & Environment Committees

Young Eun Kim
Director, PR & Communications

ECCK Services & Programs

Committees & Forums

Committees and Forums are the centrepieces of ECCK's activities. Comprised of participating member companies, Committees and Forums assist members to keep informed of regulations, to improve market intelligence, and to express positions on specific trade issues. Committees address industry-specific issues to Korean government counterparts. Meanwhile, Forums focus primarily on cross-industry topics, such as human resources, which are open to all members free of charge.

Events

The ECCK organises conferences and seminars of industrial relevance for knowledge sharing. In particular, we are actively engaged in dialogues with government agencies to represent the European industries' concerns and issues. Furthermore, formal and informal networking events are hosted to encourage information exchange and business relationships. Finally, the ECCK functions as the first point of contact for European executives and officials coming to Korea.

Publications

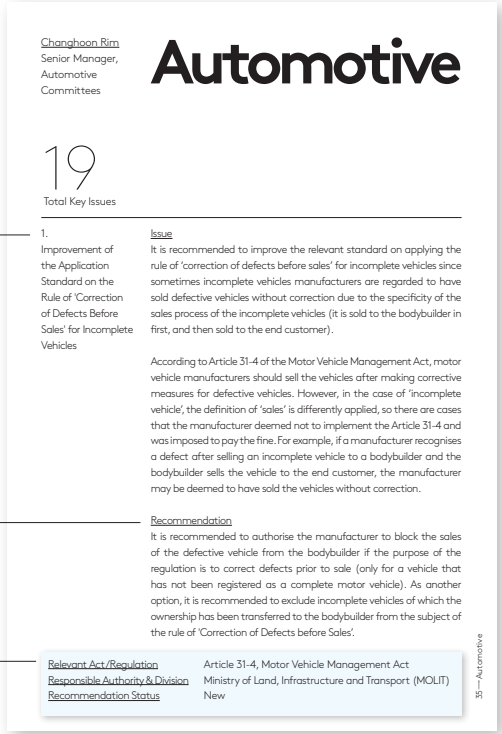
As a platform of communication, the ECCK produces regular publications to inform our members of the current market situation, key regulatory issues, and social trends in Korea. In addition, we conduct surveys on the business climate in Korea and interviews with industry experts. Major publications include:

- ECCK White Paper
- Business Confidence Survey
- ECCK Connect Magazine (digital)
- ECCK Membership Directory (yearly update of ECCK membership)
- Weekly Newsletter (weekly update to ECCK members)

How to read ECCK White Paper Key Issues and Recommendations

The ECCK White Paper 2022 presents a total of 96 industry issues and recommendations intended to improve the business environment in Korea. The recommendations are developed through extensive consultations with our European members participating in our 18 industry committees. The purpose of the White Paper is to serve as a constructive communication tool to the Korean government and European counterparts, and therefore every issue included in the publication is presented with a realistic recommendation that could be implemented by the relevant authorities.

The issues and recommendations take the following format:



Changhoon Rim
Senior Manager, Automotive Committees

Automotive

19
Total Key Issues

1. Improvement of the Application Standard on the Rule of 'Correction of Defects Before Sales' for Incomplete Vehicles

Issue
It is recommended to improve the relevant standard on applying the rule of 'correction of defects before sales' for incomplete vehicles since sometimes incomplete vehicles manufacturers are regarded to have sold defective vehicles without correction due to the specificity of the sales process of the incomplete vehicles (it is sold to the bodybuilder in first, and then sold to the end customer).

According to Article 31-4 of the Motor Vehicle Management Act, motor vehicle manufacturers should sell the vehicles after making corrective measures for defective vehicles. However, in the case of 'incomplete vehicle', the definition of 'sales' is differently applied, so there are cases that the manufacturer deemed not to implement the Article 31-4 and was imposed to pay the fine. For example, if a manufacturer recognises a defect after selling an incomplete vehicle to a bodybuilder and the bodybuilder sells the vehicle to the end customer, the manufacturer may be deemed to have sold the vehicles without correction.

Recommendation
It is recommended to authorise the manufacturer to block the sales of the defective vehicle from the bodybuilder if the purpose of the regulation is to correct defects prior to sale (only for a vehicle that has not been registered as a complete motor vehicle). As another option, it is recommended to exclude incomplete vehicles of which the ownership has been transferred to the bodybuilder from the subject of the rule of 'Correction of Defects before Sales'.

Relevant Act/Regulation	Article 31-4, Motor Vehicle Management Act
Responsible Authority & Division	Ministry of Land, Infrastructure and Transport (MOLIT)
Recommendation Status	New

35 — Automotive

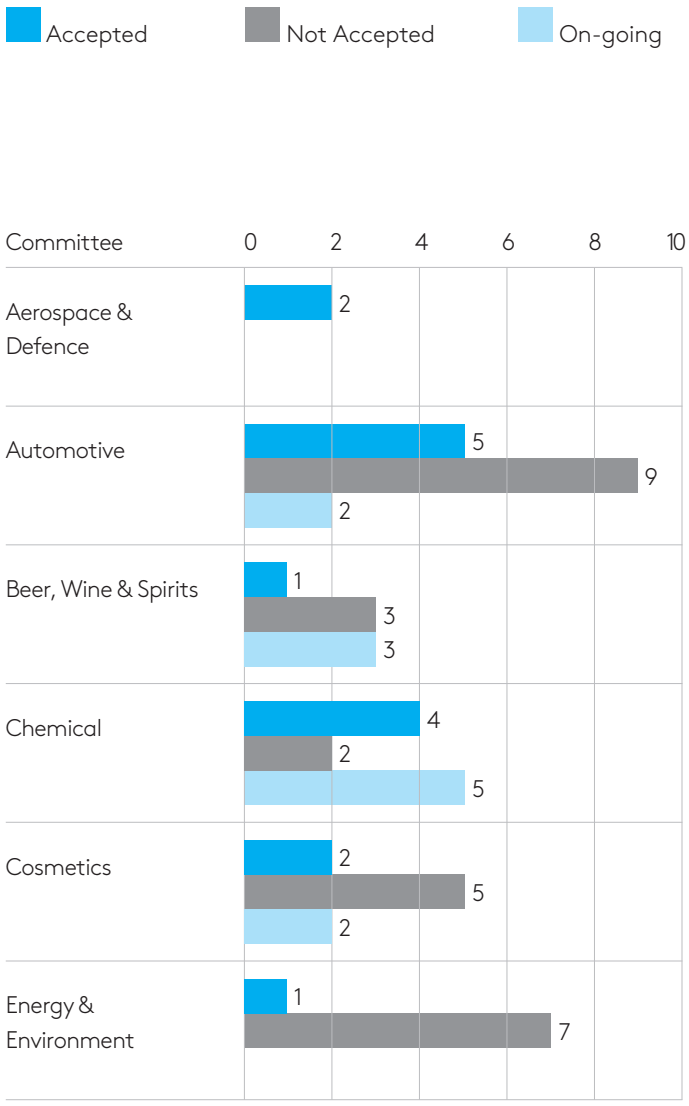
Issue Description
Details the present-day situation and how it affects the industry.

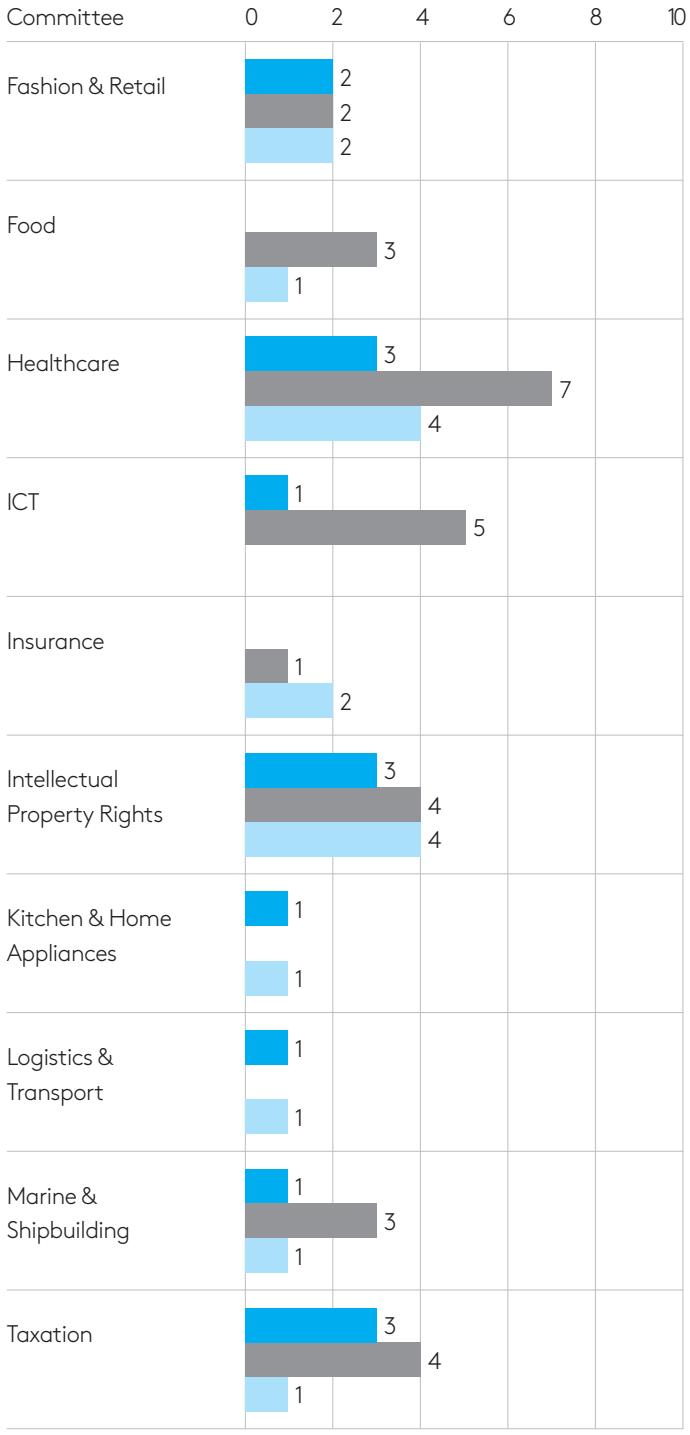
2022 Recommendation
Presents specific actions that could improve the situation for all parties.

Related Laws/Authorities
Recommendation Status
Indicates a recommendation has been either 'Retained' or 'Updated' from last year's white paper, or it is a 'New' recommendation for 2022.

2021 Review

In 2021, the ECCK committees across 16 different sectors have raised 114 key industry issues and suggestions to the Korean government. The government's feedback per each committee are listed in summary as below.





This section outlines the details of the 2021 issues and recommendation with the government's feedback and ECCK's future actions as below.

Government Feedback
- Accepted
- Partially Accepted
- Not Accepted
- On-going

ECCK Future Action
- Closed (Success)
- Closed (Drop)
- Need to Monitor
- Readdress

	Issue	Government Feedback	ECCK Future Action
Aerospace & Defence	1. Extension of Period of Offset Implementation		
	2. Offset Performance Bond		
Automotive	1. Improvement of Scope of Recalls - Corrective Actions on Unsold Vehicles		
	2. Establishment of the Specific Cases Which are Excluded from the Calculation of Total Repair Period		
	3. Introduction of Application Fees for the Motor Vehicles Exchange/Refund Arbitration		
	4. Clarification on the Definition of Serious Defects and General Defects		
	5. Revision of Scope of Data Submitted by Motor Vehicle Manufacturers		
	6. Application of Flexibility on Vehicle Width Standards		
	7. Approval on Vehicles with New Technologies or Features		
	8. HS Code of Semitrailer-Towing Tractors		
	9. Stipulation of the Modification Report in Law		
	10. Adoption of Super Credit System to the Fleet Average System for Hydrogen and Electric Vehicles		
	11. Clarification and Harmonisation with the International Standard on the Calculation Method of Greenhouse Gas Emission of Medium-to-large Commercial Vehicles		
	12. Timing Improvement of Announcement for the Subsidy Support Standards of Electric Vehicles		
	13. Ensuring the Preparation Period to Achieve the Low/Zero Emission Vehicles Supply Target		
	14. Reduction of Time Required to Register Environmentally Friendly Vehicle		
	15. Examination of the Designating of the Used Vehicle Sale Business and Small Volume Automobile Repair Business as Businesses Suitable for Livelihood		
	16. Clarification Needed to Enhance Motor Vehicle Certification Process		
Beer, Wine & Spirits	1. Allowing Smart-Order for Gift Purpose		
	2. Plan to Expand Liquor Type Subject to Specific Duties		
	3. Reconsidering Alcohol Level Restriction on Broadcast Advertisements		
	4. Allowing Promotions and Discounts via Online Giveaway		

	Issue	Government Feedback	ECCK Future Action
	5. Reconsidering Applying Different Unit Prices for Packaging Material Recycling Contribution for Products Exempt from Recycling Grade Indication	⊗	⊗
	6. Reinforce of Consumer Safety Management and Strengthen of Responsibility for Parallel Imported Foods	✓	✓
	7. Allowing Full E-Commerce of Alcoholic Beverages	↻	↻
Chemical	1. Fulfillment of Obligation to Notify Technical Barrier to Trade (TBT) Pursuant to WTO Agreement	✓	✓
	2. Confirmation of Chemical Substance Information Communicative Organization Members when Lead Registrant Submits Joint Dossier According to K-REACH	✓	✓
	3. Ease off Permission Procedures when Changing Mosquito Repellent's Scent	⊗	⊗
	4. Exemption for Surface Treated Substance from Hazards·Dangers Investigation Report	↻	↻
	5. Liable Person for Material Safety Data Sheet (MSDS) Obligations on Chemical Products of Consignment Manufacturing (OEM, ODM)	↻	↻
	6. MSDS Number Interlocking on IT System: MSDS Obligations for Products Contained Confidential Raw Materials	✓	✓
	7. Grace Period of MSDS Submission	✓	✓
	8. Exclusion for Small Quantity R&D Sample from MSDS Trade Secret Approval	↻	↻

	Issue	Government Feedback	ECCK Future Action
	9. MSDS Trade Secret Approval: Acceptance of Classification based on Scientific Evidence	✓	✓
	10. Phase-Out Period During Approval of Biocidal Product	✓	✓
	11. Excessive Regulation of Household Disinfectant Product Managed by K-BPR	⊗	⊗
Cosmetics	1. Development of Various Eco-friendly Packaging and Recycling Industry	⊗	✓
	2. Provision of Sufficient Grace Period and Reasonable Introduction of Amendments to Packaging- Related Laws and Regulations	⊗	↻
	3. Introduction of an Integrated Operating System on the Effective Date when Labeling is Changed Due to the Revision of Packaging Related Laws	✓	✓
	4. Timing of Evaluation of Packaging Material and Structure	⊗	⊗
	5. Relaxation of Standard for the Quality·Structure and Recyclability of Packing Materials	⊗	⊗
	6. Harmonised Interpretation for Packaging Method Standard	⊗	↻
	7. Measurement Method for Packaging Space Ratio and Number of Times Packaged for Set Products Including a Pouch, etc.	⊗	↻
	8. Request to Exclude from the Packaging Material and Structure Evaluation If Sticker Label, etc. are Applied to Display Indication Requirements in Accordance with the Laws of the Exporting Country	↻	✓
	9. Application of Optional Indication for Cosmetic Manufacturer	↻	✓

	Issue	Government Feedback	ECCK Future Action
Energy & Environment	1. Direct Contract of Natural Gas Purchasing for Raw Material between KOGAS and Industrial Gas·Chemical Companies		
	2. Domestic Recognition of EPD in Accordance with ISO 14025		
	3. Aligning with IEC Standard on Offshore Wind Turbine Generator (WTG) Certification		
	4. Improvement on Long-term Fixed-Price PPA (Power Purchase Agreement) Process for On·Off Shores Wind Power		
	5. Improvement on Weighting REC (Renewable Energy Certificate) for Direct PPA		
	6. Limitation for Development Premium and Civil Complaints		
	7. Clean Energy Production through Fuel Flexibility and Enhanced Efficiency		
	8. Ease in Regulations Regarding Licenses for Radioisotopes Handling (RI License)		
Fashion & Retail	1. Labelling of Consumer Products		
	2. Price Labelling Requirement		
	3. Packaging Recyclability Labelling and Separate Discharge Mark		
	4. Safety Testing Standard for Infant Textile Products		
	5. Safety Control of Imported Food Containers		
	6. Safety Control of Household Chemical Products		

	Issue	Government Feedback	ECCK Future Action
Food	1. Harmonisation of International Food Standards and Specifications – 'Natural' Labelling		
	2. Improvement for Equity in Administrative Measures against Domestic Food Manufacturers, Processors and Importers, Sellers of Imported Food		
	3. Improvement of Labelling of Natural and Synthetic Flavors		
	4. Ease of the Non-GMO Labelling Standards		
Healthcare	1. Renovate Drug Reimbursement Listing Process and Price Management System for Better Patients Access to Innovative Pharmaceuticals		
	2. Fairness and Global Harmonisation Improvement for Risk Sharing Agreement (RSA) Re-Reevaluation		
	3. Fair Certification Standards for Selection of Innovative Pharmaceutical Companies		
	4. Consideration of Different Policy Approaches to the Introduction of Innovative Cell and Gene Treatments		
	5. Enhancing Access to Drugs for Rare and Incurable Cancer Patients		
	6. Enhancing Transparency and Clear Role Sharing for National Health Insurance Committee Decisions		
	7. Creating a Mutual Recognition Agreement (MRA) with EU		

	Issue	Government Feedback	ECCK Future Action
	8. Transparent Data Sharing – NIP Big Data Utilisation in Vaccine	⊗	↻
	9. Standardisation of New Vaccine Listing Process for NIP	⊗	↻
	10. Recognition of Proper Value of Vaccines with Differentiated Pricing for Sustainable Access of Innovation for Public Health	✓	↻
	11. Improving Inoculation Fee System	⊗	↻
	12. Improve Vaccine Risk Level Classification Evaluation Standards	⊗	↻
	13. Improvement of Reagent Related Customs Clearance	⊗	↻
	14. Approval of Before and After Pictures Related to Fillers (Injectables) Usage	⊗	↻
ICT	1. Network Requirement for Cloud Computing Service Provider in Financial Service Industry	⊗	∿
	2. System and Template Structure for Government ISP (Information Strategic Planning) Project Planning, Development, and Submission	⊗	⊗
	3. Cloud Security Assurance Program (CSAP)	⊗	∿
	4. E-government Standard Framework Preferred Application Agencies	⊗	∿
	5. Application of Foreign Vendor Standard Contract by Public Agencies	⊗	∿
	6. Technology Neutrality in Mobile Communication Frequencies	✓	⊗

	Issue	Government Feedback	ECCK Future Action
Insurance	1. Release of Standardised Repair Cost and Hours of Imported Cars	◔	∿
	2. Exemption Against Accidents while Driving Under the Condition of Drugs, Narcotics, etc.	◔	↻
	3. Mandatory Issuance of Health Insurance Medical Care Benefit Statement by the National Health Insurance Corporation	⊗	∿
Intellectual Property Rights	1. Studies about Economic Impact of IP Infringements in the Digital Environment	◔	↻
	2. Reasonable Sentencing for IP Related Crimes as Effective Deterrents	◔	∿
	3. Strengthening Border Measures against IP Infringing Goods	⊗	↻
	4. Enforcement Against Resellers Infringing IPRs	✓	∿
	5. Annual Report on Seizure of Counterfeit Products at Customs	⊗	↻
	6. Enhancement of Effectiveness of EMS Project	⊗	↻
	7. Designation of Special Judicial Authority to Local Government Officials	⊗	↻
	8. Enforcement Against Lookalike Products	✓	∿
	9. Pro-active Measures by Online Intermediaries on Counterfeit Goods	✓	∿
	10. Stakeholder Cooperation on Online Enforcement	◔	↻
	11. Standard Essential Patents	◔	∿

	Issue	Government Feedback	ECCK Future Action
Kitchen & Home Appliances	1. Converting KC Certificate into Electronic Document and Improving Data Search on Safety Korea		
	2. Adoption of Regular Timeline on Changed Regulation		
Logistics & Transport	1. Direct Shipment Requirement – General		
	2. Direct Shipment via Transit Hubs/Change of Mode of Transportation		
Marine & Shipbuilding	1. Practice of the Lowest Price Bidding System in Domestic Shipyards		
	2. Planned Merger of Hyundai Heavy Industries Holding (HHIH) and Daewoo Shipbuilding & Marine Engineering (DSME)		
	3. The 52-hour workweek system		
	4. Unfair Opportunities to Access R&D Funds and Programs as Foreign Invested Firms in the Maritime Industry		
	5. COVID-19 Management		
Taxation	1. Necessity to Establish Standard For a Substantial Owner of Income Derived by Foreign Corporations Through a Pass-through Entity that is not an Overseas Investment Vehicle (OIV)		
	2. Improving the Convenience and Administrative Efficiency of Individual Income Tax Return Filing and Tax Payment Procedures for Non-resident Partners for Foreign Law Firms		
	3. Deductions for Overseas Education Fees		

	Issue	Government Feedback	ECCK Future Action
	4. Public Notice of a List of Foreign Corporations by Category		
	5. Facilitation of the Pre-filing Process for Advance Pricing Agreements		
	6. Tax Exemption on Qualified Housing Benefit for Foreign Employees		
	7. Duty Exemption on Foreign Goods Stored in a Bonded Area Destroyed or Lost Due to Fire		
	8. Duty Reduction on Foreign Goods Returned From a Duty-free Shop		

ECCK Committee Reports

Changhoon Rim
Senior Manager,
Aerospace &
Defence
Committee

Aerospace & Defence

1
Total Key Issue

1.
Improvement of
Offset Policy

Issue

The DAPA has continuously modified the offset policy. There are several points that need to be improved urgently in the current scheme. The key issues are as follows:

- In case the rules for the offset are changed, the new rules will be applied to the amendment of the main contract. This could drastically change the initial business plan of the contract.
- There are cases that create the distortion of the principle of competition. Some Korean defence markets are open to both private and public bidders. For these markets, some foreign states are exempt from any offset obligation under the foreign sales policies in which the foreign state takes responsibility for the sales of equipment.
- It is necessary to increase the flexibility of eligibility criteria. For projects which aim to transfer technologies or include manufacturing, Korean large companies should not be excluded from the eligible list for offset, especially when these companies sub-contract to Korean SMEs.
- It is necessary to increase the transparency of the eligibility criteria and the valuation process. Particularly for the valuation process, it is recommended to consider the cost of progressed technologies and add values for repeated orders on the same product.
- It is recommended to enlarge the 'banking' system and make it more flexible. The banking system should allow the acquisition of credits in a certain contract and use them for following contracts.
- It is necessary to re-introduce a capping system for the penalty amount on late payments.

Recommendation

It is recommended to avoid any negative impact on the business plan of the company from amending the offset guidelines, and to enhance the principle of fair competition in the offset program. It is also recommended to increase transparency in the eligibility criteria and valuation process and adopt the 'banking' system in the offset program. Last of all, it is recommended to re-introduce a capping system on the penalty amount for late payment.

Relevant Act/Regulation	Offset Program Guidelines
Responsible Authority & Division	Defence Acquisition Program Administration (DAPA)
Recommendation Status	New

Changhoon Rim
Senior Manager,
Automotive
Committees

Automotive

19
Total Key Issues

1. Improvement of the Application Standard on the Rule of 'Correction of Defects Before Sales' for Incomplete Vehicles

Issue

It is recommended to improve the relevant standard on applying the rule of 'correction of defects before sales' for incomplete vehicles since sometimes incomplete vehicles manufacturers are regarded to have sold defective vehicles without correction due to the specificity of the sales process of the incomplete vehicles (it is sold to the bodybuilder in first, and then sold to the end customer).

According to Article 31-4 of the Motor Vehicle Management Act, motor vehicle manufacturers should sell the vehicles after making corrective measures for defective vehicles. However, in the case of 'incomplete vehicle', the definition of 'sales' is differently applied, so there are cases that the manufacturer deemed not to implement the Article 31-4 and was imposed to pay the fine. For example, if a manufacturer recognises a defect after selling an incomplete vehicle to a bodybuilder and the bodybuilder sells the vehicle to the end customer, the manufacturer may be deemed to have sold the vehicles without correction.

Recommendation

It is recommended to authorise the manufacturer to block the sales of the defective vehicle from the bodybuilder if the purpose of the regulation is to correct defects prior to sale (only for a vehicle that has not been registered as a complete motor vehicle). As another option, it is recommended to exclude incomplete vehicles of which the ownership has been transferred to the bodybuilder from the subject of the rule of 'Correction of Defects before Sales'.

Relevant Act/Regulation	Article 31-4, Motor Vehicle Management Act
Responsible Authority & Division	Ministry of Land, Infrastructure and Transport (MOLIT)
Recommendation Status	New

2.
Modification of the Deadline for Submission of Data Submitted by Motor Vehicle Manufacturers

Issue

Regarding the data submitted by motor vehicle manufacturers to the Ministry of Land, Infrastructure and Transport (MOLIT) on a monthly basis, it is recommended to improve the deadline for submission, because there are some cases in which motor vehicles manufacturers are having difficulties to meet the submission deadline realistically.

According to Article 33 of the Motor Vehicle Management Act, motor vehicle manufacturers are submitting details of gratuitous inspections and repairs to the MOLIT on a monthly basis. According to Paragraph 2, Article 52 of the Enforcement Rule of the same Act, data must be submitted "within 10 days from the end of the month in which the repair was implemented", however there are some cases where it may be challenging to meet this deadline. For example, in the case that the repair was started on an end of the month Friday, it may be difficult to submit the data within 10 days next month considering the time spent on the repair. Moreover, in case the external service provider conducts repair, the manufacturer is not able to submit the data unless the manufacturer receives the relevant data from the service provider. If the data is not submitted within the deadline for these reasons, the MOLIT can regard it as a "delayed report" and judge that the data was intentionally omitted or concealed.

Recommendation

Considering that the purpose of the regulation for the government is to respond to flaws and defects in advance by expanding the scope of the submission, it is recommended to provide sufficient time for manufacturers to prepare and submit the data. Therefore, it is recommended to add the provision in the regulation on the deadline (within 10 days from the end of the month in which the repair was completed) that 'in case the service provider conducts the repair, within 10 days from the end of the month in which the manufacturer received the information on the repair from the service provider'.

Relevant Act/Regulation	Article 33, Motor Vehicle Management Act
Responsible Authority & Division	Ministry of Land, Infrastructure and Transport (MOLIT)
Recommendation Status	New

3.
Introduction of a Fast Arbitration Review Procedure in the Automobile Replacement and Refund System

Issue

Regarding the system of motor vehicle replacement and refund, in which the owner of the motor vehicle can request the replacement/refund to the manufacturer, it is recommended to introduce a separate procedure in which the requirement for replacement/refund can be promptly judged.

In the current arbitration review procedures, there are several arbitration review procedures on the merits including the review of written answers, opinion hearings, submission of additional evidence documents, and vehicle inspections regardless of the type of flaws claimed by the applicant. However, in the case of emotional quality such as noise, vibration and smell, it can be determined promptly whether the vehicle can be the subject of replacement or refund only by an expert's vehicle inspection.

As a lot of effort is spent several times on the arbitration review and submission of evidence documents even for cases which can be determined promptly whether the vehicle can be the subject of replacement or refund, it is recommended to operate the different arbitration review procedures depending on types of flaws claimed.

For reference, the Korea Commercial Arbitration Board is operating a fast arbitration procedure in which the case is determined by document review or oral hearing for the application of which amount is not exceeding KRW 100 million (not exceeding KRW 500 million for international arbitration).

Recommendation

It is recommended to introduce a fast arbitration procedure in which the technical expert conducts the vehicle inspection after the oral hearing for arbitrations related to emotional quality such as noise, vibration, and smell.

Relevant Act/Regulation	Regulation of Automobile Replacement and Refund Arbitration
Responsible Authority & Division	Ministry of Land, Infrastructure and Transport (MOLIT)
Recommendation Status	New

4.
Application of Flexibility on Vehicle Width Standards

Issue

It is recommended to improve the vehicle width standards in Korea since there is the difference of the standard between Korea and Europe.

Article 4 of the current "Rules on Performance and Standards Motor Vehicles and Parts" stipulates that the width of a motor vehicle cannot exceed 2.5m. As the vehicle width standard in Europe is set at 2.55m, buses and some trucks built on a 2.55m width standard can not be introduced in the Korean market.

The motor vehicle width standard needs to be examined in connection with the road width standards. Current domestic road width standards are defined from 3m to 3.5m, providing flexibility on the width standard depending on the operation conditions. Given this, it seems technically feasible to give additional flexibility of 0.05m to the current vehicle width standard of 2.5m, permitting a 2.55m standard, equivalent to that of Europe. In particular, the flexibility for expanding the distribution of environment-friendly vehicles, such as electric trucks, can be considered in accordance with the recent policy for the distribution of environment-friendly vehicles for the improvement of air quality. In this regard, it is recommended to review whether the 2.55m width standard is acceptable for vehicle categories such as freight/special motor vehicles, double-decker buses, environment-friendly vehicles, etc.

In addition, there are differences with the standard in the EU in items which are excluded from measuring the vehicle width. For example, air spoiler part can be excluded from the width measurement in the EU, however it cannot be excluded in Korea.

Recommendation

It is recommended to permit a 2.55m width standard for categories such as trucks/special motor vehicles, double-decker buses, environment-friendly vehicles, etc. In addition, it is recommended to harmonise the standard of items excluded from the vehicle width measurement with Europe.

Relevant Act/Regulation	Article 4, Rules on the Performance and Standards of Motor Vehicles and Parts
Responsible Authority & Division	Ministry of Land, Infrastructure and Transport (MOLIT)
Recommendation Status	Retained

5.
Enhancement of Practicality of Recognition on International Standards

Issue

It is necessary to improve the relevant systems which recognise the international standards in Korea in order to operate it more practically.

Korea, as a member of the WP29 1958 agreement, has actively carried out the harmonisation of domestic motor vehicle safety standards with international standards such as UNECE. However, it takes a relatively long time to revise domestic safety standards because it requires necessary administrative procedures (draft preparation, pre-announcement, solicitation of public comments, etc.).

In the Korean regulation, there is one table that could solve the difficulties of those differences between international standards and domestic standards [Table 4, Enforcement Regulations on the Performance and Standards of Motor Vehicles and Parts (hereafter 'Table 4')]. For safety standards included in this table, the test report of the relevant UNECE standards can substitute for the test report of the corresponding domestic safety standard. However, the items in 'Table 4' are not updated in a timely manner following the update of domestic safety standards.

Cf.) For European manufacturers, international standards can be recognised in Korea according to the relevant provisions in the Free Trade Agreement (FTA). However, in case the vehicle cannot be recognised as product from European origin, then the relevant provision of recognition of international standards as defined in the FTA cannot be applied to the product.

For example, for the rear visibility safety standards, the vehicle that complies with the international standard (UNECE R-46) could be recognised to satisfy the corresponding domestic standards. However, the Korean safety standards were amended in 2017, and the recognition of international standards through 'Table 4' is not effective anymore. Currently, the Korean safety standard for the rear visibility is not harmonised with the latest international standard (UNECE R-46). Hence, the European automobile manufacturers have to develop separate products complying with Korean safety standards.

Recommendation

It is recommended to harmonise the domestic safety standards with international standards in a timely manner in consideration of their implementation dates in Europe. This would help European manufacturers not to develop separate products for the Korean market alone.

Also, it is recommended to update 'Table 4' periodically so that international standards can be recognised in Korea even before domestic safety standards are not yet harmonised with international standards.

Relevant Act/Regulation	Rules and Enforcement Regulations on the Performance and Standards of Motor Vehicles and Parts
Responsible Authority & Division	Ministry of Land, Infrastructure and Transport (MOLIT)
Recommendation Status	New

6. Revision of HS Code of Semitrailer-Towing Tractors

Issue

The semitrailer-towing tractor is excluded from the subjects of Annex 2-C, of the EU-Korea FTA.

During the EU-Korea FTA negotiations, the HS Code of semitrailer-towing tractors was incorrectly stated in the Annex 2-C-1 of the EU-Korea FTA. This resulted in the exclusion of semitrailer-towing tractors from the subjects of Annex 2-C (Motor Vehicles and Parts) of the EU-Korea FTA and the exclusion of semitrailer-towing tractor from the subject of technical standard equivalence stipulated in Annex 2-C.

For example, the safety standard of seat belt anchorage, the standard is included as an item for safety standard equivalence recognition according to Annex 2-C of the EU-Korea FTA. Due to the exclusion from the scope of the annex, it has not been applied as the subject of the provision in the Annex 2-C of the EU-Korea FTA although it can be recognised as satisfying the Korean safety standards if the vehicle satisfies the relevant UNECE standards.

This leads to additional cost for the EU automobile manufacturers as they have to develop separate vehicles that meet the Korean safety standards. Furthermore, it restricts them to export vehicles with more diverse specifications to Korea. Due to this factor, it seems that the EU automobile manufacturers and Korean customers are not fully benefiting from the FTA.

Recommendation

It is recommended to revise the related articles of the EU-Korea FTA to allow semitrailer-towing tractors to be included in Annex 2-C (Motor Vehicles and Parts) of the EU-Korea FTA.

Relevant Act/Regulation	Annex 2-C, Appendix 2 to Annex 2-C-1 (Motor Vehicles and Parts) of the EU-Korea FTA
Responsible Authority & Division	Ministry of Land, Infrastructure and Transport (MOLIT)
Recommendation Status	Retained

7. Improvement of the Process of the Modification Reporting

Issue

Regarding the modification reporting system which requires motor vehicle manufacturers to report modifications to the Ministry of Environment for changes which do not affect the environment negatively, it is recommended to improve the relevant procedures because the system is being operated as a de-facto approval system, deviating from the original purpose of this reporting system.

According to Paragraph 3, Article 67 of the Enforcement Rules of the Clean Air Conservation Act, the manufacturer is required to report modifications to the Minister of Environment (President of the National Institute of Environmental Research in case of imported vehicles) if there was a change in certification details, but no increase in the amount of emissions (Modification Report). The purpose of this system is to simplify the existing modification certification system by reporting that the modification has no influence on an increase of emissions based on the manufacturer's technical judgment and data submission.

However, in its practical implementation, the person representing the manufacturer visits the Transportation Pollution Research Center (TPRC) of the National Institute of Environmental Research in person and proceeds with the report only after the review and determination of the TPRC whether it is subject to modification reporting. During this process, it may be requested to submit additional documents according to the individual judgment of the official in charge at the TPRC. As a result, a lot of administrative work has to be done on the

prior review for the modification report, which makes it difficult to proceed with the modification report smoothly.

Recommendation

It is recommended to simplify the administrative procedure of the modification report which is being operated as a de-facto approval system. As one of the measures for simplifying the system, it is recommended to recognise that the manufacturer fulfils its legal responsibility on the modification report once the manufacturer submits the modification report to the authority.

Relevant Act/Regulation	Paragraph 3, Article 67, Enforcement Rules of the Clean Air Conservation Act
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	New

8. Abolition of the Report for the Voluntary Free Repair Which Does Not Affect Emissions

Issue

It is recommended to improve the relevant system since manufacturers are required to report and receive the approval from the authority even on the voluntary free repairs that are only intended for performance improvement.

The Transportation Pollution Research Center (TPRC) of the National Institute of Environmental Research requests manufacturers to report and receive the approval on the voluntary free repair (so-called 'campaign') that does not affect the emissions. During this process, sometimes it happens that manufacturers are requested to submit detailed and excessive data beyond the scope of the repair depending on individual judgement of the official in charge. Also, it may take an excessively long time to review and receive the approval.

Recommendation

It is recommended to exclude the voluntary free repair (so-called 'campaign') from the subject of the report to the TPRC since its legal ground is unclear. If it is necessary to report those repair cases, it is recommended to close the procedure once the manufacturer submits the report and the TPRC confirms the submission itself.

Relevant Act/Regulation	Clean Air Conservation Act, etc.
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	New

9. Providing Flexibilities to Fleet Average System (FAS)

Issue

The Ministry of Environment regulates the average emission volume per unit of motor vehicles through the Fleet Average Systems (FAS) in the Clean Air Conversation Act. It is recommended to introduce flexibility that helps manufacturers achieve the target in this system.

The Fleet Average System calculates the average value of emitted gas of vehicles sold each year by vehicle types and ensures that the value complies with the established emission standards. Even though many automobile manufacturers are endeavouring to increase the volume of eco-friendly vehicle sales, it is still very difficult to comply with the stringent emission criteria. In this regard, it is necessary to introduce flexibility which would help sustaining the existing business with the spread of environment-friendly vehicles.

As a measure of the flexibility, it is suggested for the ME to allow emission credit trading system under FAS among automobile manufacturers. The emission credit trading system can contribute to sustaining business and utilizing it as a key means to compensate for automobile manufacturers' efforts in distributing more low-emission vehicles in the market.

For reference, the corporate average CO2 regulation under the Clean Air Conservation Act allows CO2 credit trading, and total emission management of business sites under the 'Special Act on the Improvement of Air Quality in Air Control Zones' also allows the emission credit trading.

Recommendation

It is recommended to adopt an emission credit trading system for FAS, which enables the emission credit trading among automobile manufacturers to achieve the target.

Relevant Act/Regulation	Article 50-2 (Average Emission Quantities of Motor Vehicles, etc.), Clean Air Conservation Act, [Table 19-2] Permissible Emission Levels, etc, Enforcement Rules of Clean Air Conservation Act
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	New

10.
Clarification on the Cold CO Test Requirement for Plug-In Hybrid Electric Vehicles

Issue

It is recommended to clarify the test requirement for Plug-In Hybrid Electric Vehicles (PHEV) since the test requirement of the Cold CO test for PHEV is not clearly defined.

Article 3 of the 'Regulations for Test Procedure of Manufactured Motor Vehicles (ME Notification)', stipulates the emission measurement for hybrid and electric vehicles should follow the method defined in 'Table 5' of the notification. However, a specific method for a Cold CO measurement is missing in 'Table 5'. Therefore, it is unclear which method the manufacturer should follow for a Cold CO measurement for PHEV.

'Table 3' of the notification stipulates the measurement method of the Cold CO test; however, the subject of vehicles in this table is defined as gasoline-powered vehicles. Therefore, it is unclear whether the method can be applied to PHEV.

The Transportation Pollution Research Center of the National Institute of Environmental Research shared its plan to revise the ME Notification adding 'gasoline electric hybrid vehicles' in the scope of 'Table 3' at the round table meeting with manufacturers. However, the ME Notification has not been amended yet (as of June 2022).

Recommendation

It is recommended to add PHEV in the subject vehicles of 'Table 3' of 'Regulations for Test Procedure of Manufactured Motor Vehicles' to clarify the Cold CO test requirements for PHEV.

Relevant Act/Regulation	Regulations for Test Procedure of Manufactured Motor Vehicles
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	New

11
Improvement of Formula for the Measurement of Evaporative Emissions

Issue

It is necessary to improve the formula for the measurement of evaporative emissions according to international standards.

When measuring the evaporative emissions, a fixed volume enclosure or a variable volume enclosure can be used for the test. However, in the regulation in Korea [E-(9), Table 1, Regulations for Test Procedure of Manufactured Motor Vehicles], there is the hydrocarbon (HC) calculation formula only for fixed volume enclosure which is different from the variable volume enclosure formula.

For reference, there is a simplified formula to calculate the HC mass for variable volume enclosures. This formula is part of the US Regulations (40 CFR 86) as well as the UNECE regulation (UNECE R 83-07).

Recommendation

It is recommended to add a variable volume enclosure formula to calculate the evaporative emission (HC) according to the relevant international standards (UNECE R 83-07, Annex 7, Article 6.1.2).

Relevant Act/Regulation	Regulations for Test Procedure of Manufactured Motor Vehicles
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	New

12.
Clarification of Certification Procedures for Electric Vehicles

Issue

It is recommended to enhance the certification procedure for electric vehicles since some procedures are not clearly defined in the regulation.

For electric vehicles, the details of the current certification procedure are not clearly defined in the laws, lower statutes, and notifications. Manufacturers are requested to submit the necessary data for the certification by the relevant authority, but the legal ground and judgment standards for the data are unclear. Manufacturers are often required to supplement the data several times with unclear grounds, which leads to difficulties such as delaying the overall certification procedure.

Recommendation

It is recommended to improve the relevant system on the certification procedures for electric vehicles. It is recommended to specifically define the list of items to be submitted in order to reduce delays in certifications caused by repeated requests for additional supplementary documents.

Relevant Act/Regulation	Clean Air Conservation Act, Regulations of Certification, Inspection Methods, and Procedure, etc. for Manufactured Motor Vehicles
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	New

13. Harmonisation of Test Procedure Requirements for Plug-In Hybrid Electric Vehicles and Electric Vehicles

Issue

It is recommended to harmonise the test procedure requirement for plug-in hybrid electric vehicles (PHEV) and electric vehicles since the similar test procedures are described differently in two regulations.

The test procedures for PHEV are stipulated in 'Regulations for Test Procedure of Manufactured Motor Vehicles', the notification of the Ministry of Environment and 'Regulation for Test procedures for Energy Efficiency, Greenhouse Gas Emission and Fuel Economy for Motor Vehicles', the joint notification of the Ministry of Environment (ME), the Ministry of Trade, Industry, and Energy (MOTIE) and the Ministry of Land, Infrastructure and Transport (MOLIT). However, there are differences between two notifications in similar test procedures. For example, there are differences in overnight charging procedure, current/voltage measurement using onboard data, and determination of DC recharge energy. These differences create complexity in operational work and potential risk of misunderstanding the test standards.

European regulation describes emission and fuel/energy consumption test requirements in one regulation (EU 2017/1151). The US test procedures requirements are linked to SAE standards which also stipulate emission and fuel /energy consumption requirements in one document (e.g. SAE J1711).

Recommendation

It is recommended to harmonise the similar test requirements in the test procedure for PHEV and EV among the ME, MOLIT, and MOTIE. In addition, it is recommended to accept international regulations (e.g. UNECE R-154) and consider overseas regulations (e.g. SAE J1634/ SAE J1711).

Relevant Act/Regulation	Regulations for Test Procedure of Manufactured Motor Vehicles, Notification of Test Procedures for Energy Efficiency, Greenhouse Gas Emission and Fuel Economy for Motor Vehicles
Responsible Authority & Division	Ministry of Environment (ME), Ministry of Trade, Industry and Energy (MOTIE), Ministry of Land, Infrastructure and Transport (MOLIT)
Recommendation Status	New

14. Requirements on All Electric Range Test at Cold Temperature for Electric Vehicles

Issue

It is necessary to improve the heater setting requirement applied during the driving mileage test for electric vehicles to reflect the actual driving environment.

According to 'Table 5-2' of the 'Regulations for Test Procedure of Manufactured Motor Vehicles', the heater setting requirement for an all-electric range test at the cold temperature (-6.7°C) is regulated to be 'heater operated at maximum'. The test takes several hours and the temperature inside the vehicle during the test could be very high above 40°C under the 'maximum' heater setting condition. This can cause difficulties for the operator during the certification tests and at the same time does not reflect a realistic driving situation.

For reference, in the US, the climate control setting should be on "Auto setting" with 72°F (= 22°C) (40 CFR Part 1066, Subpart H). It is also stipulated in 'Auto setting' in China with 22°C (GB/T 18386). In both cases, it reflects the realistic driving situation.

Recommendation

It is recommended to change the heater setting condition during all-electric range test at cold temperature (-6.7°C) from "Maximum Setting" to "Auto Setting" of 22°C.

Relevant Act/Regulation	Regulations for Test Procedure of Manufactured Motor Vehicles
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	New

15.
Request for the Issuance of Performance Certificate of Average Energy Consumption Efficiency of Motor Vehicles

Issue

Since the certificate of the manufacturer's performance result has not yet been issued, it is recommended to follow up on necessary actions regarding the 'Average Energy Consumption Efficiency System' in which automobile manufacturers have to achieve the standard of average energy consumption efficiency for automobiles sold by manufacturers.

In 2021, the Ministry of Environment and the Transportation Pollution Research Center (TPRC) shared the performance result from 2016 to 2020 (without eco-innovation data) with each manufacturer through press releases. However, the official performance certificate for this result has not yet been distributed (as of June 2022) [Performance settlement is not yet completed as well in Korea Emission & Noise Certification Information System (KENCIS)].

Recommendation

It is recommended to issue the performance certificate for average energy consumption efficiency as soon as possible so that each manufacturer can officially check the achievement result on average energy consumption efficiency (over/underachieved).

Relevant Act/Regulation	Notification of the Standards for Average Energy Efficiency/Permissible Levels of Greenhouse Gas Emission for Motor Vehicles and Its Application/Management etc.
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	New

16.
Rationalisation of Standards for Average Greenhouse Gas Emission for Heavy Duty Vehicles

Issue

It is recommended to improve the standards of average greenhouse gas emission for heavy-duty vehicles reasonably from the current standards.

In the current 'Guideline for Application and Management of Standard of Average Energy Consumption Efficiency and Permissible Levels of Greenhouse Gas Emissions for Heavy Duty Vehicles', the voluntary reduction target of average greenhouse gas emission for heavy-duty vehicles manufacturers during the period of 2023-2025 is indicated.

Meanwhile, the current reduction target standard is defined to reduce a certain percentage of the average greenhouse gas emission generated during the reference period (2021-2022), and as a result, different reduction targets are set for each manufacturer. In the current standards, which give individual reduction targets to manufacturers, the manufacturer who had relatively small amounts of greenhouse gas emissions during the reference period may have a disadvantage in achieving the reduction goal compared to the manufacturer who had a relatively large amounts of greenhouse gas emissions. It will be difficult to achieve additional reduction targets for a manufacture who already has applied the advanced technology for low greenhouse gas emissions.

Therefore, it will be reasonable to give the same reduction target to all manufacturers based on the industrial average emissions value during the reference period.

In addition, when calculating the industrial average of greenhouse gas emissions, it is necessary to use the unified and harmonised method with overseas standards for factors that may affect the calculation result of the industrial average. For example, since there are three different methods for calculating the air resistance coefficient, it is necessary to calculate using the constant speed resistance value in the European method. Also, it is necessary to reflect the factors of mileage and payload which are being applied in Europe for the calculation.

Recommendation

For the reduction target of average greenhouse gas emissions for heavy-duty vehicles, it is recommended to calculate the industrial average of greenhouse gas emissions during the reference period and provide the same reduction target based on the industrial average to manufacturers. In addition, it is recommended to apply the method harmonised with overseas (Europe) for factors which could affect the calculation result of the industrial average.

Relevant Act/Regulation	Guideline for Application and Management of Standard of Average Energy Consumption Efficiency and Permissible Levels of Greenhouse Gas Emissions for Heavy Duty Vehicles
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	New

17. Improvement of Reporting Procedure of Energy Consumption Efficiency for Motor Vehicles

Issue

It is recommended to enhance the current system for reporting energy consumption efficiency for motor vehicles since the system is being operated as an approval system even though it should be operated as a reporting system, and accordingly, it can cause a potential delay of customs clearance and subsequently sales of imported automobiles.

The energy consumption efficiency of motor vehicles is regulated to be operated by the manufacturer's reporting. However, in practice, it is rather operated as an approval system in which the relevant agency (Korea Energy Agency: KEA) reviews all details reported and confirms them. The main reason for the delay in the reporting procedure is that the agency requests supplementation (submission of additional data) to manufacturers, but from the manufacturer's point of view, the ground of the request for the supplementation may not be clear. In addition, the review process is sometimes delayed because the period within which the agency shall complete the review is not stipulated in the relevant notification (in some cases, it takes 3 months). There are cases that the vehicle sales schedule is postponed due to the prolonged review period at the agency.

Meanwhile, Paragraph 1, Article 216 (Reporting and Importing of Efficiency Management Machinery, Equipment, or Materials) in the current Integrated Public Announcement stipulates 'the importers of efficiency management machinery equipment or materials shall report the measurement results to the Korea Energy Agency and receive the confirmation letter in accordance with Paragraph 3, Article 15 of the Act and Paragraph 1, Article 9 of the Enforcement Rule of the same Act'. This may be understood as 'customs clearance can be made only after receiving a confirmation letter for the report', and in that case, it defeats the purpose of the reporting system.

Recommendation

Considering that the motor vehicles energy consumption efficiency is regulated in a reporting system, it is recommended to revise the related regulations (Integrated Public Announcement, regulations related to administrative procedure, etc.) so that once the manufacturer submits the report of a vehicle's energy consumption efficiency to the KEA, the manufacturer can proceed the customs clearance for automobiles separately from the review process by the KEA.

Relevant Act/Regulation	Rules on Energy Consumption Efficiency and Grade Indication for Motor Vehicles, Integrated Public Announcement
Responsible Authority & Division	Ministry of Trade, Industry and Energy (MOTIE)
Recommendation Status	New

18. Improvement of Registration Procedures for Environment-Friendly Vehicles

Issue

For the procedures in which automobile manufacturers apply low/zero emission vehicles to be designated as the environment-friendly vehicle by the Ministry of Trade, Industry and Energy (MOTIE), it is recommended to reduce the time taken until the registration as an environment-friendly vehicle.

In order to get tax benefits, etc., for low/zero emission vehicles, the vehicle model should be designated as an environment-friendly vehicle by the MOTIE. To be designated as environment-friendly vehicle, the vehicle model should be registered in the relevant notification (Regulation on the Criteria of Environment-Friendly Motor Vehicles), and it is taking a long time to be registered as an environment-friendly vehicle since the notification needs to be amended. This causes difficulties for manufacturers to release electric vehicles in the market in a timely manner.

There are documents that must be prepared to the MOTIE for registration of the environment-friendly vehicles including emission certificate, energy consumption efficiency test report, and notification of specifications which were submitted to the

Ministry of Environment, the Ministry of Land, Infrastructure and Transport, and the MOTIE. Manufacturers can proceed the registration procedure for the environment-friendly vehicle after submitting all documents. However, since the examination of these documents has already been completed by each government department, reviewing these documents again seems to be the unnecessary administrative procedure. Due to this overlapping process for the document submission and review, manufacturers face administrative burden, and it takes a long time until the registration to the environment-friendly vehicle.

Recommendation

It is recommended to reduce the time taken for the registration as the environment-friendly vehicle so that the manufacturer can distribute the environment-friendly vehicle in a timely manner. It is recommended to abolish the submission/review process for overlapping or unnecessary data and operate the current registration system (registration in the notification) with more flexibility.

Relevant Act/Regulation	Regulation on the Criteria of Environment-Friendly Motor Vehicles
Responsible Authority & Division	Ministry of Trade, Industry and Energy (MOTIE)
Recommendation Status	Retained

19. Integration of Government Authorities Regulating Motor Vehicles

Issue

It is recommended to integrate government authorities that govern regulations concerning motor vehicles since the current management on motor vehicles is operated separately by different ministries.

The regulatory control of motor vehicles is complexly executed by different ministries. The motor vehicle policies and safety standards, emissions and noise, and energy consumption efficiency are respectively managed by the Ministry of Land, Infrastructure and Transport (MOLIT), the Ministry of Environment (ME), and the Ministry of Trade, Industry and Energy (MOTIE) as well as the MOLIT.

As the technologies for zero emission motor vehicles, such as electric and hydrogen vehicles, have developed and those vehicles are increasingly available in the market, the ground for the current distributed management structure has been weakened. For example, in the case of the EV mileage per charge, these 3 ministries regulate and exercise administrative power on their respective grounds. In order to accelerate the development of the related industrial ecosystem of future automobiles, it is necessary to promote the integration of authorities that govern regulations of motor vehicles.

Recommendation

It is recommended to establish a single government agency that is dedicated to governing regulations concerning motor vehicles taking overseas cases into consideration, [e.g. Federal Motor Transport Authority in Germany (KBA)].

Relevant Act/Regulation	Motor Vehicle Management Act, Clean Air Conservation Act, Energy Use Rationalization Act
Responsible Authority & Division	The Office for Government Policy Coordination
Recommendation Status	New

Hyokyung Suh
Director,
Beer, Wine &
Spirits Committee

Beer, Wine & Spirits

3
Total Key Issues

1.
Harmonise Liquor E-Commerce Delivery to Consumers for All Retail License Holders

Issue

E-commerce is a key component of the consumer market in Korea; almost 99.5% of households have internet access via a PC, mobile, or other device.

Key statistics demonstrating potential of the e-commerce market include:

- Domestic online purchases reached $136.5 billion in 2020 up from $116.0 billion in 2019.
- The second most popular products sourced online in 2020 were food & beverages (12.4%).
- Mostly unregulated cross border e-commerce continues to increase because of pricing differentials even after adding-in shipping fees and duties. Cross border e-commerce has reached $3.5 billion in 2020[1]. According to Korean Statistical Information Service(KOSIS), the second most popular foreign sourced products from online retailers by South Koreans in 2020 were food & beverages (24.5%).

In 2020, the NTS announced that, starting from April, consumers would be able to place liquor orders online, using the internet or smart-phone apps, before picking up their orders at retail establishments such as restaurants, supermarkets, and convenience stores. The pilot program was to improve efficiency of store management and increase liquor sales for retailers, while saving waiting and ordering time for consumers. While alcohol sales with food delivery is permitted, this is limited in practice. While the online sale and delivery to consumers of 'Korean traditional alcohol' is allowed without restrictions, the same cannot be said in the case of beer and imported wine and spirits, where delivery direct to consumers remains prohibited.

Whilst originally designed to prevent undesired market behaviour, the continued prohibition on retail alcohol license holders' e-commerce may inhibit the growth and competitiveness of small producers in Korea. Korea has seen a significant growth in the number of small and "craft" producers of beer, wine, and sprits, resulting in independent distillers, soju producers, and breweries with well-established reputations for quality and craftsmanship spreading across the country. An opportunity exists, for Korea to become an innovator in bringing new types of beers, wine, and spirits to the country's discerning consumers, the region, and beyond.

President Yoon is committed to delivering concrete benefits to Korea's consumers, workers, and small businesses. In the alcohol sector, benefits from bringing Korea's system in line with most OECD countries, will include being able to provide more choice, better service, and lower prices to consumers through the establishment of a competitive market, on and offline, as well as fairer opportunities for small businesses and entrepreneurs to compete. Equalising treatment between traditional and modern products, importers, and manufacturers, will help small businesses and new entrants get their products to market faster and reach more consumers. This approach will also deliver best results for government, businesses, and consumers alike in Korea. Doing so will deliver convenience, choice, and cost benefits for Korea's sophisticated and digitally connected consumers.

Recommendation

It is strongly recommended that current practices differentiating between traditional Korean alcohol and other types of alcohol in alcohol e-commerce be amended in favour of a system which supports fair, open, efficient, and transparent e-commerce in Korea.

It is also recommended that lessons learnt from the implementation and operation of the initial Smart Order program be considered, alongside global best practices, for a wider regulatory reform of e-commerce alcohol sales in Korea.

Now is the time to consider changes to the alcohol e-commerce market that will modernise alcohol e-commerce so all retail license holders can deliver direct to consumers, provide flexibility and innovation within a regulatory framework, and recognise changes in industry practices and consumer expectations.

The ECCK commends the Government and NTS on the Smart Order regulatory sandbox[1] for liquor. While Smart Order does not allow delivery of alcoholic beverages direct to consumers, it has delivered important policy and regulatory learnings that could be used to produce an ideal e-commerce framework for all alcohol retail license holders and products. Continued limitations on alcohol e-commerce and differentiation between product categories run contrary to best practices and lead to unintended consequences and sub-optimal outcomes. Therefore, it is recommended that reform should now adopt the following best practice principles and learnings from the Smart Order sandbox:

- Proportionality & equity: regulations should be proportionate to the risk they are trying to mitigate, and should apply consistently to goods according to how they are categorised, e.g. as "alcohol", by producer, by origin, etc.
- Transparency & simplicity: regulations should be clear, simple, predictable, and easy to interpret and apply. They should also be informed by the practices of industry stakeholders, who are required to comply with the regulations.
- Compliance & convenience: regulations should be clear, leaving no room for ambiguity so that compliance is convenient, straight forward, and practical. This will reduce the risk of both accidental non-compliance and intentional malpractice.
- Efficiency & sustainability: the application, monitoring and enforcement of regulations should be efficient and sustainable over the long-term. This should include fit-for-purpose regulatory administration practices and costs for both government and industry.

Relevant Act/Regulation	Liquor Tax Act, Notice of Delegated Orders Concerning Mail Order of Liquor
Responsible Authority & Division	National Tax Service (NTS) (Excise Tax Division)
Recommendation Status	Updated

1. This is a policy initiative that allows live, time-bound testing of innovations under government oversight without actual changing related regulations or laws. https://www.sandbox.go.kr

2. Plan to Develop Alcohol Tax Policy Roadmap Subject to Specific Duties

Economic efficiency, equity, transparency, compliance, and enforceability are the general principles that guide taxation policy. In addition to this, alcohol taxation requires balancing various policy objectives, including the need to raise revenue, encouraging responsible drinking choices, and easing administration.

To meet these principles and balance these objectives, the Government introduced a new standard liquor taxation system that shifted from ad valorem duty to specific duty for beers and takju (traditional rice-based alcoholic drinks) in 2020. After the introduction of the new taxation system, beer and takju manufacturers have become more competitive with their products and consumers are benefiting from a wider variety of premium products.

As the market has changed rapidly due to COVID-19, consumer demand for premium products has increased nationwide. Demands for premium fermented alcoholic drinks like wine, cheongju (rice wine), and yakju (herbal wine) are especially prominent. Following this market trend, the need to level the playing field for similar liquor categories is increasing from the perspective of manufacturers and importers.

Expanding the standard liquor taxation system will generate not only an increased competitiveness of the liquor industry, but will also directly benefit the Korean economy, such as by upscaling the labour force (i.e. mixologists, sommeliers and consultants), whilst delivering strong indirect benefits as a result of a higher demand placed on linked businesses in areas such as warehousing and logistics, education, and tourism.

Recommendation

Following the MOEF statement in 2020 that they 'will consider applying this system to other types of liquor after collecting sufficient opinions', the ECCK would appreciate the opportunity to listen to the NTS's next plan for the development of a sensible tax policy roadmap that acknowledges the practical dynamics of Korea's beverage alcohol market while ensuring a more simple and efficient system.

Relevant Act/Regulation	Liquor Tax Act
Responsible Authority & Division	Ministry of Economy and Finance (MOEF)
Recommendation Status	Updated

3. Implementing QR Code Labelling (E-Labels)

In Korea, alcohol labelling continues to be governed by a complex set of often overlapping and conflicting regulations administered by a large number of government agencies spanning 8 ministries, agencies, and departments that include MOTIE, MFDS, FTC, KCS, MOHW, NTS, ME, MOGEF. All of these agencies exercise jurisdiction on alcohol labelling.

Laudably, the relevant Government departments had agreed to unify governance and develop a reform plan to simplify alcohol labelling administration in Korea. Unfortunately, progress on this reform has been stalled. A reformed labelling regulatory framework would provide an opportunity to Korea to respond to consumers' increased transparency expectations while harmonising communication and the ECCK supports such an adoption of new mandatory labelling rules.

The European Union endorsed the alcohol sector's self-regulatory approach to respond to consumers' needs regarding the provision of energy information (on-label) and the list of ingredients (on-line), without losing sight of sector-specific aspects and the existing legal framework. New rules specifically applicable to wine were adopted by the EU in the fourth quarter of 2021, and, by November 2023, all wines will have to communicate a list of ingredients and full nutrition declaration on-label or online. The U-LABEL platform developed as a response is an online tool created to support wine and spirits companies in providing EU consumers with relevant, accurate and detailed information about their products by means of an e-label, accessible to consumers through a QR-code printed on the back-label of the bottle.

Consumers worldwide including Korea have gained familiarity with machine-readable codes, especially QR codes, over the COVID-19 pandemic. A rise in consumer, business, and government awareness could be a powerful catalyst for e-labelling reforms in Korea. Korea's Ministry of Environment (ME) has recently invited biocide manufacturers and importers to volunteer for a "QR code on products" pilot scheme. The ministry plans to expand a voluntary QR code labelling system to all 39 types of consumer chemical product, subject to safety verification, from next year. The ME pointed out that QR codes will provide rapid, accurate public access to product information and prevent any misuse or overuse of such products. As more countries consider allowing e-labels for regulatory purposes, Korea's regulators and policymakers should collaborate to develop standards and practices for e-labelling across categories.

Recommendation

It is recommended that a unified framework be developed that authorises alcoholic beverages to communicate mandatory information via e-labels in Korea. The aim should be to develop regulations that allow any wine or spirit company, small or large, to give consumers in Korea relevant, standardised, and detailed product information, such as a list of ingredients, nutritional information, responsible drinking guidelines and information about sustainability via an easy to administer QR e-label.

Relevant Act/Regulation	Act on Labelling and Advertising of Foods
Responsible Authority & Division	Ministry of Food and Drug Safety (MFDS) (Food Policy of Labelling and Advertising Division)
Recommendation Status	New

Taeyang Kim
Manager,
Chemical
Committee

Chemical

5
Total Key Issues

1.
Request for Harmonisation with International Standards

Issue
Laws related to chemical substances, such as the 'Act on the Registration and Evaluation, etc. of Chemical Substances' and 'Act on Consumer Chemical Products and Biocides Safety Control', refer to EU laws such as REACH and BPR. However, there are some contents which have not been harmonised with global regulations. For example, in the case of the Korean REACH, when manufacturing and importing more than 0.1 tpa of a new chemical substance, data on the toxicity and various characteristics of the substance is required for registration.

In the EU, Japan, and China, registration is obligatory only when 1 tpa or more of new chemicals are used, and in the United States, when more than 10 tpa are used. In addition, registration of polymer substances under K-REACH is only implemented in Korea, and a QR code implementation plan for household chemical products (plan to become legal in 2022) is currently being considered only in Korea.

Excessive regulations that do not meet international standards affect the development of the domestic chemical material industry, undermining the export competitiveness of Korean companies and becoming an international trade barrier when considering global chemical material supply chains.

Recommendation
In Europe, REACH aims to protect human health and the environment from chemicals, as well as to strengthen and maintain the competitiveness of the EU's chemical industry. For the health and safety of the public, the first goal of all chemical regulations should be the first goal of the industry as well.

However, Korea's current chemical laws and communication plans related to chemical policy making are leading to unnecessary use of resources, money, and time as domestic regulations are set excessively compared to those of other developed countries, despite enhancing inter-country industrial competitiveness. As such, it is recommended that the communication plan for Korea's chemical laws and policies be harmonised with global regulations.

Relevant Act/Regulation	Act on the Registration and Evaluation, etc. of Chemical Substances, Consumer Chemical Products and Biocides Safety Control Act
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	New

2.
Unpredictable Law Amendments, Short Comment Periods, and Grace Periods

Issue
Currently, chemical and environmental regulations are announced and finalised immediately after a short comment period of about 20 days. It is more of a one-way notification than communication, and the process of discussing opinions is absent.

If the Ministry of Environment announces several establishments/amendments at the same time, it is difficult to gather sufficient opinions due to the tight timing. In the end, this makes companies difficult to continue their business in Korea. Changes to laws related to environmental labelling in particular occur several times a year, and a sufficient grace period is essential for businesses that are obligated to change the raw materials and packaging of products. However, in most cases, the grace period is as short as six months. This is especially problematic when the comment period is short.

Recommendation
It is recommended that legislation be discussed after going through a process of sufficiently collecting opinions and a sufficient review be conducted to assess what changes should be expected for stakeholders who are bound to be affected. Moreover, it is recommended that if it has not been through such a process, it should be considered even at the implementation stage.

Accordingly, in the case of public notices, it is recommended that at least 60 days prior notice of legislation and at least 40 days of administrative notice is given. In addition, if the prior opinion gathering

period is insufficient or absent, and product change is required, a grace period of at least two years is recommended, in consideration of the resources required to update product inventory statuses, change package designs, etc.

Relevant Act/Regulation	Chemical-Related Regulations and Environmental Regulations
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	Updated

3. Request for Importing, Manufacturing, and Selling within the Grace Period for Biocidal Products Containing Approved Active Substances

Issue

Accurate interpretation is required for the grace period for manufacturing, importing, and selling disinfectant products that contain approved active substances but have no plan for biocidal product approval.

These products do not have an approval plan because they do not meet the criteria for excessive effect and efficacy requirements, or because of expensive product approvals cost.

After the approval of existing active substances, the grace period for approval of biocidal products should be done until December 2024. Failure to submit documents for biocidal product approval by December 2023 may result in an immediate ban on the import·manufacture, or sale of the product. This may result in the forced recall of the product being sold.

Recommendation

Currently, companies that have used existing active substances but have no plan for approval of active substance can secure a grace period for manufacturing·importing·selling·storing etc. by 'December 31, 2022 if they submitted a statement of reasons for not submitting approval application data to the ME within December 31, 2021 unlike the original measure to immediately prohibit manufacturing·importing·selling·storing etc. as withdrawing the status of existing active substance.

It is recommended that, as with active substances, manufacturing·importing selling etc. of biocidal products need to be allowed until December 31, 2024 (when originally given the grace period for the biocidal product) if companies that have done business in the market submit a statement of reason for not submitting approval application data (approval not applied).

Moreover, it is recommended that, in the case of products (unlike substances) if 'Reason for non-submission of approval application data (approval not applied)' is not allowed, accurate guidance on when to ban import, manufacture, and sales be given to biocidal product companies as soon as possible, as it takes product makers more than a year to prepare for the recall of products and exhaustion of stock. We hope that as a result of this quick guide there will be no disadvantages for companies that are preparing for recall in advance.

Relevant Act/Regulation	Consumer Chemical Products and Biocides Safety Control Act
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	Updated

4. Improvement of Fragrance Labelling Standards for Household Chemical Products Subject to Safety Verification

Issue

According to the current regulations, if the fragrance is the main ingredient, the representative substance of the perfume could be labelled. However, if the fragrance is categorized as an 'Other substance', all ingredients of the fragrance should be labelled one by one. This conflicts with cases in which it is used it as a main ingredient.

In most cases, fragrances are purchased and used from fragrance manufacturers, and so it is very difficult to receive all substance information as the entire composition of fragrance is considered a trade secret.

In other laws (Quasi-drugs, Cosmetics, Food, Hygiene), fragrance is labelled as fragrance, not by a specific chemical name.

Recommendation

We recommend one of the following solutions:

Option 1) Fragrances for household chemical products are provided by raw material suppliers as fragrances, and the substances used are labelled as 'fragrance'. Therefore, it is recommended that substances corresponding to fragrance among other substances be labelled as 'fragrance'.

Option 2) As with allergen labels, it is recommended to label the fragrance of other substances only when the content of such fragrance substances is 0.01% or more.

Relevant Act/Regulation	Consumer Chemical Products and Biocides Safety Control Act, Designation of Household Chemical Products subject to Safety Verification and Safety Labelling Standards
Responsible Authority & Division	Ministry of Environment (ME)
Recommendation Status	New

5. Modification of Method to Establish Chemicals Trade Secret Names (TSN) on Material Safety Data Sheet (MSDS)

Issue

A TSN should be created by the way described in the "Preparation Method of Data Protection Application and the Protection Data Management Method (hereinafter 'Data Protection Method')" regulated by the Ministry of Environment when applying a trade secret protection on MSDS. However, the TSN created by ME's Data Protection Method can expose confidential business information (CBI) since it is easy to infer the original chemical name or chemical structure from the TSN itself.

In accordance with the current regulation, there are polymers that are unable to be created with a TSN. For example, a TSN of new polymer synthesised by A, B, C monomers shall be A', polymer B' and C' by using generic name of A, B, C. However, the generic name of monomer cannot be used with a TSN if a monomer is designated as hazardous substance although the new polymer itself is non-hazardous (i.e. A', polymer B' and C if C monomer is classified as toxic substance). Polymer's TSN also has low readability since it has long and complicated name, therefore it has no utility for workers.

Therefore, it makes companies unable to prepare and submit a TSN which results in impossible applying for trade secret protection on MSDS. It causes greatly damage to a company's CBI protection.

Recommendation

It is recommended that eased standards for TSNs should be applied, or that a TSN itself requested by the submitter should be accepted in line with the intent to protect CBI.

Relevant Act/Regulation	Occupational Safety and health Act, Standard for Classification·Labelling of Chemical Substance and Material Safety Data Sheet
Responsible Authority & Division	Ministry of Employment and Labour (MOEL)
Recommendation Status	New

Ansook Park
Director,
Cosmetics
Committee

Cosmetics

5
Total Key Issues

1. Simplified Measurement Method for Product Packaging and Provision of Guidelines

Issue

According to Article 9 of the "Act on the Promotion of Saving and Resources", a person who manufactures, imports, or sells products shall comply with the standards for space ratio and number of packaging, which need to be measured in accordance with the Ministry of Environment's notification "Simplified Measurement Method for Product Packaging Materials and Methods". However, since there are various types of product packaging, it is not easy to apply the right method to each packaging, and in some cases, testing agencies apply different measurement methods to the same packaging. In addition, new standards on product packaging for consumer transportation purposes (50% of empty space ratio of packaging or less) were established in April 2022 and calculating the empty space ratio for each shipping box is difficult due to the variety of items that are packed quickly in warehouses.

Recommendation

Simplified Measurement Method for Product Packing Materials and Methods shall be further streamlined so that complex packaging types can be easily and simply measured. It is especially recommended that simple and clear standards that can be applied to product packaging for consumer transportation purposes be established. In addition, it is necessary to distribute materials such as casebooks, guidelines, etc., to reduce discrepancies of measurement methods among testing agencies.

Relevant Act/Regulation	Simplified Measurement Method for Product Packaging Materials and Methods
Responsible Authority & Division	Ministry of Environment (ME) (Resources Circulation Policy Division)
Recommendation Status	Updated

2.
Introduction of Pre-Inspection on Packaging Method

Issue

Along with the bill proposed by several lawmakers including Song Eon-seok, the introduction of pre-inspection of packaging methods (number of packaging and empty space ratio) and the labelling of inspection results are currently under discussion. The purpose of this bill is to make it mandatory to label the packaging methods on the packaging so that consumers can refer to them when choosing a product. However, while the time and cost that companies need to spend for the pre-inspection and the labelling are huge, the actual benefits (reduction of packaging waste through the provision of information on packaging) are unlikely to be significant. Indeed, this is because most packages are expected to be labelled with the same value as there is almost no empty space just to comply with the current standards (10% space for cosmetic unit products and 25% for set products) and the inspection results could vary depending on the person measuring the packaging.

Recommendation

The introduction of pre-inspection of packaging methods, especially the labelling of packaging methods on the packaging, is not efficient and the impact on reducing packaging waste is not expected to be significant, therefore it is recommended that the introduction should be re-considered.

Relevant Act/Regulation	Act on the Promotion of Saving and Recycling of Resources
Responsible Authority & Division	Ministry of Environment (ME) (Resources Circulation Policy Division)
Recommendation Status	New

3.
Measurement Method for Space Ratio and Number of Packaging for Set Products including Pouches

Issue

When packaging a set product, there are cases where components are put into a pouch, eco-bag, etc. and provided as a gift for consumer convenience. In this case, the pouch, eco-bag, etc. can be considered as a component as they have product value in themselves.

According to current measurement standards, these products are considered "components" if they are separated from other components, but they are regarded as "packaging materials" if other components are included in them. According to Article 2 of the "Act on the Promotion of Saving and Recycling of Resources", "packaging materials" are defined as materials or containers used as the packaging of products for the purpose of protecting their value and/or status, or preserving quality during transport, storage, handling, and/or usage, and the gifts mentioned above do not correspond to this definition of "packaging materials". As there is a lack of consistency in the current standards that interpret pouches as packaging materials and not as separate products, simply because they contain other components, this issue creates confusion to the industry and consumers.

In addition, if other components are included in these products, packaging efficiency may increase, reducing the volume of outer packaging materials used and allowing for reuse, therefore they are more suitable for protecting the environment in comparison to other disposable packaging materials.

Recommendation

Pouches, eco-bags, cloth bags, etc. provided for consumer convenience should be classified as components, not packaging, and it is recommended that these gifts be excluded from the measurement of the number of packaging and space ratio of packaging.

Relevant Act/Regulation	Rules about Standards for Packaging Materials and Packaging Methods
Responsible Authority & Division	Ministry of Environment (ME) (Resources Circulation Policy Division)
Recommendation Status	Retained

4.
Application of Optional Indication of Cosmetic Manufacturer

Issue

The Korean language indication labelling required by the current regulations is to strengthen safety and clarify responsibility for when consumers purchase products but providing them manufacturer information other than responsible seller information is not suitable for this purpose. This is because when consumer guidance about manufacturer and quality control, etc. is required, the responsible seller who is the importer (responsible seller) can provide it. The responsible seller is indeed wholly responsible for the quality of imported products such as recording domestic sales and distribution as well as conducting quality inspections.

Information on the manufacturer is not indicated on the

packaging of products even overseas, and in the case of imported cosmetics, such information can be obtained and confirmed by the indicated responsible seller. Proposals for voluntary labelling are also being made for domestic products since the labelling of the manufacturer causes issues such as an OEM monopoly, similar formulas, and counterfeits.

Recommendation

As the information of the responsible seller is already indicated as per the consumer's right to know, it is necessary to consider the introduction of an optional indication system for the cosmetic manufacturer.

Relevant Act/Regulation	Article 19-7, Attachment 4 of Enforcement Rule of the Cosmetics Act
Responsible Authority & Division	Ministry of Food and Drug Safety (MFDS) (Cosmetics Policy Division)
Recommendation Status	Retained

5. Acceptance of E-copy Submission of TSE/BSE-related Documents

Issue

Electronic copies of "Manufacturing and Free Sales Certificates" were made available for online submission in March 2021 with the aim of improving the process of reporting standard customs clearance of imported cosmetics. However, only the original paper copy of TSE/BSE-related documents shall still be submitted under the provisions of Article 35, Paragraph 12 of the Consolidated Public Notice, which state that "the original notarized documents must be submitted/confirmed".

In view of the fact that the reporting, reviewing, and storing processes were trouble-free when the electronic copies of "Manufacturing and Free Sales Certificates" were submitted online to the Korea Pharmaceutical Traders Association (KPTA), the original TSE/BSE-related documents should also be in the hands of the responsible seller and submitting electronic copies for review should be allowed as well. In doing so, the time and cost spent will be reduced, there will be less administrative work, and the risk of losing original documentation will be mitigated.

Recommendation

In addition to "Manufacturing and Free Sales Certificates", it is recommended that TSE/BSE-related documents also be accepted for online electronic copy submission.

Relevant Act/Regulation	Article 35 (Import of Medicines, Medical Devices, and Cosmetics), Paragraph 12 of Consolidated Public Notice
Responsible Authority & Division	Ministry of Trade, Industry and Energy (MOTIE) (Trade Policy Division) Ministry of Food and Drug Safety (MFDS) (Cosmetics Policy Division)
Recommendation Status	New

Taeyang Kim
Manager,
Energy &
Environment
Committee

Energy & Environment

6
Total Key Issues

1.
Incentivising Long-Term Local Supply Chain Development for Wind Power

Issue

Korea's exploration of supply chain development policy has to date focused on offering an incentive based on achieving greater than 50% local content within a project based on a limited set of the project's goods and services that would be used during the project's lifetime.

Whilst a pro-rated solution may provide a more viable incentive that appropriately recognises Korea's existing supply chain capabilities better, alternatives to local content requirements should be considered in order to further build the country's existing capability, while meeting decarbonisation targets and domestic green economy development at the same time.

Recommendation

It is recommended that, instead of fixing local content requirements to individual project revenues, alternative measures to assess existing supply chain capabilities, identify growth areas, and promote the investment and skills needed to support growth should be leveraged for the long term.

Even when offered as an incentive, the Government's current proposals may conversely delay delivery of projects if demand for local content for a limited set of components may not be met and if the components and facilities are not available to projects in the amount of time, quantity, and quality required. We have seen projects instead struggle where local content requirements exist abroad. This will cause the industry to get weak and slow down which goes against the Korean Government's targets of 12GW in 2030 and carbon neutrality by 2050.

This issue must be anticipated as a supply chain needs time to grow and be competitive, while development and planning requires time and stability. Expanding Korea's domestic supply chain must result in suppliers being able to offer multiple stakeholders each with a long-term capacity at market price to provide the parts that the government wishes to promote.

For example, publishing a yearly assessment of the stakeholders and their activities would support the market's expansion. Then the evaluation of the local supply chains' development would be fairly assessed in case the local market was not able to provide parts or services. The existence of an assessment may also become a mechanism through which to discover opportunities and promote suppliers, making them visible to projects.

These trade promotion activities also exist in other countries, such as Japan's supply chain investment programme and the UK Offshore Wind Growth Partnership.

Relevant Act/Regulation	Act on the Promotion of the Deployment, Use and Diffusion of New and Renewable Energy, Guidelines on the Management and Operation of Obligatory Renewable Energy Supply Program, Regulation on the Issuance of Renewable Energy Certificate and the Operation of the Certificate Market
Responsible Authority & Division	Ministry of Trade, Industry and Energy (MOTIE)
Recommendation Status	New

2.
Improvement on Resident Consent Guideline Based on EBL (Electricity Business License)

Issue

Repeated complaints have been filed regarding offshore windfarm development due to the absence of integrated guidelines concerning civil complaints resolution when developing offshore windfarms. This has resulted in delayed projects, increasing uncertainty, and an increase in total development expenditure.

In the beginning stages, such as when getting a measurement installation permit and EBL, the trend is that residents request developers for compensation. The problem is that there is no specific regulation which limits the boundary between public acceptance and compensation for stakeholders. This leads developers to get confused whom they should approach to settle public acceptance or to provide compensation.

Residents are requesting developers to give them more and more compensation. So public acceptance tends to be replaced into competitive financial compensation. However, there is a process for receiving compensation through fishery impact assessments in the development stage. It is unclear what the compensation required by residents is for.

Recommendation

It is recommended that comprehensive guidelines for the public acceptance be prepared which are divided into resident and fishery acceptance in line with the regulations so that timely expansion of huge-sized wind farm projects may lead to Korea achieving carbon neutrality in 2050.

In the UK, the government, fisheries, and industry formed the Fishing Liaison with Offshore Wind and Wet Renewable Group (FLOWW) which prepared guidelines for fishing dispute settlements and community funds, as well as an economic assessment of fisheries based on best practices. The guidelines provide the principles for a disruption settlement process, with fishermen and economic assessment methods and acceptable data types when commercial fishing is closed or restricted as a result of offshore renewable energy installation.

Relevant Act/Regulation	N/A
Responsible Authority & Division	Ministry of Trade, Industry and Energy (MOTIE)
Recommendation Status	Updated

---

3. Electricity Business License Evaluation Body for Projects Located in Unclear Jurisdiction Areas Between Local Governments

Issue

The minister of MOTIE has the right to give the permission under Electric Utility Act when it comes to Wind Power Generation business. However, in the case of the Jeju Self-Governing Province, the authority to permit electricity business under 'Electric Utility Act' has been delegated to the Jeju Self-Governing Province governor in accordance with the 'Special Act for the Establishment of Jeju Special Self-Governing Province and the Creation of a Free International City' (hereinafter the 'Jeju Special Act').

However, in the case of wind power generation projects which are located in unclear jurisdiction areas between Jeju Special Self-Governing Province and other regional governments, and in cases where the electricity supply and power system are supplied nationwide inland, the body in charge of evaluation and issuance of such areas' electricity business license is not clearly defined.

Recommendation

It is recommended that the body in charge of evaluation and authorisation of electricity business licenses should be the Electricity Committee of the MOTIE, which is the central administrative ministry, in the case of constructing transmission lines inland and supplying electricity nationwide from the wind farms located in the sea area where the jurisdiction between Jeju and other regional governments (Jeonnam-do and Gyeongsangnam-do) is not clearly defined, or in the case of waters under the jurisdiction of both local governments.

The purpose of the 'Jeju Special Act' is premised on supplying electricity in connection with the local power system, which is distinguished from the national power system, as local power is resourced from wind power on Jeju Island.

Relevant Act/Regulation	Electric Utility Act, Special Act for Establishment of Jeju Special Self-Governing Province and Creation of Free International City
Responsible Authority & Division	Ministry of Trade, Industry and Energy (MOTIE), Jeju Special Self-Governing Province
Recommendation Status	New

---

4. Proposal for Market Implementation of Offshore Wind Energy Exclusive REC

Issue

Offshore wind energy can realise relatively large-scale power generation in comparison to other renewable energy sources developed on land, and the impact on the area around the site is also relatively small compared to that of on land. Furthermore, a comprehensive cycle of the offshore wind farm development process involves various key industries such as offshore engineering, manufacturing, shipbuilding, etc. Therefore, offshore wind energy is regarded as one of the key energy sources needed to promote a low carbon economy.

In this context, not only is Europe actively developing offshore wind farms based on governments' various forms of political support, but the U.S. and other Asian countries are too.

In Korea's case, even though the volume of REC supply, price, and multiplier play a crucial role in determining the feasibility of offshore

wind projects, unless the RPS obligation target continues to increase after 2026, REC demand is expected to exceed REC supply around 2027, contributing to increased uncertainty in the offshore wind business.

Meanwhile, since the pressure of high REC prices on RPS obligors will affect tax increases, which will in turn lead to burdening electricity consumers, there is a growing concern that a REC fixed contract price, which is mainly applied to offshore wind projects, should not be excessively higher than the REC spot market price.

Recommendation

Therefore, it is recommended to take steps to mitigate the uncertainty of REC supply volume for offshore Wind Energy projects and promote market-based competition which will contribute to a more competitive REC price.

It is recommended that a RPS obligation target be exclusively applied to offshore wind energy that will provide a predictable REC volume signal to the offshore wind market while reflecting the differentiated levels of cost of Electricity (LCOE) for each energy source. (RPS mandatory supply capacity for each energy source).

Once the government announces the current year's offshore wind REC demand volume (e.g. obligation target), based on the premise that business risk caused by System Marginal Price (SMP) fluctuation is resolved through methods such as long-term fixed power sales agreement, REC can be auctioned among offshore wind developers based on competitive bidding.

This will contribute to guaranteeing a certain volume of REC and strengthening business feasibility in the market, as well as lowering the REC price for the government. However, for offshore wind developers that successfully win the auction based on competitive REC price proposals, grid connection shall be guaranteed or prioritised to streamline the process from REC offtake contracts to grid connection.

Relevant Act/Regulation	Act on the Promotion of the Deployment, Use and Diffusion of New and Renewable Energy, Revision Proposal of Regulations on the Issuance of Renewable Energy Certificates and Operation of the Certificate Market
Responsible Authority & Division	Ministry of Trade, Industry and Energy (MOTIE), Korea Energy Agency (KEA)
Recommendation Status	New

5. Efficient Grid Usage and Prevention of Grid Capacity Pre-Emption

Issue

By following 'Criteria of Electrical System Reliability and Electrical Quality Maintenance' which was amended on January 27th, a plan has been announced for a 'Joint Connection Facility ("JCF", a facility that links electricity generated from OSW site to common grid connection facility) Pre-Investment System'—a system in which KEPCO invests in JCF in advance, while operators need to pay back throughout the operation.

The 'JCF Pre-Investment System' is regarded as a positive solution to lower risks caused by grid uncertainty—although it is expected that it will take more than 8 years to construct the JCF after the grid connection agreement, and some are concerned that interests between operators who will access the same JCF may conflict due to differences in development speed or project location.

Meanwhile, as a result of the 'Revision of the Regulations for the Use of Electrical Equipment for Transmission and Distribution', efficient grid control and prevention of grid capacity pre-emption of insincere developers is expected. This will provide an opportunity to genuine developers for fair grid connection.

Against this backdrop, the following is recommended in order to effectively execute the above-mentioned regulations.

Recommendation

It is recommended that specific coverage guidelines of whether the 'plan for grid capacity pre-emption prevention and insincere developer management' through 'Revision of the Regulations for the Use of Electrical Equipment for Transmission and Distribution' be applied only to offshore wind developers who have individually signed the grid connection agreement, or to developers who have signed a contract to use common grid connection facilities through the 'JCF Pre-Investment System'.

It is further recommended that developers who have signed a contract to use a common grid connection facility have specific business plans and execution capabilities verified before contracting and should play a significant role in offshore wind projects in the energy cluster. In doing so, the permit or project progress delays of individual developers shall not impact the construction of common grid connection facilities or

projects within the relevant energy cluster. Moreover, there should be no hindrance to the business of genuine developers being connected to common grid connection facilities as scheduled.

Regarding the announced plan to monitor individually contracted developers' progress post grid connection agreement, it is also recommended that more detailed guidelines about required information and documents, as well as their usefulness, be clarified to ensure that genuine developers can satisfy the requirements. Furthermore, it is recommended that an additional safeguard be added to discriminate between genuine and insincere developers at the stage of signing the contract, by making applicants pay a deposit or guarantee payment of part of the grid construction and usage costs within a certain period. In doing so, genuine developers should be guaranteed not only a grid connection but also a timeline which will mitigate critical uncertainty about grid connectivity.

Relevant Act/Regulation	Criteria of Electrical System Reliability and Electrical Quality Maintenance, Revision Proposal of the Regulations for the Use of Electrical Equipment for Transmission and Distribution
Responsible Authority & Division	Ministry of Trade, Industry and Energy (MOTIE), Korea Electric Power Corporation (KEPCO)
Recommendation Status	New

6. Direct Contract (Wholesale Pricing) of Natural Gas Purchasing for Raw Material between KOGAS and Industrial Gas·Chemical Companies

Issue

Industrial gas companies produce H2/CO using natural gas (NG) as a raw material, and supply H2 and/or CO to customers who produce their final chemical products using CO/H2 as intermediate. This is the value chain of main business. The customers' final products (TDI/MDI/PC) are exported mainly to overseas markets. Some industrial gas companies also supply H2 to Hydrogen Mobility, like the Hydrogen Refuelling Station (HRS) operation as a part of H2 mobility business.

According to Article 2-3 of the Urban Gas Business Act, a wholesale business means supplying gas to massive consumers defined by the Enforcement Rule. Article 2, 2-2 of the Enforcement Rule states that users of power generation, power and heat generation and hydrogen production (for fuel cell installed mobilities and facilities) are entitled to receive NG directly from the wholesaler.

Industrial gas companies who are using NG for raw material, which shall be excluded for fuel purposes, should also be able to receive NG directly from the wholesaler so that they can increase their customers' competitiveness in the overseas market and expand the business territory to Hydrogen Mobility. In general, the ratio between raw material and fuel purpose in the hydrogen manufacturing process is 80:20 respectively.

Recommendation

We recommend amending Article 2 (2) 2 of the Enforcement Rule as follows: "Users of Power generation, Power and Heat generation and Mobilities' Hydrogen, as well as users for industrial gas production with NG consuming plants who use it for raw materials (fuel purpose shall be excluded) are entitled to receive NG directly from the wholesaler."

Currently the government only allows power generation companies and Hydrogen for mobilities manufacturers such derogation to deal directly with KOGAS and access KOGAS wholesale prices. However, existing plants that have already used city gas are not allowed to import LNG directly, unlike new plants directly importing LNG from overseas which results in an unfair competition structure. No issues are found in EU countries as it is already a fully deregulated market for natural gas.

Relevant Act/Regulation	Urban Gas Business Act, Enforcement Rule of Urban Gas Business Act
Responsible Authority & Division	Ministry of Trade, Industry and Energy (MOTIE)
Recommendation Status	Retained

Eunsung Na
Manager,
Fashion & Retail
Committee

Fashion & Retail

3
Total Key Issues

1. Labelling of Consumer Products

Issue

According to the Korean Agency for Technology and Standards (KATS) notification on the 'Safety Standards of the Consumer Products Subject to Compliance with Safety Standards', manufacturers, or importers of consumer products subject to safety standards are required to label their products with information such as manufacturing dates, import dates, season of first sale, and lot numbers, in accordance with the requirements specified in the respective annexes of the safety standards. However, compared to textile products and sunglasses, which can be labelled with one of various indication methods, it is difficult to label leather products and metal jewellery in contact with skin as they are only allowed to be labelled with manufacturing dates as an indication method.

For instance, while labelling with manufacturing dates, season of first sale, lot numbers, style number of the product, bar codes, QR codes, etc. is allowed for textile products, only the manufacturing date is recognised as an indication method for leather products and metal jewellery in contact with skin.

Recommendation

It is recommended that import dates shall be recognised as one of the indication methods for textile products as it enables an objective tracking of the product.

Furthermore, as it is difficult to identify the manufacturing date for imported leather products and metal jewellery in contact with skin, it is recommended that they be allowed to be labelled with season of first sale, import date or lot number.

Relevant Act/Regulation	Safety Standards of the Consumer Products Subject to Compliance with Safety Standards (KATS Notification)
Responsible Authority & Division	Korean Agency for Technology and Standards (KATS) (Consumer Product Safety Division)
Recommendation Status	Updated

2. Standards for Lead Content in Metal Accessories

Issue

On December 29, 2021, the Ministry of Environment revised its notification of the 'Designation of Restricted and Prohibited Substances' (Ministry of Environment Notice No. 2021-295) to strengthen the standard of the mixture content of restricted substances 06-5-8 (lead and mixtures containing 0.06% of lead or more) that are manufactured, imported, sold, stored, transported, and used for paint and metal jewellery, from 0.06% to 0.009%.

However, as the revised notification was not promoted enough to the fashion industry, relevant associations could not participate in the public hearing and deliver opinion in advance, therefore the industry's difficulties were not reflected sufficiently. In addition, as the definition of metal jewellery stated in the notification is unclear, it is difficult for industry to set the scope of metal jewellery. Furthermore, domestic standards of lead in metal jewellery are excessive compared to the ones in the EU or other overseas countries (e.g., the United States, the United Kingdom, China, Brazil, etc.).

Recommendation

It is recommended that in the case of notices that manage both paint and metal jewellery, such as the 'Designation of Restricted and Prohibited Substances' (Environmental Notice No. 2021-295), all related industries be fully informed when they are revised.

It is also recommended that as in other countries, paint and metal accessories be separately regulated and restricted, and the domestic regulations for metal jewellery be relaxed to 0.06% as before to ensure compatibility with international standards.

Relevant Act/Regulation	Designation of Restricted and Prohibited Substances
Responsible Authority & Division	Ministry of Environment (ME) (Chemicals Policy Division)
Recommendation Status	New

3.
Safety Testing Standards for Infant Textile Products

Issue

Under the current regulations, only five domestic testing agencies are available to provide certification pertaining to the 'Article 22 (3) of the Special Act on the Safety of Children's Products', and infant textile products that have already invested significant efforts and costs and have been proved to be safe through overseas tests must go through additional safety tests in domestic agencies. According to the 'Article 22 (6) of the Special Act on the Safety of Children's Products', a testing and inspection agency may sign a contract with domestic and foreign agencies that conduct testing and inspection on children's products subject to safety verification, to mutually recognise the results of product safety verification tests and inspections. However, this policy has not been used in practice due to the lack of information on the specific standards and procedures of recognition.

Recommendation

It is recommended that specific standards and procedures on the policy that mutually recognises the results of product safety verification tests and inspections with overseas agencies be provided to the industry so that it can avoid duplicate safety verification testing in Korea which is a huge financial and administrative burden.

Relevant Act/Regulation	Special Act on the Safety of Children's Products
Responsible Authority & Division	Korea Agency for Technology and Standards (KATS) (Consumer Product Safety Division)
Recommendation Status	Updated

Hyokyung Suh
Director,
Food
Committee

Food

2
Total Key Issues

1.
Scope of Administrative Disposition for Food Import and Sales Business

Issue

A person who has filed a business report for Food Import and Sales Businesses is permitted to import and sell imported food as well as operate a retail business that sells food in off-line stores, such as department stores. When a business receives an administrative disposition of business suspension in accordance with the Enforcement Rules of the Special Act on Imported Food Safety Control ("Imported Food Act") [Table 13] Administrative Disposition Standards, and the Enforcement Rules of the Food Labelling and Advertising Act ("Food Labelling and Advertising Act") [Appendix 7] Administrative Disposition Standards I.12.

When the scope of business suspension is interpreted excessively, the business operator is required to suspend retail business as well. This is against principle of proportionality and results in excessive consequences including the suspension of all forms of sale, not only the import and distribution of foods but even retail of all items sold by the company. On the other hand, domestic food manufacturing businesses receive a disposition of suspension of manufacturing specific items for the same violation. This results in unfairly excessive administrative dispositions in comparison to importers, who are not engaged in retail business. For instance, in the event of a business suspension due to a violation of product labelling standards as a result of machine malfunction, if the scope of the business suspension is interpreted as all types of business that the company is engaged in, the company should suspend the retail as well as import and distribution of the foods. This results in tremendous financial damage, millions of dollars of sales loss, and irreparable damage to its brand value. On the other hand, other retailers, such as supermarkets are able to sell

the violating product from that company as usual during the suspension period.

The type and scope of business for Food Import and Sales Businesses under the Imported Food Act is distinct from the Other Food Sales Businesses under the Food Sanitation Act, and Mail-order Businesses under the Electronic Commerce Act in terms of the facility requirements and other business report requirements.

Article 2, Item 1 of the Imported Food Act Enforcement Decree defines the scope of Food Import and Sales Businesses as the "business of 'importing' and 'selling' imported food, etc." In addition, Article 15 (1) [Attached Table 7] of the same act's enforcement rule specifies facility requirements for each business type. Food Import and Sales Business is required to establish "storage warehouse" unlike other types of businesses. In contrast, Article 21 of the Enforcement Decree of the Food Sanitation Act does not require the installation of a separate "storage warehouse" for Other Food Sales Business for food retail, except a refrigeration facility or sales stand.

The provision of requiring a "storage warehouse" is proof that the law is distinguishing the scope of business of Food Import and Sales Businesses from Other Food Sales Businesses (the business of selling foods directly to end consumers).

Therefore, direct retail sales of imported food to department stores or electronic commerce channels by Food Import and Sales Business holder should be deemed as sales by Other Food Sales Business holder or general retailers, and not as sales by the importer of the food.

Comparative analysis of the Imported Food Act's and Food Sanitation Act's applicable business scope and facility standards

	Food Import and Sales Businesses under the Imported Food Act	Other Food Sales Businesses under the Food Sanitation Act
Business Scope	The business of 'importing' and 'selling' imported food, etc.	Food sales in department stores, supermarkets, chain stores, etc. of a certain size or larger as specified by the Ordinance of the Prime Minister, excluding edible ice sales, food vending machine sales, distribution specialised sales, and food sales at group cafeterias.
Facility standards	Independent business office and warehouse for the hygienic storage of imported foods, etc.	Refrigeration facility or refrigerator, display stand and sales stand

Recommendation

It is recommended to clearly differentiate between the business of importing food, storing it in a warehouse, and then selling it to retailers; and other food retail businesses that sell directly to consumers off-line, such as in department stores, or via e-commerce channels. Even if a Food Import and Sales Business holder also engages in the retail of imported food, it is unreasonable to suspend all business activities such as food retail.

In this regard, it is recommended to strictly limit the scope of business suspension for Food Import and Sales Businesses to importation and distribution of food as defined in the Imported Food Act.

Relevant Act/Regulation	Enforcement Rules of the Act on Labelling and Advertising of Foods [Appendix 7], Enforcement Rules of the Special Act on Imported Food Safety Control [Attached Table 13]
Responsible Authority & Division	Ministry of Food and Drug Safety (MFDS) (Food Labelling and Advertising Policy Division, Imported Food Policy Division)
Recommendation Status	New

2. Labelling of "Unsalted" Butter

Issue

In Europe, butter is categorised as "salted" or "unsalted" and labelled on the product accordingly. Indeed, this is to indicate whether salt (sodium), a factor that greatly affects the taste and texture of butter, is added or not. Such labelling aims to provide consumers with information for product selection, which distinguishes it from nutrition claims.

Currently, labelling standards for "no salt added (=unsalted)" do not exist in Korea for food without added salt. According to the Ministry of Food and Drug Safety, such labelling is only allowed if "salt-free" standards stated in the "Labelling Standards of Foods, Etc" are met.

	EU	Korea
Labelling standards for "salt-free" claim	Less than 5 mg of sodium per 100 g of food	Less than 5 mg of sodium per 100 g of food * For salt, less than 13 mg per 100 g of food
Labelling standards for "unsalted" (butter)	Indication of whether salt is added or not	N/A

1) CODEX[1]: Standard for Butter – Butter may be labelled to indicate whether it is salted or unsalted according to national legislation.
2) EU[2]: Protected Designation of Origin (PDO), "the butter may be either salted or unsalted".
3) US[3]: Nutrient content claims for the sodium content of foods, the terms "unsalted," "without added salt," and "no salt added" may be used on the label or in labeling of foods only if: (i) No salt is added during processing.
4) Japan[4]: An example of the label indicating that salt has not been added is "no salt added" or other similar labeling.

If butter meets the "salt-free" standards under the EU Standards of Food Nutrition Claims[5] , it is labelled with "salt-free" or "sodium-free" claims, and the standards are the same as those of Korea. However, "unsalted" does not mean "salt-free" (no salt) and does not refer to a nutrition claim, as it signifies that no salt has been added to the raw material. Butter contains sodium (milk naturally contains sodium), so to create a salt-free state of butter, an additional salt removal process is required.

Recommendation

It is recommended that labelling of "unsalted" butter be interpreted as an indication of whether salt is added or not during the manufacturing process of butter, and not interpreted as a nutrition claim.

It is also recommended that new standards for "unsalted" labelling be established to provide the right information to consumers through harmonisation with international standards.

Relevant Act/Regulation	Labelling Standards of Foods, Etc, Standards of False Labelling or Advertising of Food
Responsible Authority & Division	Ministry of Food and Drug Safety (MFDS) (Food Policy of Labelling and Advertising Division)
Recommendation Status	New

1. CODEX Standard for butter CXS 279-1971
2. (2022/C 159/14) Publication of an application for approval of a non-minor amendment to a product specification pursuant to Article 50(2) (a) of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs
3. 21 CFR 101.61 Nutrient content claims for the sodium content of foods
4. 식품의표시기준에 대해서 (본체): https://foodlaw.foodinfo.or.kr/lawview/detail.do?docNo=969&docDtl=1012&docGrpCd=51&menuKey=143#tPageNo=1
5. REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 December 2006 on nutrition and health claims made on foods

Ansook Park
Director,
Healthcare
Committee

Healthcare

22
Total Key Issues

1. Expansion of the Scope of PE Exemption Application for "Severe Incurable Disease Treatments" and "Number of Patients"

Issue

Policy support is provided to drugs used for serious life-threatening diseases such as Risk Sharing Agreement (RSA) or Pharmacoeconomic Evaluation (PE) exemption. However, in the case of diseases that are not life-threatening, they cannot be provided with policy support although they deteriorate the quality of life chronically, making it difficult to lead a normal daily life.

In particular, the diseases are excluded from social interest if the number of patients is low or no treatment has been developed, and there are many cases where they are not subject to benefit extension because they are not designated as rare diseases due to low socioeconomic costs for diagnosis and treatment.

Most of these diseases are difficult to diagnose and must be fought for life, but even if their drugs are recognised abroad as innovative orphan drugs, the requirements to prove that the life expectancy is less than two years cannot be met in most of the situations, thus they are excluded PE exemption, hindering patient access.

As drugs eligible for PE exemption are subject to hard expenditure cap (100% refund), there are very low concerns about uncertainty in terms of financial management, therefore access to treatment for isolated rare disease patients can be improved with the predictability of finance.

Over the past decade, the reimbursement coverage rate of rare disease treatments has been 46.7%, which is significantly lower

than that of cancer or severe incurable diseases, and particularly in the case of orphan drugs that are not subject to benefit extension, the reimbursement coverage rate is only 20%.

To apply for PE exemption under the current regulations, it is required to prove that the number of patients is less than 200, but this corresponds to only 0.0003% of the Korean population. Although the definition of rare diseases can be interpreted in many ways, according to the table below, drugs for ultra-rare diseases are those that are used to treat diseases that affect one per 100,000 people, which means about 510 to 520 people, based on the number of people in Korea.

Term	Definition
Drugs for rare diseased (DRDs)	Drugs used to treat diseases that affect ≤ 50 per 100,000 people.
Drugs for ultra-rare diseases (DURDs)	Drugs used to treat diseases that affect ≤ 1 per 100,000 people.
Drugs for other rare diseased (DORDs)	Drugs used to treat diseases that affect > 1 to 50 per 100,000 people.

Ref) Orphanet Journal of Rare Diseases (2018) 13:15

Recommendation

Even if it is not yet designated as a rare disease and is not life-threatening (less than 2 years of life expectancy), it is recommended that can be subject to PE exemption if 1) it seriously degrades the quality of life, and 2) the drug is used for a small number of patients.

It is recommended that the criteria applied in PE exemption scheme (less than 200 patients) be revised upwards.

Relevant Act/Regulation	Article 6 (2) of the Regulation for Evaluation Criteria and Procedures, etc. for Reimbursement Eligibility, etc. of Drugs (Drugs Eligible for PE Exemption)
Responsible Authority & Division	Ministry of Health and Welfare (MOHW) (Division of Pharmaceutical Benefits) Health Insurance Review and Assessment Service (Pharmaceutical Benefit Department (New Drugs Registration Division))
Recommendation Status	New

2. Expansion of Scope of Application for Risk Sharing Agreement (RSA) for Orphan Drugs and Low QoL Chronic Disease Drugs

Issue

Although the Risk Sharing Agreement (RSA) including the refund type are only applied to severe disease drugs such as anticancer drugs or rare disease drugs,

- Recognition for RSA application is required for orphan drugs that are designated by the Ministry of Food and Drug Safety (MFDS). Indeed, although the requirements of orphan drugs designated by the MFDS resemble those of rare disease drugs designated by the Korea Disease Control and Prevention Agency (KDCA) that are subject to application of RSA, the number of Korea passing cases is increasing and access to orphan drugs is further restricted.
- If additional indications of risk-sharing drugs are not subject to RSA application, proof of cost-effectiveness is required based on actual value for additional indications subject to expansion of reimbursement coverage. In this case, as the cost-effectiveness threshold is evaluated based on the cost-effectiveness evaluation of chronic diseases and not of drugs subject to RSA, it is inevitably accompanied by significant drug price reduction and refund rate, it is practically impossible to expand the reimbursement coverage.

Recommendation

It is recommended that the refund type of RSA be applied to the orphan drugs as below, to improve patient access to orphan drugs by actively utilising the refund type of RSA.

- Applied in the case of listing of new orphan drugs, or
- Applied in the case of drug price reduction resulted from post management such as Price-Volume Agreement (PVA) of listed orphan drugs and expansion of reimbursement coverage, etc.

In the case of low QoL (Quality of Life) chronic disease drugs, an extended review is needed for them to be subject to RSA application. To allow such review, specific criteria need to be provided if their low QoL is proved in a clinical trial, even if they do not correspond to diseases subject to benefit extension.

Relevant Act/Regulation	Article 7 (Evaluation for Drugs) of Decision and Adjustment Guideline on Drugs Regulation for Evaluation Criteria and Procedures, etc. for Reimbursement Eligibility, etc. of Drugs Detailed Evaluation Guideline for Negotiation Subjected Drugs such as New Drugs, 1.8. Evaluation Standard for Drugs with Manufacturers or etc. Obligation Conditions
Responsible Authority & Division	Ministry of Health and Welfare (MOHW) (Division of Pharmaceutical Benefits) Health Insurance Review and Assessment Service (HIRA) (Pharmaceutical Benefit Department)
Recommendation Status	New

3. Improvement of RSA Re-evaluation and Re-reevaluation Post Management

Issue

Since the introduction of the Risk Sharing Agreement (RSA) in 2014, there have been improvements to its scheme to respond to social and medical needs, such as the introduction of Pharmacoeconomic Evaluation (PE) exemption, expansion of reimbursement standards for RSA drugs, RSA eligibility expansion including follow-on drugs, etc. It has also been confirmed in several studies that the RSA scheme has been contributed to improve patient access. However, in the 9th year of RSA introduction, there is a strong need to improve the RSA re-evaluation of drug post management system that can reliably ensure patient access, requiring regulatory innovation.

The RSA drugs that have undergone an economic evaluation at the time of listing addressed their financial risks already. However, for RSA drugs subject to re-reevaluation that have undergone an additional 2nd round of economic evaluation when being re-evaluated, it is unreasonable to repeatedly proceed with the current re-reevaluation that is almost similar to the new drug listing.

Despite having been listed through proof of economic evaluation using net drug prices at a level equivalent to that of other drugs, it seems that applying standards of drug price newly listed by other companies continuously and repeatedly on re-evaluation, just because they are listed under RSA, is an unreasonable and excessive regulation in terms of equity and policy predictability.

This is because post drug price management rules are based on the internal factors of the drug itself after listing, such as the pre-price cut for reimbursement expansion, price-volume agreement (PVA), actual transaction pricing (ATP), etc. Therefore, the RSA re-evaluation system should be improved to ensure the equity for RSA drugs.

In addition, it should be considered that RSA drugs have already been applied and managed by various post price control measures like other drugs.

As RSA re-evaluations have been repeatedly conducted, the value of new drugs continues to decline, leading to a vicious cycle that undermines stable patient access. In addition, this raise concerns as well that it will be difficult to ensure patient access to new drugs currently under clinical study.

Recommendation

Cost-effectiveness assessment and contract price negotiations need to be omitted in the case of re-evaluation and re-reevaluation of listed RSA drugs that have already undergone an economic evaluation and addressed financial risks, to ensure equity, predictability, and sustainable patient access. In addition, improvement is needed to extend the term of the RSA contract through the verification of contract extension.

Relevant Act/Regulation	Article 7 (Evaluation for Drugs) of Decision and Adjustment Guideline on Drugs Regulation for Evaluation Criteria and Procedures, etc. for Reimbursement Eligibility, etc. of Drugs Detailed Evaluation Guideline for Negotiation Subjected Drugs such as New Drugs, 1. Evaluation Standard, 1.8. Evaluation Standard for Drugs with Manufacturers or etc. Obligation Conditions (RSA), 1.8.3. Post Management "3) Evaluation Related with RSA Contract Term Termination" (ref. HIRA Drug Affairs Regulation book published in Dec. 2021, p. 1320)
Responsible Authority & Division	Ministry of Health and Welfare (MOHW) (Division of Pharmaceutical Benefits) Health Insurance Review and Assessment Service (HIRA) (Pharmaceutical Benefit Department)
Recommendation Status	Retained

4.
Improvement of Rules for Expansion of Benefit Standards for Risk Sharing Agreement (RSA) Drugs

Issue

The revised standards for new drugs require proof of cost-effectiveness through economic evaluation regardless of the magnitude of the fiscal impact when a risk-sharing drug applies for an expansion of the benefit standards. As a result, patient access is delayed and administrative power is wasted due to the preparation and review of economic evaluation data even for cases which are expected to have a negligible fiscal impact such as rare diseases (a small number of target patients), improvement of reimbursement standards for cases that are impossible to prove cost-effectiveness, etc.

Due to the revision of the guidelines of the Health Insurance Review and Assessment Service in October 2020, cost-effectiveness must be proven when expanding benefit standards for subsequent indications. Therefore, there is a concern that patient access may be further hindered due to the extended review period and the requirement to prove cost-effectiveness compared to new drugs released later. In particular, the comparison of drug prices with later released drugs may raise equity issues with non-risk-sharing drugs. It is also problematic in that it does not acknowledge the innovativeness of first-in-class drugs.

When expanding the reimbursement of risk-sharing drugs, the cost-effectiveness must be proved based on the actual price. Nonetheless, when a new dose is added to a subsequent indication, the patient access is hindered due to the requirements of going through unnecessary procedures such as calculation procedures (marked price) and cost-effectiveness verification procedures (actual price).

Recommendation

Exemption of pharmaco-economic evaluation is suggested when the expected additional claim is less than 1.5 billion KRW after applying the adjusted upper limit amount of the drug with the expansion reimbursement standards, such as small number of patients, requests of improving reimbursement standards for indications for which cost-effectiveness has already been evaluated, etc.

Simple price comparisons with later released drugs need to be avoided, and the setting of reimbursement standards and practical review of economic evaluation need to be simultaneously conducted when requesting for expansion of RSA reimbursement. Through this process, excessive administrative waste, and shift to a procedure to improve patient access is required.

In particular, the establishment of procedures is needed such as a fast track for drugs with high medical unmet needs, for paediatric drugs and rare diseases.

Relevant Act/Regulation	Article 7 (Evaluation for Drugs) of Decision and Adjustment Guideline on Drugs Regulation for Evaluation Criteria and Procedures, etc. for Reimbursement Eligibility, etc. of Drugs Detailed Evaluation Guideline for Negotiation Subjected Drugs such as New Drugs, 1.8. Evaluation Standard for Drugs with Manufacturers or etc. Obligation Conditions
Responsible Authority & Division	Ministry of Health and Welfare (MOHW) (Division of Pharmaceutical Benefits)
Recommendation Status	New

5.
Improvement of Separation of Refunding System from RSA Scheme

Issue

A7 countries' share of the total drug market revenue for patented drugs (new drugs) is 51%, compared to 25% in Korea.

Domestic drug price level of the original drugs is 64.6% compared to 32 OECD countries.

The reality is that the value assessment for innovative new drugs such as severe and rare diseases drugs is based on the current drug price level in Korea, and to prove its cost-effectiveness, the domestic price level is mostly lower than global price level. In addition, the domestic price level corresponding to the Korea's economic level cannot pass the economic evaluation in Korea due to the higher ICER value than domestic standards.

Although the refunding drugs with proven economic evaluation contribute to financial neutrality while improving patient access, there is a great risk that simply because they are risk-sharing drugs, strong post price management rules will lead to difficulties in ensuring stable patient access unlike other drugs.

Regardless of RSA drugs or non-RSA drugs, as various post price control measures are already in place, continuous reduction of drug price is required. In particular, in the case of new drugs such as RSA drugs, etc., as operating predictable business according to the global price standards is difficult, this may have a negative impact on the introduction of new drugs currently under clinical study.

Recommendation

RSA drugs that have passed economic evaluation need to be separated from the RSA scheme.

It is required to apply the refunding system to both listing and post price control measures to ensure reliable patient access.

Relevant Act/Regulation	Article 7 (Evaluation for Drugs) of Decision and Adjustment Guideline on Drugs Regulation for Evaluation Criteria and Procedures, etc. for Reimbursement Eligibility, etc. of Drugs Detailed Evaluation Guideline for Negotiation Subjected Drugs such as New Drugs, 1. Evaluation Standard, 1.8. Evaluation Standard for Drugs with Manufacturers or etc. Obligation Conditions (RSA)
Responsible Authority & Division	Ministry of Health and Welfare (MOHW) (Division of Pharmaceutical Benefits)
Recommendation Status	Retained

6. Improvement of Procedures for Expansion of Reimbursement Standards and Transparency in Decision-Making

Issue

It is important to establish a system for health care decision-making that enables various stakeholders to maintain transparent decision-making based on evidence. Although it is true that transparency has been improved, such as procedures of the Pharmaceutical Benefit Evaluation Committee, the procedures for expanding the reimbursement standards for general drugs may be delayed indefinitely as there is no set deliberation period after submission. Moreover, there is no transparent communication during the review process.

As this significantly reduces predictability, it not only causes inconvenience to the medical staff and patients but also it is hard to identify the reason for the delay as well as ongoing issues when there is a delay during the deliberation. Even after the reimbursement standards are determined, it is difficult to proceed with the subsequent process because the results of the meeting are not disclosed to the pharmaceutical company.

Recommendation

It is necessary to prepare a system that transparently shares the progress from the application for the expansion of the reimbursement standards (e.g., granting application number, disclosure of application status, schedule of deliberation meetings, specific disclosure such as reports to the Ministry of Health and Welfare, etc.).

It is necessary to prepare regulations for setting the deliberation deadline in the same way as for new drug listing.

It is necessary to share the content after the reimbursement standard meeting (e.g., meeting minutes), even if the evaluation of reviewed items is only delivered to the pharmaceutical company (Currently, only perfunctory documents are reported, where there is only a simple indication, "reported", for instance).

Relevant Act/Regulation	Regulations on National Health Insurance Medical Care Benefit Standards
Responsible Authority & Division	Ministry of Health and Welfare (MOHW) (Division of Pharmaceutical Benefits) Health Insurance Review and Assessment Service (HIRA) (Pharmaceutical Benefit Department (Pharmaceutical Standards Division))
Recommendation Status	New

7. Improvement of Reimbursement Registration System for Rare Diseases which Chronically Deteriorate the Quality of Life

Issue

In the case of rare diseases which deteriorate the quality of life or make it difficult to lead daily lives due to irreversible degradation of the function of important organs, the treatment needs are high, but due to limitations in disease and clinical research design, they are often licensed only by improving surrogate endpoints instead of improving survival rates.

To demonstrate the cost-effectiveness, the ICER value through Life Year Gain should be proved lower than the threshold, but as clinical studies require survival improvement data and apply the same ICER threshold as other diseases to conduct an economic

evaluation that does not consider the specificity of rare diseases which make it hard to lead daily lives, it is difficult to introduce new drugs for rare diseases.

Recommendation

In the case of drugs for rare diseases which deteriorate the quality of life or make it difficult to lead daily lives due to irreversible degradation of the function of important organs, whose effect of improving survival rate through clinical studies is hard to be demonstrated, it is necessary to recognize the expected increase in survival years through improvement of the surrogate factor when reviewing the economic evaluation, or to apply a flexible ICER threshold that considers the specificity of the disease.

Relevant Act/Regulation	Regulation for Evaluation Criteria and Procedures, etc. for Reimbursement Eligibility, etc. of Drugs Detailed Evaluation Guideline for Negotiation Subjected Drugs such as New Drugs
Responsible Authority & Division	Ministry of Health and Welfare (MOHW) (Division of Pharmaceutical Benefits) Health Insurance Review and Assessment Service (HIRA) (Pharmaceutical Benefit Department
Recommendation Status	Updated

8. Improvement of Access to Medicines for Complex Chronic Metabolic Diseases

Issue

Obesity is not just a personal aesthetic problem but a complex chronic metabolic disease which accompanies various complications and whose socioeconomic cost is high. Moreover, not only the prevalence and burden of obesity increase, but they increase faster and faster. Obesity in children and adolescents especially relate to a high probability of obesity-linked complications as an adult in the future, as well as negative health impact during lifetime.

In recognition of this problem, the National Obesity Management Plan (2018-2022) was established, and bariatric surgery has been partially reimbursed for severe obesity since 2019. However, access to care is still limited with reduced treatment outcomes due to the lack of reimbursement for anti-obesity medicines.

Status of reimbursement of anti-obesity medicines in European countries

- Iceland (since 2018/1), Norway (since 2019/3), Switzerland (since 2020/4): in the case of high BMI with related complications
- UK NHS (since 2020/12), Finland (since 2021/7), Netherlands (since 2022/4), Scotland (since Q2 2022: expected): in the case of high-risk group with high BMI

Recommendation

It is recommended that an authoritative interpretation or amendment of "Table 2, Items subject to non-reimbursement, Regulation on criteria for providing reimbursed services of NHI" be provided, to acknowledge obesity as a disease requiring NHI application instead of a "condition that does not hinder work or daily life".

"Details on the applicable standards and methodologies of medical benefits": Treatment of obesity needs to be amended as eligible for reimbursement from the current non-reimbursement with exceptions applied.

It is recommended that anti-obesity medicines be interpreted as subject to the "list of drugs reimbursed and their MRP".

Relevant Act/Regulation	Regulations on National Health Insurance Medical Care Benefit Standards Details on the Applicable Standards & Methodologies of Medical Benefits Notification of List of Drugs Reimbursed and their MRP (Maximum Reimbursement Price)
Responsible Authority & Division	Ministry of Health and Welfare (MOHW) (Division of Health Insurance Policy, Division of Pharmaceutical Benefits, Division of Healthcare Security Management)
Recommendation Status	New

9. Introduction of Value-Based Pricing System for Each Indication

Issue

Recently, targeted therapies such as immuno-oncology and immunotherapies have been developed for multiple different type of diseases and indications as an extensible biological mechanism of action.

In October 2020, the revision of detailed evaluation criteria for drugs subject to negotiation, such as new drugs requested cost-effectiveness assessment to be mandatory for RSA drugs that are

subject to an expansion of reimbursement standards. Under the current system, if the drug price based on value of each indication is significantly different, it results in the lowest drug price, undermining the value of other indications, and as a result, making it difficult to reimburse for the indications.

In Germany, France, and Australia, drug prices are calculated based on the clinical value for each indication and volume-weighted average price is applied based on the financial impact for each indication. Furthermore, in Italy, net prices for each indication are applied differently through various managed entry agreements.

Recommendation

Considering the administrative burden, it is recommended that the volume-weighted average price based on the cost-effectiveness price of each indication be applied first to drugs subject to risk-sharing contract as in the cases for Germany, France, and Australia, or that a pricing system with different refund rates for each indication be introduced through pilot projects thereafter.

Relevant Act/Regulation	Regulation for Evaluation Criteria and Procedures, etc. for Reimbursement Eligibility, etc. of Drugs
Responsible Authority & Division	Ministry of Health and Welfare (MOHW) (Division of Pharmaceutical Benefits)
Recommendation Status	New

10. Exception Application and Improvement of Simple Pricing Formula for Low-Dose Paediatric Biopharmaceutical Drugs (Preferential Treatment for Paediatric Drugs)

Issue

As paediatric drugs have many restrictions on proving the effectiveness and safety of their indications through clinical trials, off-label is frequently being used as it is difficult to conduct clinical trials.

Although some drugs had developed paediatric use and dosage through separate clinical trials despite low marketability such as low number of patients, high cost and distribution structure, they are calculated at a significantly lower price than synthetic drugs when low-dose biopharmaceutical drugs are introduced, resulting in a price reversal, and thus limiting paediatric patient access to treatment. Chronic diseases that occur in childhood (e.g., atopic dermatitis) need to be treated in early stages to reduce the burden of disease and treatment costs over a lifetime, and to avoid negative physical and mental effects arising from growth.

In the case of pharmaceutical drugs without paediatric dose (low dose), it is difficult to ensure the accuracy of the patient's dosage and safety when administered, and waste drugs are generated by arbitrarily small doses of adult formulations. Particularly, in the case of only one-time self-injectors that increase the convenience of taking adult patients, it is impossible to use them in children.

In overseas countries (US, Europe, Japan, etc.), pharmaceutical companies are actively encouraged to develop paediatric drugs through various mechanisms of drug price incentives (preferential treatment for cost-effectiveness assessment, exclusion of re-evaluation, exclusion of actual transaction price reduction, etc.).

Recommendation

Considering the necessity of encouraging the development of paediatric indications and the characteristics of high-cost biopharmaceutical drugs such as raw material costs and quality control, it is recommended that regulations be amended (if all the conditions below are met), as it is necessary to apply the exception to the simple pricing formula (price nearly equivalent when dose is similar) or to improve the formula (preferential treatment for paediatric drugs) when developing low-dose paediatric pharmaceuticals.

In the case of calculation of a low-dose drug price based on a high-dose product when registering insurance benefits for low-dose paediatric biopharmaceutical drugs,

- When clinical trials are conducted for approval of paediatric use,
- If the paediatric use is specified in the permitted matters of the MFDS, and if the main reimbursement coverage of the dose corresponds to a paediatric indication.

Relevant Act/Regulation	Decision and Adjustment Guideline on Drugs Regulation
Responsible Authority & Division	Ministry of Health and Welfare (MOHW) (Division of Pharmaceutical Benefits) Health Insurance Review and Assessment Service (HIRA) (Pharmaceutical Benefit Department (Pharmaceutical Price Assessment Division))
Recommendation Status	New

11.
Allow Pre-issue of Drug Code when M&A Transferring of Pharmaceutical Products

Issue

Currently, Drug code can be issued only after the product registration completion with some *exceptions (*the M&A transfer of pharmaceutical product due to the acquisition takes approximately one month).

Packaging material can be manufactured after Drug code has issued, so it takes more than 6~7 months to make Korean packaging material and apply the drug code on the package at oversea manufacturing site. Considering the time required for local release quality test after importation to Korea, 9~10 months of stock should be prepared for pharmaceutical products and for biologics and vaccines, local release quality test takes up to 4 months, therefore a total of 13 months of stock should be prepared in advance for stable domestic supply.

However, at least 9 months and up to 13 months of inventory holding is excessively burdensome for industry in terms of import/distribution management of products.

In the case of multi-antigen vaccines, each ingredient has difference expiry date, so the remaining shelf-life of the final drug product after the quality inspection become short. Therefore, it is almost impossible to secure inventory with sufficient remaining shelf-life, and the distribution itself is impossible during M&A transfer periods. This can be a major problem in terms of the stable vaccine supply in the country, as most multi-antigen vaccines are included in the national essential vaccination program.

Recommendation

According to Paragraph 2, Article 7 of Notification on the use and management of Drug Bar codes and RFID tags, if a drug code should be inevitably granted prior to license approval such as for predictive validation, etc., exceptions are allowed to register a product information report on the portal.

It is recommended that pre-issue of Drug code be allowed in the case of M&A transferring of pharmaceutical products in addition to the above exceptions. It is expected that problems related to medicine importation and management will be improved which will enable the stable supply of medicines.

Relevant Act/Regulation	'Enforcement Regulation on the Safety of Pharmaceuticals, etc.' Article 69 Paragraph 7 'Criteria on the scope of Drug Bar Codes and RFID tags display, etc' MFDS notification 2016-22, '16.04.01 'Notification on the Use and Management of Drug Bar Codes and RFID tags' MOHW notification 2021-49, '21.02.15
Responsible Authority & Division	Ministry of Health and Welfare (MOHW), Ministry of Food and Drug Safety (MFDS)
Recommendation Status	New

12.
Rx to OTC Switch Process Establishment

Issue

After a new medical system (separation of prescribing and dispensing drugs) in 2000, there was only one total drug reclassification due to social demand in 2012.

In overseas countries such as USA, UK, and Japan, a formal Rx to OTC Switch process is in place and they reevaluate the classification in regular basis. However, in the case of Korea, there has been no Rx to OTC reclassification case since the reclassification led by the government in 2012, and the procedure of Rx to OTC reclassification itself is absent.

Due to recent COVID-19 situation in the past two years, the importance of 'self-care' and 'self-medication' is being re-evaluated. Consumers who experienced quarantine and home treatment due to COVID-19 are more actively participating in their health care than in the past. Also, for cost reduction, consumers are showing a tendency to purchase over-the-counter drugs on their own without visiting a hospital or clinics for mild symptoms. In addition, as it is difficult for patients to visit hospitals during a pandemic situation such as COVID-19, the need for expansion of consumer access to medicines through the expansion of the scope of over-the-counter medicines has increased.

Recommendation

It is recommended to establish a drug reclassification system (Rx to OTC switch process) suitable for domestic regulatory environment by referring to the system such as Rx-to-OTC Switch system in the US and the regular reclassification of prescription drugs (POM)-

pharmacy drugs (P)-free sale drugs (GSL) in the UK.

It is expected to reduce overall medical costs, improve patient access to medicines who have mild symptoms and revitalize the over-the-counter drug market in Korea.

Relevant Act/Regulation	Pharmaceutical law
Responsible Authority & Division	Ministry of Food and Drug Safety (MFDS) (Pharmaceutical Policy Division)
Recommendation Status	New

13. Separate Standards for Advertisements for General Consumers and Medical Professionals are Required

Issue

According to the scope of prohibited advertisements under the current Enforcement Rules of the Medical Device Act [Appendix 7], there is no premise regarding the specific audience that accepts advertisements. Medical devices can be advertised to a variety of targets, from general consumers to medical professionals, depending on the characteristics of the product, and the purpose and content of advertisements may differ depending on the target audience. Since there is a difference between general consumers and medical professionals in terms of the degree of their medical knowledge and the purpose of watching advertisements, separate standards for advertisements targeting medical professionals are required.

Recommendation

It is recommended that the current medical device advertisement review be conducted separately by classifying them into advertisement for general consumers and for medical professionals. In addition, it is recommended to revise the current Enforcement Rule of the Medical Device Act [Appendix 7] by classifying the scope of prohibited advertisements into those for general consumers and for medical professionals so that medical professionals can understand products more effectively and accurately by describing the performance, efficacy, and effect of the product using photos before and after use etc. and therefore, the medical industry can develop.

Relevant Act/Regulation	Enforcement Rules of the Medical Devices Act
Responsible Authority & Division	Ministry of Food and Drug Safety (MFDS)
Recommendation Status	New

14. Provide Opportunity to Participate in the Service Fee Expert Committee for Major Infectious Diseases Requiring New Service Fee

Issue

An outbreak of microbial infection is becoming a periodical event in recent 10 years, and it raised the awareness for in-vitro diagnosis. It also provided the notion to recognize the importance of accurate and rapid diagnosis of infections by micro-organisms (virus, bacteria, fungi, and parasite) in infection management controls.

Technology advancement has led to the invention of rapid diagnosis of pathogens as well as antimicrobial resistance genes within an hour while the value of the new technology has not been recognized due to the setting of same pricing with existing PCRs testing.

Compared to therapeutic materials and drugs, the cost of in-vitro diagnostics is included in the service fee, and therefore establishment or adjustment of fee is decided at the Service Fee Expert Committee.

In case of therapeutic materials, in-depth review categories (adjustment for separate reimbursement, value-appraisal, sub-category creation etc.) require detailed review scope and therefore, if the applicants request to participate in the Device Expert Committee, he or she is given the opportunity to officially provide opinions regarding the grounds for development of new technology, clinical benefit, and clinical potentials to health outcomes.

According to the Article 13 clause4 of [Decision Criteria and Standards for Service Fee and Therapeutic Materials], it allows the applicants of new service fee or device fee to participate in each relevant Expert Committee to provide opinions. However, requesting new service fee for in-vitro diagnosis is not the review on specific medical device, nor separately reimbursed, and the applicant usually request to each hospital after performing the first procedure. Therefore, it is not possible for the IVD manufacturer/importer to engage in the official process of new service fee assessment and explain about new technologies for in-vitro diagnostics, particularly for diagnosing primary microorganisms that cause infectious diseases, and their advantages.

Moreover, the decisions regarding critical infectious disease diagnosis are often decided by directives of MOHW, making it less approachable for the manufacturer/importer to officially provide expert opinions of the inventors.

Recommendation

It is recommended that the Service Fee Expert Committee prepare a formal process for the technology providers such as manufacturer/importer to participate in the Committee and provide opinions on the fee of new infectious disease diagnosis.

Relevant Act/Regulation	Decision Criteria and Standards for Service Fee and Therapeutic Materials
Responsible Authority & Division	Ministry of Health and Welfare (MOHW), Health Insurance Review & Assessment Service (HIRA)
Recommendation Status	New

15. Inclusion of Utilising Rapid AMR Tests in the National Antimicrobial Stewardship Program

Issue

According to the 'evaluation of appropriate use of antimicrobials' by Health Insurance Review and Assessment Service (hereafter HIRA), the prescription rate of antimicrobials on acute upper respiratory infection has improved (73.3% in 2022 to 38.3% in 2019) because of the appropriateness evaluation of the antimicrobials use while there still exists inappropriate prescription of antimicrobials in other infections.

Due to the COVID-19 crisis, the number of prescribing antimicrobials has increased, and the resistance rate is expected to be constantly increased as well. As a result, an evidence-based policy by identifying the current status of resistant bacteria in Korea has been promoted.

The recent [National Plan on Antimicrobial Stewardship Program] jointly published by the relevant departments in 2021 mentioned that there are performance indicators on antimicrobials achieved by 2025 and the development of rapid test on Antimicrobial Resistance as well as the expansion of national AMR control system were included as performance indicator of objective 4.

However, the Plan does not include the contents on utilizing current or existing technology of rapid diagnostics on AMR.

Even though the existing rapid test best fits the purpose of antimicrobial stewardship, it is not actively utilized due to the lack of incentives or financial support to boost the practical use at clinical setting.

Recommendation

It is recommended to include the contents on promoting the use of the rapid test for Antimicrobial Stewardship in the National Plan.

To be specific, it is recommended to prepare a mechanism to implement the use of simultaneous inspection of several infectious diseases such as acute lower respiratory tract infection and sepsis which requires timely intake of appropriate antibiotics and antimicrobial resistance genes.

Relevant Act/Regulation	The 2nd National Plan for Antimicrobial Stewardship Program (2021~2025)
Responsible Authority & Division	Ministry of Health and Welfare (MOHW), Korea Disease Control and Prevention Agency (KDCA)
Recommendation Status	New

16. Request of Set Up for Communication Channels between Private-Public and Academic when Introducing New Vaccine and Selecting Candidate Vaccines of National Immunization Program (NIP)

Issue

While the existing vaccine introduction evaluation manual is a procedure for selecting candidate vaccines that have the potential to be included in the National Immunization Program (hereafter NIP), the most important partner in the national introduction of new vaccines and its implementation which is industry is completely excluded from the procedure of the manual that proceeds in 6 steps.

The vaccine industry has extensive information and expertise on diseases, vaccines, R&D situations, and global vaccine trends. If the Korean government actively cooperates with the vaccine industry to formulate a strategic plan and support it, it is predicted that the safety of Koreans will be more effectively protected from infectious diseases.

It is important to understand the mid- to long-term direction of the government's vaccine policy through an official channel through which the Korean government can share the expertise of the vaccine industry and consider ways to improve it and establish a structure in which the vaccine industry can actively cooperate and support them.

The criteria for selecting candidate vaccines according to the manual is an approach based on universal welfare, focusing on expanding the benefits of vaccines to broaden range of people or preventing new diseases. In fact, according to the list of 9 vaccines

to be reviewed for priority evaluation presented by the NECA (National Evidence-based Collaborating Agency), the main factors are the expansion of the target population and the prevention of new diseases. It is to be thought that academics, health authorities, and vaccine industry should consider in-depth together about improving the immunogenicity according to age-specific characteristics within the existing system and efficiently developing the current system in consideration of socioeconomic effects.

Recommendation

It is recommended to establish a formal communication channel and a public-private-academic joint consultative body to construct mid- to long-term strategies (In the case of pharmaceutics, a public-private consultative body channel was created with the Ministry of Health and Welfare and Health Insurance Review and Assessment Service).

First, it is recommended to prepare an official communication channel where objective and scientific data can be sufficiently reviewed from various perspectives in the case of a demand survey for the introduction of new vaccines by expanding the scope of the survey to vaccine companies (manufacturers/importers).

In addition, it is recommended to establish a public-private-academic consultative body to consider mid-to-long-term measures that are the most effective and can optimize the value of vaccine administration in consideration of Korea's demographic characteristics and socioeconomic aspects.

Relevant Act/Regulation	N/A
Responsible Authority & Division	Korea Disease Control and Prevention Agency (KDCA)
Recommendation Status	Updated

17. Improvement of Risk Classification Evaluation Standards for National Lot Release Products (Vaccine)

Issue

One of the biggest portions on the evaluation of risk classification is the number of batch released to Korean market when referring to Attachment (Guideline-0072-02) from risk evaluation chart for test item differentiation for National Lot Release products.

However, the proportion of risk score for the number of batch released in Korea for the last 2 years is quite high than others.

In the case of imported vaccines, the number of local releases does not exceed 10 batches/year in most cases and even though the vaccine has been proven to be safe with hundreds of batches release to global, it is difficult to expect getting a Grade 1 under the current evaluation system which is evaluated by the number of domestic releases of batch.

Recommendation

It is recommended to adjust the portion of the risk score on the number of local batch release.

In order to comprehensively and substantially verify the risk of the product, it is recommended that the number of release of the manufacturer in the case of the importer and the number of overseas export release in the case of the local manufacturer be included as an evaluation criteria of the risk. For example, it is recommended to reflect the number of release for overseas manufacturers (or the number of overseas exports of local manufacturers) (weighting 70% of local lot release and 30% of overseas lot release) to the existing evaluation criteria.

Relevant Act/Regulation	Act on National lot release assignment, approval process and its procedures Guideline on Risk classification evaluation on National Lot Release products
Responsible Authority & Division	Ministry of Food and Drug Safety (MFDS) (Biomedicinal product Policy Division), National Institute of Food and Drug Safety Evaluation (Testing Division)
Recommendation Status	Retained

18. Creating a Mutual Recognition Agreement (MRA) with the European Union (EU)

Issue

The Ministry of Food and Drug Safety (MFDS) accepted the recommendation in 2019 with sharing their plan of policy research and timeline while MFDS responded the recommendation is not acceptable in 2020.

As a member country of Pharmaceutical Inspection Co-operation Scheme (PIC/s), Korea maintains high quality standard in drug manufacturing and inspection. The European Commission (EC) has been signing a Mutual Recognition Agreement (MRA) with PIC/s member countries such as Australia, New Zealand, Israel,

Japan, Switzerland, US, etc.

In order to establish a prompt and efficient distribution procedure of pharmaceutics including vaccines, the expansion in MRA between the EC and Korea is crucial.

Recommendation

It is recommended to eliminate the duplicated quality inspection process for the products which has co-manufactured under the CMO contract made in the EU and CMO companies and are finalized manufacturing and packaging in Korea so that both the EU and Korea can understand the necessity of the MRA.

As the proposed amendment which allows a waiver of special QC testing in case of urgent situation such as COVID-19 or there is a domestic consignment manufacturer is currently pending in the National Assembly, it is clear that this project is a high demand of the public.

In addition, it is recommended to first exempt the items that can be replaced by submitting quality management data for individual QC test.

For example, in case of vaccines and biopharmaceuticals, QC testing exemption for the individual batch can be possible when manufacturer submit the temperature management data and manufacture quality management summary for the imported products.

Relevant Act/Regulation	Enforcement Regulation on the Safety of Drugs, etc. Regulations on Manufacturing and Quality Control of Drugs
Responsible Authority & Division	Ministry of Food and Drug Safety (MFDS) (Pharmaceutical Quality Division, Biopharmaceutical Policy Division)
Recommendation Status	Retained

19. Recognising the Proper Value of Vaccines with Pricing Guideline with Standardized Evaluation Indicators

Issue

While the price of a vaccine is determined by the efficacy, safety, and convenience related to its application according to the general principle of the "Guideline on deciding the supply price of a vaccine for NIP", extensive values from societal perspectives are yet to be reflected.

With the current pricing method, price of a vaccine is determined based on subject's efficacy and safety that have already been evaluated during the approval process and does not embrace various aspects of a vaccine such as the value of innovation and the health outcomes it can bring into society, and thus, needs to be improved.

In addition, the current pricing guidelines focus on a low-cost approach rather than acknowledging the societal value of vaccines designed to improve public health and quality of life and moreover, the criteria for pricing are not clearly established yet.

The value of vaccines should be evaluated on a more objective and clearer basis to ensure a stable supply and continued investment of innovative vaccines that will protect public health from epidemics.

Recommendation

In the case of pharmaceuticals, 1. Clinical usefulness including replaceability, severity of disease, therapeutic benefits, 2. Cost-effectiveness such as the cost of medication, the degree of improvement of clinical effectiveness, health economics results, 3. Financial Impact on health insurance such as the number of patients covered, estimated usage, and the effect of replacing existing drugs/treatments, 4. Foreign Status, 5. Other impact on health care are comprehensively evaluated by the Drug Reimbursement Evaluation Committee(DREC) to determine reimbursement and ceiling price.

Therefore, it is recommended to systematise the vaccine pricing guideline so that the overall value can be quantitatively evaluated and reflected in the price by standardised evaluation indicators such as health economics results, budget impact, effects on replacing existing vaccines, and stable supply availability.

Furthermore, it is recommended that the procedure for notifying the company of the results within a certain period of time and of

the rationale for the price discussed at the expert advisory meeting such as KECIP (Korea Expert Committee on Immunization Practices) to be established so that the trust in the evaluation results can be built between the government and the supplier.

Relevant Act/Regulation	Guideline on Deciding the Supply Price of a Vaccine for NIP
Responsible Authority & Division	Korea Disease Control and Prevention Agency (KDCA)
Recommendation Status	Retained

20. Taking Measures to Encourage the Inoculation of Combination Vaccines through Improving the Administration Fee System

Issue

Combination vaccines greatly contribute to improving VCR and timely immunization by reducing the number of vaccinations and visits to medical institutions, thereby benefiting all vaccinees, their caregivers, and health care professionals.

Currently, combination vaccines are widely used all around the world, and it is conceivable that measures to further encourage the use of combination vaccines should continuously be developed so that Korea can also meet global standards.

Although the administration fee for tetravalent or higher combination vaccines are set higher than trivalent or less vaccines by adding 50% of the vaccination administration fee, they are still quite low compared to administration fee for vaccines when given separately. Under such circumstances, the inoculators should even inform the caregivers on new vaccination options and give additional consultations on safety.

Therefore, in order to guide inoculators to voluntarily encourage combination vaccinations, additional compensation schemes for administration costs need to be discussed.

Recommendation

It is recommended to establish a patient centered vaccination system by encouraging vaccination of combination vaccines through improvement of administration costs, and furthermore, in the long run, lay the groundwork for global companies to introduce new combination vaccines in Korea and at the same time, encourage domestic companies to invest in R&D.

In addition, it is recommended to set more suitable inoculation fee policy to guide inoculators to encourage combination vaccines and thereby provide the best vaccination options for the vaccinees and their caregivers while considering societal cost savings such as transportation and productivity loss like the case of the United States which increased the inoculation rate of combination vaccines by recognizing each component and reimbursing the inoculation fee.

Relevant Act/Regulation	Pricing Criteria for the Cost of Vaccination Administered by Commissioned Medical Institutions
Responsible Authority & Division	Korea Disease Control and Prevention Agency (KDCA)
Recommendation Status	Retained

21. Normalisation of Sharing of National Vaccination Data/ Data Segmentation and Refinement

Issue

Regarding the request for sharing big data, the response of the relevant ministry was 'National Vaccination Data are being regularly shared, monthly and quarterly.' However, data has not been shared since the first quarter of 2021 (https://nip.kdca.go.kr/irgd/index.html).

In addition, regarding the request of data segmentation which enable the demand forecast to secure stable supply, the response of the relevant ministry was 'it would review various ways of analysis and sharing of data'. However, there has been no progress yet.

Recommendation

It is recommended to consistently share the information on of national vaccination registration status through the vaccination helper site that has not been shared since the first quarter of 2021.

Furthermore, it is recommended to segment and refine the data to secure stable supply and accurately forecast demand as follows:

- Provision of individual data of Td and Tdap (While the two products are different product groups, it is difficult to accurately determine demand because the current data is mixed)
- Disclosure of more detailed data by region and age of vaccination (disclosure level of COVID vaccination information)

Relevant Act/Regulation	N/A
Responsible Authority & Division	Korea Disease Control and Prevention Agency (KDCA)
Recommendation Status	Updated

22.
Standardisation of CVS Drug Classification Decision Criteria and Transparency in Designation Committee's Operation Plan

Issue

There has been no change in the list of CVS drug since 2012 when 13 products were designated.

However, as there is no separate criteria, procedure or review period of designating drugs and agenda and results of the review of the meeting of the Designation Committee are not known in detail, it is necessary to establish a system to maintain transparent decision-making.

Recommendation

It is recommended to share meeting summary (discussion agenda and results) and operation plans of the Committee and establish specific standards and legal basis regulations in regard to the designation of drugs.

Relevant Act/Regulation	Announcement on designation of safe household medicine
Responsible Authority & Division	Ministry of Health and Welfare (MOHW)
Recommendation Status	New

Siyoon Kim
Manager,
ICT Committee

ICT

1

Total Key Issue

1.
Cloud Security Assurance Program (CSAP)

Issue

Today, for services provided to the citizens, public institutions such as the central government can use G-Cloud, however, local governments' use is limited to a dedicated cloud that others cannot access.

Other public institutions/agencies may use private cloud systems, but cloud service providers must be certified according to the Cloud Security Assurance Program (CSAP), a certification system that certifies the security of a cloud system, administered by the Korea Internet & Security Agency (KISA). There are currently 23 companies certified by KISA, which are all Korean companies. The reason for this situation lies primarily in the fact that the CSAP requires essential manpower resources to be located in Korea. Foreign companies instead ensure having sufficient resources by utilising global service partnerships to operate or manage data centers.

The ECCK understands that the main motivation of CSAP is to ensure the highest possible level of security, but also believes that same quality of security can be achieved if employees based and working abroad are qualified in the field and apply the latest business processes.

Recommendation

It is recommended to introduce a system of reciprocity to acknowledge a global certificate for guaranteeing security in the cloud security regulation and to allow remote operation rather than requiring operating entities to reside in Korea as a prerequisite.

Relevant Act/Regulation	Article 23 Paragraph 2 of Cloud Computing Development and User Protection Act
Responsible Authority & Division	Ministry of Science and ICT (MSIT) (Internet and Digital Technology Promotion Division)
Recommendation Status	Retained

Siyoon Kim
Manager,
Insurance
Committee

Insurance

3
Total Key Issues

1. No Official Notification to Non-Members on the Amendment of Insurance Act/ Enforcement Decree and Regulation of Supervision on Insurance Business by General Insurance Association

Issue

Currently, the General Insurance Association of Korea (GIAK) excludes non-members (e.g. most of foreign (re)insurers in Korea) from being notified of amendments of Insurance Business Act, Enforcement Decree and Regulation of Supervision on Insurance Business including updates of sanctions (e.g. Russia etc.) by General Insurance Association of Korea.

Non-members are mostly foreign (re)insurers, and one person handles all legal matters related to work as well as other work simultaneously. In this regard, it is difficult to comply with the amended law/ regulations without an official notification procedure. Based on Sub-paragraph 3, Paragraph 3, Article 175, GIAK has an obligation to execute work entrusted by the government. Also, it is requested that GIAK inform the insurance industry (i.e. not only members of GIAK) when the government informs the amendments of Insurance Business Act, Enforcement Decree and Regulation of Supervision on Insurance Business including financial/trade sanctions.

Recommendation

It is recommended that GIAK include non-members when it informs members the amendments of Insurance Business Act, Enforcement Decree and Regulation of Supervision on Insurance Business.

Relevant Act/Regulation	Article 175 Insurance Business Act, Sub-paragraph 3, Paragraph 3
Responsible Authority & Division	Financial Services Commission (FSC) (Insurance Division)
Recommendation Status	New

2. Standardisation of Two-wheeled Vehicle Repair Criteria

Issue

Due to the recent rapid growth of the motorcycle market, the number of registrations and accidents of two-wheeled vehicles is increasing. However, most two-wheeled repair shops write repair quotations manually when charging repair costs which causes limitations in effective loss adjustment. Also, due to the non-standardisation of auto part prices, there is lack of transparency as most auto part prices, and labour costs are charged not separately. Moreover, lack of standardised working time causes dispute as there is no reliable repair working time between the two industries, thus, the level of insurance consumers' complaints is high.

Recommendation

It is recommended to standardise the repair criteria for two-wheeled vehicles to minimize the number of disputes and gain trust by providing clear repair cost information to insurance consumers. Specifically, it is recommended to adopt a standardised repair cost quotation system between two-wheeled vehicle repair shops and the insurance industry. Also, we would like to recommend the division of repair costs according to working hours, auto part prices, and labour costs in order to improve the calculation of repair costs objectively. We believe that the connection of standardised systems to the computer network could secure trust and contribute to enhanced effective loss adjustment.

Relevant Act/Regulation	Guarantee of Automobile Accident Compensation Act, Automobile Management Act
Responsible Authority & Division	Ministry of Land, Infrastructure and Transport (MOLIT) (Automobile Operation Insurance Division)
Recommendation Status	New

3. Exemption Against Accidents while Driving Under the Influence of Drugs, Narcotics, etc.

Issue

The Financial Supervisory Service (FSS) is promoting the improvement of the automobile insurance system to reduce the number of deaths from traffic accidents. In the case of automobile insurance, the detailed enforcement regulation of insurance business supervision has been revised by newly establishing an accident charge for drug-driving at the same level as drunk-driving in order to raise awareness of serious violations of the law and to prevent accidents. (Enforcement of contract on the date of liability commencement in 2022).

Although driver insurance has the nature of insurance that covers criminal and administrative penalties in the event of traffic injuries, it is stated that, 2. Among the special clause regarding expenses, in case of traffic accident settlement subsidy, accident fine during driving, accident attorney appointment expense coverage, 'Article 3 (Reasons for not providing claim) 6. Accidents which the insured occurred during driving under the condition of alcohol or without any license stated in Articles 43 and 44 of the Road Traffic Act' is not compensated.

This is because the risk of occurrence of traffic injuries as a result of drinking under the influence is higher than that of general traffic injuries, and it is included as a prohibition in Articles 43 and 44 of the Road Traffic Act. Recently, since the frequency of accidents occurring while driving under the influence of drugs is increasing, and it is becoming a social issue, it is suggested to review the revision of special clauses of the driver insurance.

Recommendation

The authority is already reviewing the issue as a long-term task, and relevant institutions such as the Anti-Corruption and Civil Rights Commission (ACRC) are paying immense attention to it. In this regard, it is recommended to highlight and re-address this issue considering the revision and implementation of automobile insurance, urgency, and social impact of the matter.

We would like to suggest a revision of the special clause regarding the expense 'Article 3 (Reasons for not providing claim) 6. Accidents which the insured occurred during driving under the condition of alcohol or without any license stated in Articles 43 and 44 of the Road Traffic Act' to 'Article 3 (Reasons for not providing claim) 6. Accidents which the insured occurred during driving under the condition of alcohol or without any license or under the condition of drug and narcotics stated in Articles 43 and 44 of the Road Traffic Act'.

Relevant Act/Regulation	Terms and Conditions of Driver Insurance
Responsible Authority & Division	Financial Supervisory Service (FSS) (Insurance Supervision Division)
Recommendation Status	Updated

Eunsung Na
Manager,
Intellectual
Property Rights
Committee

11
Total Key Issues

Intellectual Property Rights

1. Studies About Economic Impact of IP Infringement

Issue

The Korea Institute of Intellectual Property (KIIP)'s previous research in 2018 on the 'Analysis on Economic Contributions of IP-intensive Industries'[1] provided meaningful background information and context on the contribution of IP-intensive industries to Korea's economy, particularly in relation to GDP, employment, wages, R&D investment, and advertising spending. Key findings from this research indicate significant contributions and growth in the importance of contributions of IP-intensive industries to the Korean economy. These findings have served as a useful reference and encouragement for businesses to understand the importance of investing in IP as well as its protection. According to the European Commission (EC) report[2] published in April 2021, the findings of KIIP's research provide valid quantitative confirmation of the importance of IPR in Korea and will help increase the profile of IPR protection in Korea.

The European Union (EU) publishes various reports on the infringement of intellectual property rights such as the Status Report on IPR Infringement[3], Global Trade in Fakes[4], etc., and through these reports, the EU provides updated information on the importance of intellectual property rights, measures to combat infringement, trade trends and new distribution methods of counterfeits, etc. This is indeed useful information in that it provides a quantitative analysis on the infringement of intellectual property rights and its impact on the economy. However, in Korea, research on the infringement of intellectual property rights is limited and the issue of distribution of counterfeits has not been dealt with from a national security perspective. In this regard, in addition to improving public awareness, detailed and continuous investigation and analysis on counterfeits

1. The Korea Institute of Intellectual Property (KIIP). (2018). Analysis on Economic Contributions of IP-intensive Industries
2. European Commission. (2021). Report on the protection and enforcement of IPR in third countries
3. European Union Intellectual Property Office. (2020). Status Report on IPR Infringement
4. OECD and European Union Intellectual Property Office. (2021). Global Trade in Fakes
5. Siyeol Kim. (2022). Key Points and Implications of the OECD-EUIPO Joint Report on Global Trade in Fakes. Korea Institute of Intellectual Property. IP Focus (2022-04)

affecting national security[5] as well as a quantitative study on IP infringement at the community level are needed.

Recommendation

Following the 2018 'Analysis on Economic Contributions of IP-intensive Industries', it is recommended that further quantitative research be conducted to understand the economic and social impact of IPR infringement.

Relevant Act/Regulation	N/A
Responsible Authority & Division	Korea Institute of Intellectual Property (KIIP)
Recommendation Status	Updated

2. Reasonable Sentencing for IP-Related Crimes as Effective Deterrents

Issue

Korea continues to enhance IP protection by expanding its punitive damages system to include design and trademark infringements further from patents and trade secrets cases and changing the crime of infringement of design rights and utility model rights from "crime subject to prosecution on complaint" to "crime not punishable against victim's will".

However, the low level of criminal sentencing imposed for IP infringement in Korea is still considered to be hindering effective prevention of IP infringement. The Korean Copyright Act allows for up to five years of imprisonment or a financial penalty of up to KRW 50 million, and the Trademark Act, Design Protection Act and Patent Act allow for up to seven years of imprisonment or a financial penalty of up to KRW 100 million in case of infringement. Unfortunately, the actual sentences handed down in IP infringement cases remain low compared to other developed nations. The level of sentencing in Korea was also deemed a 'systemic deficiency' as it was "considered insufficient to ensure adequate deterrence against IP infringements with regard to counterfeit and pirated goods"[6].

Particularly for actors involved in creating, distributing, and selling counterfeits "penalties and sanctions are key deterrents, as these actors will prefer to trade in goods where the rewards are highest, and the risks are lowest"[7]. While counterfeiting is met with actual prison sentences in various IP advanced countries, prison sentences on a probation basis or a relatively low amount of fines are commonly handed down to sellers of counterfeits in Korea.

6. European Commission. (2021). COMMISSION STAFF WORKING DOCUMENT - Report on the protection and enforcement of intellectual property rights in third countries.
7. OECD. (2018). Governance Frameworks to Counter Illicit Trade

Recommendation

It is recommended that the level of criminal sentencing for IP infringement be increased and further extended for repeat offenders to effectively prevent IP crime. To this end, it is recommended to increase awareness of the importance of IP and enhance understanding of the lucrative nature of the counterfeit industry so that all enforcement and judicial officials understand the implications of IP infringements and can take proper measures.

Relevant Act/Regulation	N/A
Responsible Authority & Division	Patent Court of Korea
Recommendation Status	Retained

3. Strengthening Border Measures Against IP Infringing Goods

Issue

The role of the Korea Customs Service and Customs Offices in protecting IP rights is crucial as border measures against counterfeits are the most effective to prevent IP infringement. Considering today's advanced distribution system, once counterfeits have already entered the market, tremendous amount of administrative power and personnel are required to crack down on those counterfeits and therefore, "it is clear that institutionalizing the way of stopping IP infringing goods at the border is the most efficient way of combating IP infringement"[8].

8. Junha Kang. (2018). Review on Border Measures for the Protection of Intellectual Property Rights. Journal of International Trade and Industry Studies, 23(4), 97-125.

It is deeply appreciated that the Korea Customs Service and frontline Customs Offices have continued to strive to seize IP counterfeits at the border and have provided continuous IPR training to improve employees' capabilities even during the COVID-19 crisis. However, the training for regional customs officials cannot be conducted in the first quarter of every year.

It has been noticed that most of the counterfeits distributed in Korea are imported from China and other countries rather than produced domestically. Therefore, it is important that the Customs Offices increase the current level of inspection of counterfeits and its manpower while improving expertise and capacity of customs officials to effectively seize counterfeits. In addition, it is necessary to establish a system that allows customs officials to be constantly motivated to detect intellectual property infringement items during the customs clearance process.

Recommendation

To keep pace with global trade growth, it is recommended that the current level of inspection rate, as well as the number of officials assigned to detect or conduct investigation on IP infringing goods, be increased.

In addition, to continuously strengthen the expertise of customs officials, it is recommended that the training of customs officials be conducted from the first quarter, and that customs officials be given more opportunities to participate in training sessions and seminars on IPR, including ECCK capacity building seminars.

Finally, it is recommended that a system which provides incentives to related officials be established and implemented, to ensure they recognise the importance of detecting IP infringing items and be continuously motivated.

Relevant Act/Regulation	N/A
Responsible Authority & Division	Korea Customs Service (KCS) (Inspection Policy Division)
Recommendation Status	Updated

4. Enforcement against Parallel Importers Infringing IPRs

Issue

It has been a concern for IP owners that some parallel importers or sellers have been found to be infringing intellectual property rights. Some recent observations are as follows:

Over the past few years, parallel importers have abused parallel importation, which is legal under the Korea's Trademark Act, to import counterfeits in various malicious ways. For example, importing a mixture of authentic and counterfeit goods in a package can make it difficult to determine the authenticity of the imported products.

Recommendation

It is recommended that parallel importation of counterfeits be properly scrutinized so that only authentic products can be imported through parallel importation to the extent that the function of trademark is not impaired. Actions such as false customs declaration and payment and document forgery and fraud especially should be thoroughly investigated to deter these malicious activities.

Relevant Act/Regulation	Trademark Act
Responsible Authority & Division	Korea Customs Service (KCS) (Inspection Policy Division)
Recommendation Status	Updated

5. Enforcement against Resellers Infringing IPRs

Issue

It has been a concern for IP owners that some resellers, including sellers of pre-loved products, were found to infringe intellectual property rights. Some recent observations are as follows:

Resellers of new genuine products or pre-loved items are infringing IPR by using protected trademarks and logos, advertisements, or digital creations without authorisation. These activities are likely to mislead consumers into believing that there exists a partnership between the resellers and brand owners, or that the resellers are the brand owners.

Recommendation

It is recommended that the unauthorised use of trademarks by resellers engaging in commercial activities be continuously monitored and strictly restricted by taking proper measures.

Relevant Act/Regulation	Trademark Act
Responsible Authority & Division	Korean Intellectual Property Office (KIPO) (Intellectual Property Protection Policy Division)
Recommendation Status	Updated

6. Annual Statistical Report on IPR Seizures at Customs

Issue

The Annual Statistical Report on IPR Seizures published since 2015 by the Korea Customs Service are valuable resources as they provide constructive statistics and cases of IP infringement in Korea. The publication of such reports demonstrates the Korea Customs Service's efforts to prevent and fight against IP infringement.

However, it is difficult to assess the exact size and trends of total seizures since this report has utilised 'weight (in kilogram)' to quantify seized products, indicating the size of total seizures as well as seizures by type of IPR, customs, item, country of shipment, and means of transportation. When seizures are quantified by weight, it is difficult to accurately determine the scale and variation of

the seizures due to the large difference in weight, depending on the characteristics of confiscated goods that vary from year to year. For this reason, statistics on IP infringement published by major countries/authorities, including the EU Commission and Japan, state "pieces" of seized items (rather than weight) in their customs reports.

While the report works as a useful resource for IPR holders and domestic and foreign IPR departments, it takes more than a year for the report to be published. Therefore, it is difficult to determine the size of the current counterfeit market or to obtain accurate information on the trend of counterfeit importation based on the amount seized during the customs clearance process provided in the report.

Recommendation

As the publication of yearly reports on IPR seizures demonstrates KCS' efforts to protect intellectual property rights on a global level, it is recommended that the KCS align the counting units of IPR seizures, from weight to the number of seized items, with other major countries like Japan and the European Union. This will allow the public to accurately assess the scale and variation of seizures, regardless of the characteristics of the seized goods.

In addition, it is recommended that Annual Statistical Report on IPR Seizures at Customs be published by the first half of the following year so that the public can obtain more timely data on the status of imports of counterfeits.

Relevant Act/Regulation	N/A
Responsible Authority & Division	Korea Customs Service (KCS) (Inspection Policy Division)
Recommendation Status	Updated

7. Enhancement of Effectiveness of EMS Project

Issue

Since the Korea Customs Service amended Article 8-2 of the Regulation of Customs Clearance of International Mail Items, officials were given the authority to seize and store counterfeits, rather than return these illicit products to their senders in 2018. Given this context, an initiative was launched by the KCS and industry representatives (Express Mail Service (EMS) project), to detect counterfeits more effectively through the swift assortment of parcels, authentication of products, and building of a parcel database. A further noteworthy development is the expansion of the EMS project to include parcels arriving at ports as well as parcels imported through private courier services in 2020.

While the EMS project is an effective initiative that capitalises on the cooperation of various stakeholders, structural improvement is needed to reach its full potential. First, considering the vast number of international parcels coming into Korea, only a handful of customs officials are assigned to the task, which makes it difficult to detect and manage counterfeits coming to Korea using the international parcel services. Secondly, not enough space to store seized goods is secured, slowing down the EMS project.

In addition, the Korea Customs Service has conducted special customs clearance measures, one to two times a year, to intensively crack down on express/postal items during the peak season of overseas direct purchases, and at this time, the number of seized counterfeits is extremely high. In addition, according to the Korea Customs Service, more than 98% of counterfeits are imported as express/postal items with relatively simple import procedures[9].

9. Korea Customs Service, Trade-related IP Protection Agency. (2021). 2020 Annual Statistical Report: Intellectual Property Rights Seizures

Recommendation

To allow the EMS project to reach its full potential, it is recommended that additional manpower be assigned to the detection and management of international parcels coming to Korea, and additional warehouse space be allocated to the storage of parcels seized through the EMS project.

In addition, it is recommended to increase the frequency of intensive crackdowns on express/postal items, which is conducted 1-2 times a year, to be carried out at least 3-4 times a year.

Relevant Act/Regulation	Regulation of Customs Clearance of International Mail Items
Responsible Authority & Division	Korea Customs Service (KCS) (E-Commerce Division), Korea Post (International Postal Logistics Centre)
Recommendation Status	Updated

8.
Designation of Special Judicial Authority to Local Government Officials

Issue

Industry is pleased that the sale of counterfeits in public has been rooted out at most popular tourist sites in Seoul, thanks to Seoul Metropolitan City's government officials who were designated to serve as Special Judicial Police since 2013, and is honoured that the ECCK contributed to this success by establishing a joint initiative between industry and Seoul Metropolitan City.

It is expected that such achievement can be made not only in Seoul Metropolitan City but also in Busan International Market and Daegu Seomun Market where counterfeits are sold in public.

As witnessed in some cases in Seoul, it is far more effective to root out the sale of counterfeits in public when a municipality that understands the characteristics of its region very well is involved in educating local residents and conducting frequent crackdown activities. To this end, the ECCK is prepared to actively collaborate with local government officials by providing capacity building seminars to help them develop their expertise in anti-counterfeiting activities. In addition, it is also expected that local government officials will be able to acquire expertise in the field through the joint crackdown that will resume this year.

Recommendation

It is recommended that local government officials of Busan and Daegu Metropolitan City request the Prosecution Service to assign them special judicial authority to investigate counterfeiting activities and seize illicit products pursuant to Articles 5 (38) and 6 (35) of the Act on the Judicial Police Officers and the Scope of Tasks.

Relevant Act/Regulation	Act on the Judicial Police Officers and the Scope of Tasks
Responsible Authority & Division	Busan Central District Office (Economic Promotion Division), Daegu Central District Office (Employment Economy Promotion Division)
Recommendation Status	Updated

9.
Enforcement Against Lookalike Products

Issue

Counterfeiters have sought inventive ways to circumvent the law and enforcement activities against counterfeits. To avoid seizures and enforcement actions, counterfeiters have looked at alternate methods to free ride on famous brands' attractiveness and mislead consumers. For example, some counterfeiters display unfinished products which contain the same shape as the genuine ones but without bearing any trademarks to which could be added after the product is sold. Moreover, others are selling products with removable parts that could reveal trademarks after removal.

According to Article 108 of the Trademark Act, using a trademark identical or similar to a registered trademark of another person on goods identical or similar to the designated goods can be deemed as trademark infringement and, therefore, sale of lookalike products constitutes a violation of the Trademark Act. However, enforcement activities tend to revolve around the seizure of products containing identical trademarks rather than lookalike products. The scope of protection of the trademark through trademark registration includes not only the logo of the product, but also the design, shape, etc. Therefore, if the use of a similar trademark by third parties confuses consumers, it is trademark infringement and lookalike products should be actively cracked down on so that they cannot be distributed in the market.

Recommendation

It is recommended that enforcement officials include products containing marks that are similar to protected trademarks during raids, considering these new practices of counterfeiters.

To this end, the ECCK and its members stand ready to assist officials in their enforcement activities by providing them with useful knowledge and tools on intellectual property rights.

Relevant Act/Regulation	Trademark Act
Responsible Authority & Division	Seoul Metropolitan City Special Judicial Police Bureau for Public Safety, Busan Central District Office (Economic Promotion Division), Daegu Central District Office (Economy Division)
Recommendation Status	Updated

10.
Systematic Supplement to Prevent the Distribution of Counterfeits by Online Service Providers

Issue

As e-commerce has been promoted due to COVID-19, the distribution of counterfeits via online platforms has also increased rapidly. In addition to online open markets, social media has become a major tool for transacting counterfeits, and it exposes consumers more easily to illegitimate products. Although online service providers (or online platforms) pave the way for digital transformation, they also cause problems due to the core of their business model that creates value by engaging various market players, usually consumers and sellers. Some online platforms take their own measures to prevent the sale and distribution of counterfeits, but the level of their practices varies substantially due to a lack of a legal framework.

While the Act on Consumer Protection in Electronic Commerce, etc. has been amended in 2017 to improve the reliability of online marketplaces in response to their growing role in the national economy, these amendments are not sufficient enough to combat the rise of online counterfeit sales and to properly protect consumers.

Recommendation

The ECCK is pleased that the KIPO considers amending the Trademark Act to impose liability on online service providers for the distribution of counterfeits as mentioned in the KIPO's response to ECCK's White Paper 2021 and its announcement last October regarding 'Plan on Online Prevention of Counterfeits'. It is additionally recommended that discussions such as roundtable meetings among all stakeholders, including trademark holders, online marketplaces, and social media be held continuously to draw meaningful opinion collection and thus achieve a resulting revision of the Trademark Act.

Relevant Act/Regulation	Trademark Act
Responsible Authority & Division	Korean Intellectual Property Office (KIPO) (Trademark Examination Policy Division)
Recommendation Status	Updated

11.
Stakeholder Cooperation on Online Enforcement

Issue

To combat online counterfeit sales, the European Union took the initiative to sign a Memorandum of Understanding (MoU) in 2011 between online platforms and IP rights owners, including trademark holders, followed by an MoU in Thailand and the Philippines in 2021.

10. European Commission. (2020). Report on the functioning of the Memorandum of Understanding on the sale of Counterfeit Goods on the internet

According to a report[10] published by the European Commission in 2020, the MoU serves as a worthwhile means of exchanging information and ensuring effective cooperation between signatories. The MoU is considered useful to facilitate constructive dialogue focusing on new trends, such as design infringements, emerging fraud patterns, and variation in consumer behaviour. In addition, it contributes to an examination of the impact of the COVID-19 crisis on anti-counterfeiting.

In practice, direct communication between trademark owners and online service providers based on an MoU will enable two stakeholders to collaboratively combat sellers of counterfeits and prevent consumer damage. For example, trademark holders can obtain accurate information about the various measures that each online service provider is taking and actively utilise such measures to prevent the distribution of counterfeits. In addition, a seller detected selling counterfeits on a certain platform is most likely to offer them on other platforms with the same registration information, so right holders and online service providers can share information and respond effectively to these habitual/malicious sellers.

While an MoU aimed at decreasing the availability of counterfeits on online platforms was signed between the KIPO and online service providers in 2019, industry has not been included in any discussion in this regard. Trademark owners who have not been invited to sign the MoU do not have sufficient opportunity to collaborate with other stakeholders in regards to addressing online counterfeit sales.

Recommendation

The KIPO has facilitated cooperation on online anti-counterfeiting among various stakeholders by operating the "Anti-Counterfeiting Council". In addition to that, it is recommended that an MoU be prepared amongst all stakeholders (i.e., online service providers, trademark owners/associations and relevant government), which will enable prompt and effective communication between online service providers and trademark holders to curb online counterfeit sales.

Relevant Act/Regulation	N/A
Responsible Authority & Division	Korean Intellectual Property Office (KIPO) (Intellectual Property Investigation Division)
Recommendation Status	Updated

Hyokyung Suh
Director,
Kitchen & Home
Appliances
Committee

Kitchen & Home Appliances

3
Total Key Issues

1. Converting KC Certificates into Electronic Documents

Issue

The electrical appliance safety certificate (KC Certificate) is issued by three test laboratories: 1) Korea Testing Laboratories (KTL), 2) Korea Testing & Research Institute (KTR), and 3) Korea Testing Certification Institute (KTC).

Companies are required to keep the original paper copy of the KC Certificate for renewal, cancellation, and return of the certificate. Except in such cases, the original paper certificate is not used in general. When updating the KC Certificate, the original must be submitted to the testing laboratory, which takes time and money for the company to send it by courier or express, or to submit it in person. On the other hand, by switching to electronic documentation, laboratories can reduce the use of paper and companies do not need to keep separate hard copies, which increases efficiency in document management and reduces logistics costs. It also enables efficient management of the certificates.

Recommendation

If the KC Certificate is converted into an electronic document, it is expected that more efficient management and storage will be possible. In this regard, an electronic documentation of the certificate is recommended.

In the feedback on the White Paper 2020 and 2021, KATS commented that to make an electronic copy of a 'KC certificate' available, a budget should be secured first for the establishment of a system through which electronic document can be issued and verified, and certification information can be shared systematically with safety certification institutions. In this regard, it is recommended that KATS provide updates on the current state if a mid- to long-term plan has been established or internal discussion is taking place.

Relevant Act/Regulation	Electrical Appliances and Consumer Products Safety Control Act
Responsible Authority & Division	Korean Agency for Technology and Standards (KATS) (Electrical & Telecommunications Product Safety Division)
Recommendation Status	Retained

2. Improving Data Search on Safety Korea

Issue

The electrical appliance safety certificate (KC Certificate) is issued by three test laboratories: 1) Korea Testing Laboratories (KTL), 2) Korea Testing & Research Institute (KTR), and 3) Korea Testing Certification Institute (KTC).

From the point of view of a company that must manage certificates for multiple products, the efficiency of work is very low as it must visit and make enquiries at each of the three laboratory websites when searching for product certificates. In this regard, the efficiency of certificate management will be increased for manufacturers/importers if there is a website that integrates and manages certificates. Indeed, although some information on certification data from the three laboratories owned by manufacturers/importers is currently available on the Safety Korea website, extracting it in Excel is impossible and there are limits in verifying detailed information as the data contains only basic information.

Recommendation

It is recommended that the system be upgraded by expanding the certification data information to that which has already been shared on the Safety Korea website, to allow for verification of certificate information without searching on a separate testing laboratory website and enable its extraction in Excel.

Relevant Act/Regulation	Electrical Appliances and Consumer Products Safety Control Act
Responsible Authority & Division	Korean Agency for Technology and Standards (KATS) (Electrical & Telecommunications Product Safety Division)
Recommendation Status	Retained

3.
Improving Labelling Requirements for Manufacturing Date

Issue

According to the attached Table 5 of the Administrative Rules on Conformity Assessment of Broadcasting and Communications Equipment, "Labelling Standards and Methods of Conformity Assessment of Broadcasting and Communications Equipment", the manufacturing period of a product must be labelled with its "manufacturing date" (YY/MM). On the other hand, the "manufacturing period" of a product prescribed in the Administrative Rules on Safety Management of Electrical Appliances and Consumer Products is "a mark that indicates the manufacturing period of the product". In this regard, there are cases where the manufacturing period must be repeatedly indicated in different forms simultaneously for products that are electrical appliances and that follow the Radio Waves Act, according to the respective regulations.

	Administrative Rules on Conformity Assessment of Broadcasting and Communications Equipment	Administrative Rules on Safety Management of Electrical Appliances and Consumer Products
Labelling Method	Manufacturing date" (YY/MM)	A mark that indicates the manufacturing period of the product (e.g., manufacturing date (YY/MM), LOT number, a mark that the manufacturer can prove the manufacturing period)

Recommendation

It is recommended that the labelling requirement of the manufacturing period of a product in "Labelling Standards and Methods of Conformity Assessment of Broadcasting and Communications Equipment" be changed from "manufacturing date" (YY/MM) to "a mark that indicates the manufacturing period of the product".

Relevant Act/Regulation	Administrative Rules on Conformity Assessment of Broadcasting and Communications Equipment
Responsible Authority & Division	National Radio Research Agency (ICT Conformity Assessment Division)
Recommendation Status	New

Cassandra Talbot
Manager,
Logistics &
Transport
Committee

Logistics & Transport

3
Total Key Issues

1.
Enhancing Trade Capacity Through Expanding Access to Regulated Trade Routes Along the Yellow Sea and to Japan

Issue

The Yellow Sea trade routes are only open to ships under Korean and Chinese flags. Moreover, trade routes from Korea to Japan are only open to ships under Korean flags, although the reverse routes from Japan to Korea are open to foreign carriers.

Recommendation

It is recommended that the above-mentioned trade routes are opened to non-member lines and foreign carriers, or what has been agreed between the Korean and the Chinese and/or Japanese governments is shared with them. As a result of doing this, non-member lines and foreign carriers could support trade by providing additional capacity which could aid Korea's trading companies as they export and import to and from China and Japan.

Relevant Act/Regulation	Internal Rules on Vessel Deployment and Management in the China-Korea Trade Routes (Yellow Sea Liners Committee)
Responsible Authority & Division	Ministry of Ocean & Fisheries (MOF)
Recommendation Status	New

2.
Expanding Cargo Export Capacity Through Gradual Lifting of Cabotage Rules

Issue

Foreign carriers are only allowed to shuttle on the routes from Incheon to Gwangyang and from Gwangyang to Busan. Routes from other niche ports to Busan, Gwangyang, Incheon, and Incheon-Busan shuttle routes cannot be operated by foreign carriers. Consequently, there is a lack of capacity to export cargo from Incheon or niche ports to transshipment ports.

Recommendation

It is recommended that cabotage rules be lifted one by one as the Chinese government did. This would support the overall operational effectiveness of cargo shipment to and from Korean niche ports.

Relevant Act/Regulation	Ship Act
Responsible Authority & Division	Ministry of Ocean and Fisheries (MOF)
Recommendation Status	New

---

3. Enhancing Safety Management Through the Reassessment of the Scope of Liability Related to the Terminal Safety Management Fee

Issue

The Ministry of Ocean and Fisheries (as of August 8, 2022) is about to implement a Terminal Safety Management Fee in the amount of 237 KRW/TEU to be charged to shipping carriers. Despite this safety management fee, shipping lines would still be held responsible for terminal accidents on vessels involving lashers (union) and tallymen.

Recommendation

It is recommended that the scope of liability related to the Terminal Safety Management Fee be reassessed and redefined as follows:

- If the shipping lines pay this new charge item for safety, then a risk assessment and accident prevention plan should be provided by the terminal.
- Safety management personnel should be appointed by the terminal operator with an independent safety budget financed by the funds collected from the safety management fee.
- Shipping lines should be made exempt from any responsibility should an accident occur.

Relevant Act/Regulation	Guidelines on the Operation of Port Safety Management Fees, Notification of New Port Safety Management Fee Among Port Unloading Charges and Request for Cooperation, Harbor Transport Business Act, Port Safety Special Act, Serious Accidents Punishment Act
Responsible Authority & Division	Ministry of Ocean and Fisheries (MOF)
Recommendation Status	New

Andrew Millard
Marine & Shipbuilding Committee

Marine & Shipbuilding

4

Total Key Issues

---

1. Practice of the Lowest Price Bidding System in Domestic Shipyards

Issue

Domestic shipbuilding equipment companies have adopted bidding practices for orders from domestic shipyards, including bidding for total costs that are below their production cost.

These practices unfairly decrease competition and cause a deterioration in product quality, result in maintaining the status quo, decreasing investments in research and development, curbing innovation, and leading to unsustainable business.

Recommendation

To allow for fair competition and to further enhance sustainable business practices, it is recommended that the government actively promotes due consideration for safety, technology, quality, and business experience, rather than merely focusing on price during the bidding processes.

Relevant Act/Regulation	N/A
Responsible Authority & Division	Korea Fair Trade Commission (KFTC)
Recommendation Status	Retained

---

2. 52-hour Workweek System

Issue

The implementation of the 52-hour workweek system in 2018, led to considerable impact on business. The rigid imposition of the system without considering specific workplace conditions has been undermining the industrial foundations. Although the act was revised several times to ensure more flexibility, the 52-hour workweek is still harming certain industries where flexibility is required.

Recommendation

To promote effective business practices and to further enhance sustainable development and work-life balance, it is recommended that the government recognizes specific conditions of respective workplaces. It is further recommended that the maritime industry is to be included as one of the exempted industries (agriculture, livestock, poultry, and fishery) and / or to let industry operate on a flexible workweek system all year round (instead of maximum six-month period) by having employees work extended hours during peak seasons and later go on deferred leave.

Relevant Act/Regulation	Labor Standards Act
Responsible Authority & Division	Ministry of Employment and Labor (MOEL), Ministry of Trade Industry and Energy (MOTIE)
Recommendation Status	Retained

3. Opportunities to Access R&D Funds and Programs as Foreign-invested Firms in the Maritime Industry

Issue

Since COVID-19, there have been many R&D funds and program opportunities in the maritime industry. However, it seems that the local foreign-invested firms are "prohibited" from seizing such opportunities. The word "prohibited" is utilized here as our qualified member companies in the business have been always eliminated from the first step of the selection process although it seems like they perfectly meet the requested requirements.

Recommendation

To promote a fair and non-discriminatory business environment and transparent competition, it is recommended to clarify how foreign invested firms can gain access to funds destined for R&D activities and create a transparent platform that will enable them to do so.

Furthermore, the ECCK suggests compiling a list of previous and future R&D pilot projects based on the industry segments listed in the government portal.

Relevant Act/Regulation	N/A
Responsible Authority & Division	Korea Fair-Trade Commission (KFTC), Ministry of Oceans and Fisheries (MOF)
Recommendation Status	Updated

4. Opposition to Amendment of the Marine Traffic Safety Examination Implementation Guidelines

Issue

To develop the offshore wind farm, it is necessary to proceed with a Marine Traffic Safety Examination("MTSE"). The MTSE is to examine and secure marine traffic safety. However, there is no specific regulation for defining marine traffic routes but instead determined through consultation by MTSE. MOF plans to establish new MTSE criteria to secure marine traffic safety through the amendment of their implementation guideline.

New guidelines include:

- Safety distance between marine traffic routes and wind farms
- Passage control for vessels in the wind farm
- Maximum separation distance between each Wind Turbine Generation (WTGs)

The offshore wind developers carry out the MTSE, and based on those results, consult with the MOF and local communities. If implementation guidelines are amended and applied, it is expected that it will be difficult to ensure acceptance from local communities due to backlash from fishermen. Additionally, the cost burden for developers will increase significantly.

Recommendation

It is recommended that the guidelines should not be amended so that the developers and local communities can consult with flexibility to prepare and apply alternatives suitable for the features of the sea area and region as it is now.

Relevant Act/Regulation	Marine Traffic Safety Examination Implementation Guidelines
Responsible Authority & Division	Ministry of Oceans and Fisheries (MOF) (Marine Safety Policy Division)
Recommendation Status	New

Cassandra Talbot
Manager,
Sustainability
Committee

Sustainability

1
Total Key Issue

1.
Sustainability/ Circular Economy in Education

Issue
In the recent past, more meaningful sustainability initiatives have been laid out by Korea, the majority of which were included in the Green Deal by the previous administration. The Yoon administration has also confirmed Korea's target of "net zero" by 2050. Although government-led initiatives will for sure contribute to a considerable degree of target achievement, a shift is needed in the mindset of the general population towards a more sustainable way of living. More qualified people in those new areas of circular economy are also needed.

Recommendation
It is recommended that in elementary, middle, and high schools a higher focus be set on teaching "green", and that at universities more future professionals be trained in sustainable business life cycles, sustainable product design, and cradle-to-grave sustainability (circular economy).

Relevant Act/Regulation	N/A
Responsible Authority & Division	Ministry of Education (MOE)
Recommendation Status	New

Siyoon Kim
Manager,
Taxation
Committee

Taxation

3
Total Key Issues

1.
Deductions for Overseas Education Fee

Issue
Eligible individuals may claim 15% of tax credit for overseas education fees of dependents within the limit of up to KRW 3 million (per child for school fees up to high school) and KRW 9 million (per child for university fees) under Article 118-6, paragraph 5 of the Presidential Decree of the Individual Income Tax Law. However, these deductions are only available to Korean nationals, and foreign national residing in Korea are not eligible for such deductions.

Recommendation
To make the tax system more equitable it is recommended to revise the tax law so that the above education related deductions are also available to foreign nationals residing in Korea.

Relevant Act/Regulation	Individual Income Tax Law
Responsible Authority & Division	Ministry of Economy and Finance (MOEF) (Tax Policy Division)
Recommendation Status	Retained

2.
Tax Exemption on Qualified Housing Benefit for Foreign Employees

Issue
The qualified employer-provided housing benefit had been excluded from employment income, but it is now treated as non-taxable employment income due to the change of provisions relating to the scope of non-taxable employment income. Due to this change, the foreign employees applying the flat tax rate in accordance with Article 18-2 of Special Tax Treatment Control Law ("STTCL") is required to include the qualified employer-providing housing benefit as taxable income.

As a transitional measure, the non-taxable treatment of qualified housing benefit applies from the income earned after January 1, 2024 for the foreign employees who elect to apply for the flat tax rate under Article 18-2 of STTCL. Therefore, the income tax burden of foreign employees who apply for the flat tax rate is expected to increase significantly from January 1, 2024.

Although the purpose of the change of relevant provisions is not to expand the tax base but to clarify the scope of non-taxable employment income, it will result in a side effect of excessively increasing the burden of income tax on foreign employees applying the flat income tax rate.

The qualified housing benefits, which had not been treated as taxable income for either Korean or foreign nationals equally, will be taxed differentially only on foreign employees. It is also against the purpose of Article 18-2 of STTCL of attracting high-end foreign talents.

Recommendation

It is recommended to revise the tax law so that the qualified housing benefit can be excluded from employment income for the foreign employees applying the flat tax rate even after January 1, 2024.

Relevant Act/Regulation	Enforcement Decree to the Income Tax Act Article 17-4
Responsible Authority & Division	Ministry of Economy and Finance (MOEF) (Tax Policy Division)
Recommendation Status	Updated

3. Penalty Waiver for the Voluntary Reporting of Foreign Bank and Financial Accounts and Foreign Real Property

Issue

In accordance with Articles 62 and 63 of the International Tax Adjustment Act, the failure to report foreign financial accounts and foreign real estate is subject to penalties of up to 20% of the amount of non-reported balance and KRW 100 million, respectively.

Until the tax authorities detect non-compliance and impose the penalties, the resident can proceed with late filing or amended filing. However, when late filing or amended filing is made, the penalty will still be assessed even though it can be reduced by 30~90% depending on the time of filing.

Therefore, if a resident who becomes aware of this obligation past the due date voluntarily submits the report, they are subject to penalties for each non-compliance year. If the unreported balance or transaction amount is high, the penalty can be considerable even in the case where the penalty is reduced by 90%. Furthermore, there have been cases where the tax authorities assessed penalties to residents who filed this year's report for non-filing of previous years' reports. This practice discourages foreign residents who were not aware of this obligation but are now willing to be compliant going forward.

Especially for the foreign residents, they are subject to this obligation when they stay in Korea for more than 5 years during the 10-year period. In most cases, it is very difficult for the foreign taxpayer to be aware of this obligation. Furthermore, when the 5-year time-period is considered, the concept of domicile or place of residence is very ambiguous as there is no straightforward residency test, and all other facts and circumstances shall be considered. Even if they become aware of this, if the 5-year time-period has already passed, it is difficult to comply with it starting from this year due to the severe penalties for previous years.

Also, if the penalties are imposed to the person who filed the report, it may cause incorrect perception that the voluntary reporting is more disadvantageous than non-compliance.

In most cases, foreign residents who are subject to these obligations due to the passage of time had have certain balances exceeding the threshold in foreign accounts and had hold properties in foreign countries even before they came to Korea. It should not be treated as willful non-compliance which is subject to severe penalties.

Recommendation

Since the purpose of the law is to establish an institutional infrastructure to prevent overseas tax evasion, the voluntary disclosure should be distinguished from the case detected by the tax authorities. Therefore, it is recommended that an amendment be made to the relevant provisions so that the penalty for previous years' non-reporting can be fully waived provided the taxpayers voluntarily report the current year's report.

Relevant Act/Regulation	Article 62 of International Tax Adjustment Act, and Article 102 of its Enforcement Decree Article 63 of International Tax Adjustment Act, and Article 103 of its Enforcement Decree
Responsible Authority & Division	Ministry of Economy and Finance (MOEF) (Tax Policy Division)
Recommendation Status	New

Cassandra Talbot
Manager,
Tourism
Committee

Tourism

1
Total Key Issue

1.
Limitation of External Hotel Signage

Issue
The external signage of hotels is regulated as such that hotels are limited to two (2) external building signs with a width not exceeding half of the building width. In contrast to normal office buildings and signs, it is of the utmost importance for hotels to make potential customers aware of their business, to make potential customers aware of their hotels but this limitation, in some cases, causes bad visibility due to small lettering.

Recommendation
It is recommended that these limitations be reviewed, and more flexibility be allowed, especially in the case of buildings with small building widths.

Relevant Act/Regulation	Enforcement Decree of the Act on the Management of Outdoor Advertisements, etc. and Promotion of Outdoor Advertisement Industry
Responsible Authority & Division	N/A
Recommendation Status	New

Abbreviation

Abbreviated	Expanded
ABV	Alcohol by Volume
APA	Advance Pricing Arrangement
ATP	Actual Transaction Pricing
CAPEX	Capital Expenditures
CBI	Confidential Business Information
CHP	Combined Heat and Power Applications
CITL	Corporate Income Tax Law
COVID-19	Coronavirus Disease 2019
CRO	Contract Research Organization
CSAP	Cloud Security Assurance Program
CSP	Cloud Computing Service Provider
DREC	Drug Reimbursement Evaluation Committee
DSS	Dynamic Spectrum Sharing
EC	European Commission
EEZ	Exclusive Economic Zone
EMS	Express Mail Service
EPD	Environmental Products
EPI	Expanded Program on Immunization
FAS	Fleet Average Systems
FP	Formulated Products
FRAND	Fair, Reasonable and Non-Discriminatory
GMO	Genetically Modified Organism
HCP	Healthcare Professionals
HES	Heavy-duty Vehicle Emission Simulator
HRQOL	Health-Related Quality Of Life
HRS	Hydrogen Refueling Station
HST	Highly Specialized Technology
HTA	Health Technology Assessment
ICER	Incremental Cost-Effectiveness Ratio
IEC	International Electronical Commission
IoT	Internet of Things
IPC	Innovative Pharmaceutical Companies
ISO	International Standards Committee
ISP	Information Strategic Planning
K-BPR	Household Chemical Products and Biocides Safety Acts
KC	Korea Certification
KOSHA	Korea Occupational Health and Safety Agency
K-OSHA	Occupational Safety and Health Act
KPX	Korea Power Exchange
K-REACH	Act on Registration, Evaluation, Etc. of Chemicals
LNG	Liquefied Natural Gas
LOC	Letter of Confirmation
LPG	Liquefied Petroleum Gas
LR	Lead Registrant
MNCs	Multinational Corporations
MoU	Memorandum of Understanding
MRA	Mutual Recognition Agreement
NIP	National Immunization Program
OEM	Original Equipment Manufacturing
OIV	Overseas Investment Vehicle
OPEX	Operating Expenditure
OR	Only Representative
PCR	Post Consume Recycled
PE	Pharmacoeconomic Evaluation
PIC/s	Pharmaceutical Inspection Co-operation Scheme
PL	Product Liability
PPA	Power Purchase Agreement
PVA	Price-Volume Agreement
QC	Quality Control
QSM	Quasi-drug Standard Manufacturing
REC	Renewable Energy Certificate
RM	Raw Material

Abbreviated	Expanded
RNA	Rotor, Nacelle, Assembly
RPS	Renewable Portfolio Standards
RSA	Risk Sharing Agreement
SEP	Standard Essential Patent
SPC	Special Purpose Companies
STTCL	Special Tax Treatment Control Law
TBT	Technical Barrier to Trade
UL	Underwriter Laboratories
VECTO	Vehicle Energy Consumption Calculation Tool

Abbreviation

Organisations

Organisations	Expanded
ACRC	Anti-Corruption and Civil Rights Commission
DAPA	Defence Acquisition Program Administration
FSC	Financial Services Commission
FSS	Financial Supervisory Service
FTC	Fair Trade Commission
GIAK	General Insurance Association
HIRA	Health Insurance and Review Assessment
KATS	Korean Agency for Technology and Standards
KCS	Korea Customs Service
KDCA	Korea Disease Control and Prevention Agency
KEA	Korea Energy Agency
KECO	Korea Environment Corporation
KEITI	Korea Environmental Industry & Technology Institute
KEPCO	Korea Electric Power Corporation
KFTC	Korea Fair Trade Commission
KHIDI	Korea Health Industry Development Institute
KIIP	Korea Institute of Intellectual Property
KIPO	Korean Intellectual Property Office
KISA	Korea Internet & Security Agency
KOSIS	Korean Statistical Information Service
KTC	Korea Testing Certification Institute
KTL	Korea Testing Laboratories
KTR	Korea Testing & Research Institute
MAFRA	Ministry of Agriculture, Food and Rural Affairs
ME	Ministry of Environment
MFDS	Ministry of Food and Drug Safety
MOEF	Ministry of Economy and Finance
MOEL	Ministry of Employment and Labor
MOF	Ministry of Oceans and Fisheries
MOGEF	Ministry of Gender Equality and Family
MOHW	Ministry of Health and Welfare
MOIS	Ministry of the Interior and Safety
MOLEG	Ministry of Government Legislation

Abbreviated	Expanded
MOLIT	Ministry of Land, Infrastructure and Transport
MOTIE	Ministry of Trade, Industry and Energy
MSIT	Ministry of Science and ICT
MSS	Ministry of SMEs and Startups
NHIS	National Health Insurance Service
NIER	National Institute of Environmental Research
NSSC	Nuclear Safety and Security Commission
NTS	National Tax Service
OSHRI	Occupational Safety and Health Research Institute
PCIP	Presidential Council on Intellectual Property
QIA	Animal and Plant Quarantine Agency
TPRC	Transportation Pollution Research Center