EUROPEAN CHAMBER OF COMMERCE IN KOREA

ECCK White Paper 2020

Chairperson's Message

Dear Valued Members and Friends,

Following the successful launch of ECCK White Paper in 2015, I would like to proudly present the sixth edition of the White Paper, a compilation of key industrial issues and recommendations from the European business community in Korea, covering the year 2020.

The ECCK always strives to position itself as the major communication platform for the European companies in Korea. In order to effectively represent our members' interests and implement the necessary changes to better the Korean business environment, we have several standing industrial committees to collect issues and opinions. To better provide information and transparency, the ECCK White Paper took shape as a medium to share such information. The views put forward in this publication is solely intended to promote open and effective dialogue and offer constructive recommendations for the improvement of European-Korean business relations. Furthermore, the White Paper provides an overview of the regulatory landscape in Korea as well as industry-specific challenges and prospects.

This year, the world is facing unprecedented challenges. We are experiencing a very chaotic time with the outbreak of COVID-19, public health emergencies and growing protectionism which are threatening global trade, supply chains and economies, is forcing everyone to adapt to the 'New Normal' way of life. However, we believe it is also a period full of opportunities and new exciting initiatives, such as the Green and Digital economic plans announced by the European Union and Korea.

Each year, Korea and Europe are becoming better, balanced trade and investment partners, and 2020 marks the 10th anniversary of strategic partnership between the two sides. Considering the ever-developing relationship between Korea and Europe, the significance of knowing the market trends, regulatory framework, and emerging opportunities in Korea is paramount. On that note, the ECCK will continue to stand in the forefront of these issues and be the first point of contact for our members.

As we hope to grow and improve from this publication, we heartily encourage and welcome your feedback. I hope many good dialogues will be sparked by the White Paper, and a special thanks to our members for their input into this publication.

Thank you.

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

ECCK EUROPEAN CHAMBER OF COMMERCE IN KOREA

ECCK White Paper 2020

Table of Contents

Introduction to ECCK

ECCK Introduction

The European Chamber of Commerce in Korea (ECCK) is a distinguished association of European companies operating in or related to Korea. With the authorization from the Ministry of Trade, Industry, and Energy, the ECCK was officially founded as a non-profit organization on December 3, 2012.

Established with the blessings of the EU Delegation and the European business community in Korea, the ECCK's primary objective is to provide its members with information, communication, and access pertaining to the business and regulatory environment of Korea. While European firms form the largest membership base of the organization, the ECCK welcomes companies of all nationalities to join and share the experience first-hand.

Entrusted with member's mandate, the Board of Directors presides over the organization. The Advisory Board embodies representatives of national chambers and embassies, providing general guidance and advice. The Secretariat functions to execute the Chamber's day-to-day activities and operations.

The ECCK aims to promote a sustainable relationship between European corporations and Korean government by working hand-in-hand with both parties. Furthermore, the Chamber strives to cultivate an optimal business environment and community for the European companies all the while operating for the benefit of the Korean society.

ECCK Vision & Mission

The ECCK is committed to advancing the interests of companies from Europe operating in Korea. We cooperate with organizations 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 the business as well as economic and regulatory developments in Korea and Europe
- Creating networking opportunities for members and partners
- Contributing to the Korean society by supporting corporate social responsibility activities and promoting good corporate governance practices
- Becoming a commercial and cultural ambassador to Korea

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

Dirk Lukat is a German citizen and has been Managing Director & CEO of Schenker Korea Ltd in Seoul since January 2015. He started his career at the former Schenker & Co. GmbH in Frankfurt and held a number of management positons 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 European Business Council. 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 in January 2015.

Hyun-Nam Park (Korea)
Vice Chairperson of the Board
Managing Director
Deutsche Bank Seoul Branch

Hyun-Nam Park is a Korean citizen and is Managing Director for Deutsche Bank Seoul Branch. She is also Head of Global Markets, Korea. Hyun-Nam also holds various senior positions in the Financial Industry. She is Vice Chairperson of the Foreign Bankers Group in Korea and a member of Korea Financial Hub Committee in Financial Services Commission Korea.

Jan Benggaard (Denmark)
Vice Chairperson of the Board
Managing Director
Oerlikon Balzers Korea

Jan Benggaard is a Danish citizen and is the Managing Director of Oerlikon Balzers Korea Ltd 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.

Julien Samson (France)
Vice Chairperson of the Board
Vice President and General Manger
GSK Pharmaceuticals Korea

Julien Samson is a French citizen and has been VP & GM of GSK Pharmaceuticals Korea since March 2018. He was VP & Medicine Commercialization Leader for Relvar/Breo, Seretide/Advair, Arnuity & Closed Triple Asthma in GSK Global Respiratory Franchise (2015-2018) and VP & Head of Primary Care in France (2012-2015). Prior to joining GSK, he was Deputy General Director of the Academic Medical Center of Lyon, social welfare adviser to Mr. Nicolas Sarkozy, President of the French Republic and to Mr. Thierry Breton, Minister of Economy, Finance & Industry and responsible for healthcare & solidarity policies for the Directorate of Budget in the Ministry for the Economy & Finance.

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

Donghwan Kim is a Korean citizen and has been working for Finnair as a Sales Manager since 2008. 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.

Gilles Fromageot (France)
Director of the Board
President & CEO
AXA Korea

Gilles Fromageot is a French citizen and is the President & CEO of AXA Korea since 2017. Prior to his post, he served as Global Cheif Financial Officer for AXA Global Director from 2015 to 2017 in Paris. Before joining AXA in 2012, he has worked with Mazars.

Gerd Bitterlich (Germany)
Director of the Board
Vice President & CFO
Mercedes-Benz Korea Ltd.

Gerd Bitterlich is a German citizen and has been Vice President & CFO of Mercedes-Benz Korea since 2017. He can look back on 30 years of professional experience with global automotive industry, mainly in Sales & Marketing and Finance & Controlling. Prior to his current position, he had two consecutive assignments in China, as General Manager Eastern Region China for Mercedes-Benz passenger cars during 2011 - 2013 and as CFO for Mercedes-Benz Vans China in 2014 - 2016. From 2007 to 2010, he was CFO of Mercedes-Benz Own Retail in Luxembourg. Before 2007, he developed his expertise by holding various senior management positions at Mercedes-Benz Global Headquarters and Mercedes-Benz Bank in Stuttgart/Germany.

Elizabeth Kyunghee Nam (Korea)
Treasurer of the Board
Finance Director
Diageo Korea

Elizabeth Kyunghee Nam is a Korean citizen and is Finance Director at Diageo Korea. She has 18 years of progressive experience in Finance and General management within the business units in the developed & emerging markets, global organization and start-up business. Before joining Diageo, Elizabeth worked with LG Telecom, Shepard, Schwartz & Harris and Philippine Airlines.

Kay-Jannes Wegner (Germany)
Trustee of the Board
Senior Attorney
Kim & Chang

Kay-Jannes Wegner is a German citizen and dual qualified lawyer (Rechtsanwalt, Germany and Solicitor, England and Wales). He has been working as a senior attorney with Kim & Chang since 2011, primarily advising European clients. Before moving to Korea, Kay-Jannes practiced with international law firms in London from 2001 to 2007 and Singapore from 2007 to 2011.

ECCK Secretariat

Christoph Heider
President

Christoph Heider was appointed as Secretary-General on June 1, 2013. Before Joining the ECCK, Christoph Heider had been with Bayer AG, a German pharmaceutical company since 1997. He held various positions in Bayer, including CFO at Bayer Korea, Head of Accounting & Reporting at Bayer Japan as well as Regional Manager for Legal Entity Accounting APAC at Bayer AG in Germany. In 2016, Heider received 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.

Bo Sun Kim
Vice President
Changhoon Rim
Head, Automotive Committees
Taeyang Kim
Manager, Chemical Committee
Ansook Park
Director, Cosmetics/Healthcare Committees
Siyoon Kim
Manager, Financial Service Committee
Eunhye Baek
Manager, Food & Beverage/
Kitchen & Home Appliances Committees
Sven-Erik Batenburg
Director, Legal & Internationl Affairs
Hyewon Shim
Manager, Event Management
Hyun Sung Rhee
Manager, Finance Control & HR
Hyeeun Cho
Manager, Membership Management
Jeong Hyun Kim
Manager, PR & Communications
So Hyeun Cho
Assistant Manager, PR & Communications
Nuri Chung
Busan Chapter Representative

ECCK Services & Programs

Committees & Forums

Committees and Forums are the centrepieces of ECCK activities. Comprised of participating member companies, Committees and Forums assist members to keep informed of regulations, to improve market intelligence, and 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 and are open to all members free of charge.

Information Sessions

Events

The ECCK organizes 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 circulates regular publications to inform our members of the current market situation, key regulatory issues, and notable 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 Annual Report (yearly review of chamber operations)
- ECCK Quarterly Report
  (quarterly review of Europe and Korea economy)
- ECCK Connect Magazine
- ECCK Membership Directory
  (yearly update of ECCK membership)
- Newsletter (weekly and monthly updates to ECCK members)

EU Sponsored Programs

The ECCK has built cooperative ties with the European Commission and have contracted to conduct research and promotional programs. Since 2013, the ECCK has contributed to Market Studies Papers as part of supporting the EU Gateway Business Mission, an EU-funded business delegation of European SMEs to Korea for successful market entry. The ECCK is also a member of the EBO Worldwide Network ASBL.

Guideline

How to read ECCK White Paper Key Issues and Recommendations

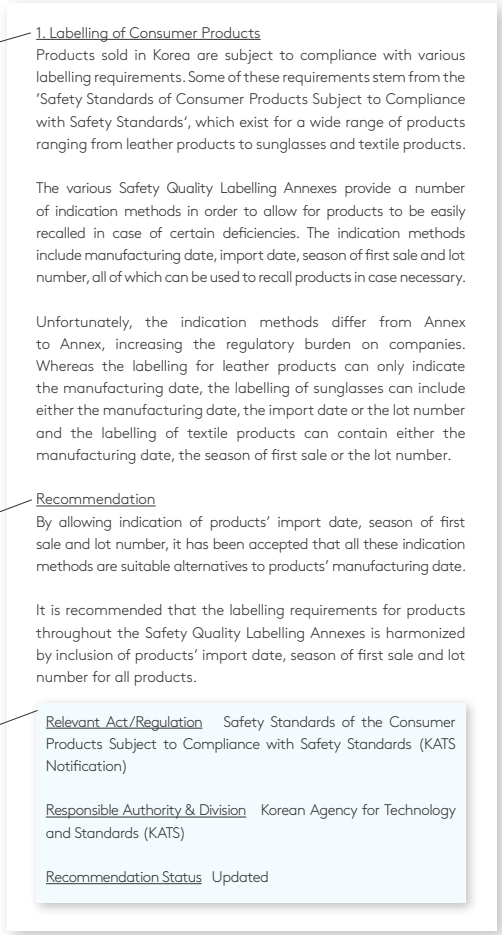
The ECCK White Paper 2020 presents a total of 145 industry issues and recommendations intended to improve the business environment in Korea. The recommendations are developed through extensive consultations with our European members participating in our 20 industry committees and working groups. The 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:

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

2020 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 2020.



1. Labelling of Consumer Products

Products sold in Korea are subject to compliance with various labelling requirements. Some of these requirements stem from the 'Safety Standards of Consumer Products Subject to Compliance with Safety Standards', which exist for a wide range of products ranging from leather products to sunglasses and textile products.

The various Safety Quality Labelling Annexes provide a number of indication methods in order to allow for products to be easily recalled in case of certain deficiencies. The indication methods include manufacturing date, import date, season of first sale and lot number, all of which can be used to recall products in case necessary.

Unfortunately, the indication methods differ from Annex to Annex, increasing the regulatory burden on companies. Whereas the labelling for leather products can only indicate the manufacturing date, the labelling of sunglasses can include either the manufacturing date, the import date or the lot number and the labelling of textile products can contain either the manufacturing date, the season of first sale or the lot number.

Recommendation

By allowing indication of products' import date, season of first sale and lot number, it has been accepted that all these indication methods are suitable alternatives to products' manufacturing date.

It is recommended that the labelling requirements for products throughout the Safety Quality Labelling Annexes is harmonized by inclusion of products' import date, season of first sale and lot number for all products.

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)

Recommendation Status Updated

Executive Summary

2020 Overview

About the ECCK White Paper

The ECCK White Paper is the chamber's annual key publication. It was first published in 2015 and since then has served as the main source of information on market access and other issues European business is facing when doing business in Korea. Thus, it aims to capture the essence of major industrial issues faced by the European businesses operating in Korea and proposes constructive recommendations to facilitate open and effective dialogue with the Korean government and relevant ministries. The White Paper is also shared with key personnel at the European Commission, the European Parliament, the European Free Trade Associations' (EFTA) Secretariat, governments of member states of the EU and EFTA, European business interest groups but also multinational organizations such as the OECD, the United Nations, and the World Trade Organization.

The White Paper is compiled by dedicated ECCK staff based on input received from experts from the chamber's member companies. In fact, almost 200 professionals representing their company in the ECCK Committees and Working Groups contributed to ECCK White Paper 2020. The White Paper 2020 includes 145 (180 in 2019) constructive recommendations to the Korean government raised through 20 (20 in 2019) ECCK Committees and Working Groups. In this year's edition, recommendations from the ICT Working Group has been included for the first time. The ECCK appreciates the outstanding support from its members which can be translated to a strong commitment of the ECCK and its member companies to further work on a betterment of the business environment for European companies operating in Korea.

In fact, the compilation of all those issues and recommendation is only half of the work to make the White Paper a meaningful publication. The ECCK wishes to credit the Korean administration but especially the Office of the Foreign Investment Ombudsman which led by the Ombudsman Kim Sung Jin for all its openness to review those recommendations, to thoroughly follow up with experts in the Korean administration and at the end shared the feedback with the ECCK. The positive feedback received at the beginning of 2020 on about 50 (30%) out of the 180 recommendations submitted in 2019 can only be interpreted in a way that collaboration and cooperation can deliver meaningful results.

The business environment in 2020 has changed drastically due to the COVID-19 pandemic. COVID-19 has brought many challenges to our community, but also new opportunities. One lesson learned while fighting the pandemic was simply, that we can succeed only together. Thus, the ECCK further hopes for even better cooperation through even a more strengthened communication with the Korean administration.

Fighting COVID-19 and Ensuring the Future

The first case of COVID-19 in Korea occurred in January 2020. The Korean administration has set up countermeasures to contain the virus and after having the number of cases per day peaked in March. In that early stage, it was generally assumed that COVID-19 might only be a regional problem but soon thereafter the virus was spreading on a global level. At the time, this Executive Summary is written, the overall situation remains fragile and the outlook for healthcare management but also for business remains unclear. In Korea the situation can be evaluated as relatively positive when taking into consideration the number of infected cases which care only about 200 and that only social distancing measures were enforced instead of a lockdown. This is the reason why the Korean economy fares fairly well with only a slight decrease in the GDP The only considerable economy country with a positive GDP will be the PR of China as all others are due to experience substantial decreases in their economic output. The situation in the US or in Europe remains fragile and therewith having a huge impact on the Korean export activities. The hope is there that there will be a rebound in economic activities in 2021 and therewith an economic recovery.

The pandemic has not only brought a negative impact on people's health but also on the economic activities on the ground. Foreign Direct Investment into Korea – which decreased already in 2019 by 26% to USD 12,854 billion (USD 17,262 billion) – is expected to decrease further in 2020 as the focus of many multinational companies rather was on ensuring liquidity; thus investments to a great extent were postponed. Trade also decreased by double digit as the virus respectively lock-downs hindered frictionless trade or the free movement of people. The disruption in supply chains lead to an additional negative impact on production – as raw

materials, parts or semi-finished products could not be imported for the production of finished products – or on product availability. Naturally, the focus during the crisis was on COVID-19 testing kits, personal protective equipment, medications produced in one part of the world, but which could not be shipped to its own market. Accordingly, the discussion is on its way and to define models such as Open Strategic Autonomy. Trade is expected to decrease in 2020 and it can be clearly stated that measures and initiative by governments to protect its own businesses might further impact global trade in the years to come.

The key for the ECCK is that country refrain from protectionist measures but to keep markets open for products, services and people. The COVID-19 pandemic also brought the need for a more sustainable business to the forefront. This is why the European Commission has launched its Green Deal and Korea its Korea New Green Deal. Naturally, those deals also should help to soften the negative economic impact but also should help to move societies towards a more sustainable society. In this respect it would be wrong to privilege local firms when foreign companies are having a better technology. Thus frictionless trade needs to be ensured to use the best technologies available to create the best possible outcome for a better sustainable future. In this respect also the harmonization of standards – better even the application of international standards – should be even pushed further. Also, agreements on reciprocity between European Union and European Free Trade Association member states and Korea shall be further extended.

The ECCK remains a strong advocate for free trade and supports all improvements in this area. Thus, the ECCK recommends to the European Commission, to the European Free Trade Association and to Korea to explore all possibilities to improve the framework which is governing trade and market access.

In this respect also a modernization of the EU-KOR FTA and EFTA-KOR FTA is highly recommended. It is essential that governments not only focus on domestic austerity measures but also to launch measures related to the facilitation trade – the modernization of the FTAs mentioned above, would not only serve as the right symbol but also would allow to optimize the FTAs in order to get the most out of it. Trade between Europe and Korea must be smooth and frictionless as Europe and Korea are creating key-technologies which are necessary to shape the future.

COVID-19 also has shown the importance of transparency, information exchange, consultation and collaboration. In this respect, the ECCK would like to encourage the Korean government to even more consult and reconcile with European business on the ground to find solutions on deregulation, legislative amendments or the implementation of new laws. Transparent and consistent policy making is a condition for further market growth and further investment. The ECCK appreciates the open collaboration and cooperation with the Korean administration but recommends to even more institutionalize the communication channels with the ECCK.

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

Key Issues

On this page, ECCK has listed 145 key issues proposed in the White Paper 2020, which are categorized as either **'Policy (P)'** or **'Regulatory (R)'**.

'Policy' related issues are industry specific issues that are raised toward the Korean government and National Assembly to establish and implement certain plans or to legislate pertinent regulations. On the other hand, **'Regulatory'** issues are closely related to specific regulations which have been implemented by the Government.

Policy: P
Regulatory: R

Automotive Committee

1. Improvement of the System of Imposing Penalty Surcharges on Voluntary Recalls	R
2. Improvement of Scope of Recalls	R
3. Flexibility for the Application of Total Repair Period of 30-days in Vehicle Exchange/Refund Regulations	R
4. Expansion of Authority of the Secretariat of the Committee for Deliberation on Safety and Defects of Motor Vehicles	R
5. HS Code of Semitrailer-Towing Tractors	R
6. Update of Annex of the EU-Korea FTA and UK-Korea FTA	R
7. Recognition on Korean Motor Vehicle Safety Standards for EU Type Approval Vehicles	R
8. Flexibility on Vehicle Width Standards	R
9. Stipulation of the Modification Report in Law	R
10. Revision of Unnecessary Testing Methods Related to Emission/Noise Certification of Manufactured Motor Vehicles	R

11. Clarification of Subject for Reporting and Management on Defects of Emission Related Components	R
12. Establishment of the Medium-and Long-term Roadmap for the Low Emission Vehicles Supply Target	R
13. Clarification of the Calculation Methods for the Achievement Result on the Distribution of Low Emission Vehicles	R
14. Flexibility in Utilization of Achievement Results in the Low Emission Vehicle Supply Targets	R
15. Examination of the Designating of 'Used Vehicle Sale Business' and 'Small Volume Automobile Repair Business' as Business Suitable for Livelihood	R
16. Unification of Similar or Duplicated Regulations Related to Motor Vehicles	P

Beer, Wine & Spirits Committee

1. Improvement of the Standard of Allowance of Testing	R
2. Offering Precise and Detailed Data of RFID System	R
3. Allowing Smart Order for Gifts	R
4. Deregulation of Digital Marketing Guideline on Smart Order	R
5. Reinforcing Regulation on Safety Management by Parallel Importers, Protecting Brand Equity and Clarifying Responsibility	R
6. Change 'Limits on Consumer Prize by Liquor Types' into 'Limits on Consumer Prize by Taxation Types' Based on Sales of the Previous Year	R

Policy: P
Regulatory: R

7. Sufficient Grace Period and Reasonable Introduction of the Revision of Packaging Related Regulations	R

Chemical Committee

1. Technical Barriers to Trade (TBT) Notification on the Amendment and Establishment of Regulations Related to Chemicals	P
2. Redundant Regulations between CCA and OSHA: Chemical Accident Prevention Plan vs. Process Safety Management (PSM)	R
3. Redundant Regulation of Import Procedures for Prohibited Substances	R
4. Test Data Regeneration for Existing Chemical Substances	R
5. Deletion of Tonnage Limits for Quantitative Structure–Activity Relationship (QSAR) Data Submission	R
6 .Detailed Proof for Notification of Hazardous Substance Designation	R
7. Individual Submission of Application Documents for Substance Approval	R
8. Technical Standard for Approval of Quasi-drugs Transferred from Ministry of Food and Drug Safety (MFDS)	R
9. Delay the Due Date of Active Substance Approval or Reduce Review Period	R
10.Guideline of Effects and Efficacy Success Criteria for Biocidal Product	R

11. Review of Designation and Management System for Hazardous Chemicals	R
12. Exclusion of Consumer Biocidal Products from Application under the Chemical Control Act	R
13. Redundant Requirements Within the CCA: Chemical Statistic Survey Report vs. Designated Hazardous Chemicals Circulation Report	R
14. Review of Trade Secret Claim on Materials Safety Data Sheet (MSDS)	R

Cosmetics Committee

1. Sufficient Grace Period and Reasonable Introduction of the Revision of Packaging Related Regulations	R
2. Package Recycle Classification Regulation in the Sensible Level	R
3. Labeling and Advertisement of Cosmetics Using Natural Related Claims	R
4. Recognition of Electronic Documents for Free Sale Certificate and Manufacturing Certificate	R
5. Expansion the Inclusion Criteria of Human Applications Test for Help Soften Red Lines Caused by Stretch Marks	R

Fashion & Retail Committee

1. Labelling of Consumer Products	R
2. Safety Testing of Infant Textile Products	R

Policy: P
Regulatory: R

Food Committee

1. Clear Grace Period for Pack Change Upon Amendments to Food Labeling	R
2. Ease the Labeling Standard Of 'Natural Flavor'	R
3. Review on Standard Of 'Natural Flavor'	R
4. Non-GMO Labeled Products from Overseas	R
5. Extension of The Scope of Permissible Recycled Plastic Resins for Utensils, Containers and Packages of Food	R
6. Sufficient Grace Period and Reasonable Introduction of the Revision of Packaging Related Regulations	R

Healthcare Committee

1. Reforming HTA Guidance to Ensure Better Access to New Medicine for Patients	R
2. Recognition of Value of Global Innovative Medicines Through New Drug Listing Policy	R
3. Reforming Combination Drug Pricing Regulation	R
4. Negotiation Target and Contents for the Agreement of Estimated Amount of Use to the Drugs which Accepted the Upper Limit Amount of Cost that are Excluded of Drug-Pricing Negotiation	R
5. Duplicated Price Containment System of the Drugs Which Can be Extended Scope of Use for National Health Insurance (NHI)	R
6. Predictability, Transparency and Flexibility of Risk Sharing Agreement (RSA) Operation	R

7. Increasing the Drug Accessibility to Rare Disease and Rare Cancer Patients	R
8. Raising Fund for Severe Cancer Patients for Better Drug Access	R
9. Organization of a New Committee Under MOHW to Improve Patient Access on Cell & Gene Therapy in Korea	R
10. Introduction of Evaluation System for Anticancer Drug Benefits Review	R
11. Relaxation of the Requirements and Improvement of the Review Process for Innovative New Drug Substances with Expedited Reviews (conditional approval)	R
12. Drug Price Agreement and Execution Terms During Price Negotiation	R
13. Enhancing Transparency and Clear Role Sharing for National Health Insurance Committee Decisions	R
14. Improving the Transparency on ATP Based Price Cut	R
15. Fair Certification Standards for Selection of Innovative Pharmaceutical Companies	R
16. Participation of Multinational Pharmaceutical Companies in the National Health Insurance Policy Deliberation Committee	P
17. Criteria for Judging Patentability for Selective Inventions in Korea	R
18. Mutual Recognition Agreement for GMP and QC Test Requirement with the EU (priority application of vaccines and biological products)	R

Policy: P
Regulatory: R

19. Reforming National Lot Release System for Imported Influenza Vaccine and its Hazardous Level Evaluation Standards	R
20. Improving the Vaccination Fee Scheme	R
21. Recognizing the Value of Innovative Vaccine Technologies for Public Health	R
22. Grace Period for Post-approval Changes for Pharmaceuticals, etc.	R
23. Replacement of Animal Testing Methods Used for Quality Testing of Biological Products	R
24. Review of Necessity for Test Items of the Specification and Analytical Procedures of Drug Products that are Additionally Established in Korea	R
25. Improving the Level of Supplementary Requests Related to CMC Review	R
26. Separation of the Release Specification and Shelf-Life Specification for Drug Products	R
27. Harmonization of International Standards for Pharmaceutical Equivalence Testing Standards	R
28. Deletion of Regulations on the Implementation of Re-Evaluation of Drugs	P
29. Unharmonized Clinical Trial Amendment Process and Inconvenience for Applying Variation Separately in the Current Clinical Trial Management System	R
30. Categorizing Regulatory Process and Exemption of Supporting Documents Based on the Risk Assessment of the Regulatory Change	R
31. Permitting E-Signature on the BSE Statement	R

32. Establish a Separate Classification System to Clarify the Management Scope of the Filler	R

Insurance Committee

1. Requesting a Supportive Review on the Proposal for Revision of Insurance Law for the Purpose of Prevention of Inheritance of Debts	R
2. Release of Standardized Repair Cost and Hours of Imported Cars	R
3. Improvement of Full Payment System In Bodily Injury For Medical Expenses	R
4. Addition of Insurance Companies to Notification Subject of Repair Estimates	R

Intellectual Property Rights Committee

1. Lack of Cooperation on IP Enforcement	P
2. Ineffective Sentencing of IP-Related Crimes	P
3. Border Seizures	R
4. Annual Report on Seizure of Counterfeit Products at Customs	R
5. Expansion of Express Mail Service (EMS) Projects	R
6. Designation of Special Judicial Authority to Local Government Officials	R
7. Open Sale of Counterfeit Products	P

Policy: P
Regulatory: R

8. Enforcement Against Similar Marks	R
9. Stakeholder Cooperation on Online Enforcement	R
10. Copyright and Royalties	R
11. Standard Essential Patents	P
12. Ambiguity as to Interpretation of Legislation Related to Control of Technology Export	R
13. Damage Calculation Methods	R

Kitchen & Home Appliances Committee

1. Improvement of the Labeling Requirement for Domestic Pressure Cooker	R
2. Converting KC Certificate into Electronic Document	R

Logistics & Transport Committee

1. Port-Mis Operational Secluding Reporting	R
2. Ocean Tariff Reporting for Korean Export/Import/Transit Cargo	R
3. Multimodal Transport Companies to Operate as Customs Brokers	R
4. Direct Shipment Requirement – General	P
5. Direct Shipment via Transit Hubs / Change of Mode of Transportation	P

Marine & Shipbuilding Committee

1. Practice of the Lowest Price Bidding System in Domestic Shipyards	P
2. Scope of Suppliers Compensation for Consequential Damages	P
3. Required Consent for Offshore Wind Projects	P

Aerospace & Defence Working Group

1. DAPA Offset Policy Guidelines –Article 13 related to liabilities for extension	R
2. DAPA Offset Policy Guidelines –Article 14 related to Offset Performance Bond	R

Energy & Environment Working Group

1. Direct LNG Import request from Companies Using City Gas NG	R
2. Direct Contract between KOGAS and Industrial Gas · Chemical Companies for NG Purchasing	R
3. Measuring Instrument Verification of EV (Electric Vehicle) Charging Stations	R
4. Plug Type of EV Charging Station	R
5. Ease in Regulations regarding Licenses needed for Handling of Radioisotopes (RI license)	R
6. Clean Energy Production through Fuel Flexibility and Enhanced Efficiency	R

Policy: P
Regulatory: R

7. Amendment of REC (Renewable Energy Certificate) Price Scheme	R
8. Differentiation of REC Price between Local and Imported WTGs (Wind Turbine Generator)	P
9. Centralized Permit Process for Renewable Energy	P
10. PPA (Power Purchase Agreement) Contract Discrimination	P
11. Financial Support for Renewable Energy: Limit of Current REC	R
12. Energy Efficiency in Building: G-SEED Certification for Green Buildings	R

HR Working Group

1. Annual Leave Entitlement	P
2. Exclusion from Benefits to Small and Medium-Sized Enterprises	P
3. Employment of Personnel with a Disability	P

ICT Working Group

1. Cloud Security Assurance Program (CSAP)	P
2. e-Government Standard Framework Preferred Application	P
3. Application of Foreign Vendor Standard Contract by the Public Agencies	R

Taxation Working Group

1. Request for a Deadline Extension of Corporate Tax Return Filing	R
2. Request to Ease Tax Requirements of Salary Income for Foreigner with Regards to COVID-19	R
3. Improving the Convenience and Administrative Efficiency of Individual Income Tax Return Filing & Tax Payment Procedures for Non-resident Partners for Foreign Law Firms	R
4. Creation of a Permanent Establishment (PE) due to the Temporary Displacement of Employees due to COVID-19 Travel Restrictions	R
5. Unclear Audit Period for Documentary Audit	R
6. Tariff Assessment on the Transfer Pricing Adjustment	R
7. The Criteria of Income Classification for Use of Software	R
8. Deductions/Credits for Housing Related Expenses	R
9. Deductions for Overseas Education Fees	R
10. Inclusion of Expenses Occurred Overseas as Global Income Tax Filing Deductible	R
11. Exclusion of Over par Purchase Bond Cost From Global Income Tax Calculation	R
12. WHT Issue When the Down Payment Paid to a Foreign Corporation is Substituted With Penalty/Compensation	R
13. Application of Transfer Pricing Regulations Under the Law for the Coordination of International Tax Adjustment to Domestic Related Party Transactions	R

Policy: P
Regulatory: R

14. Deadline for Country-by-Country Reporting Notification Form	R
15. Clarification of Conditions for Deferment of Collection	R
16. Public Notice of a List of Foreign Corporations by Category	R
17. (Special Case) Beneficial Ownership Test for Foreign Entities Other Than Overseas Investment Vehicles (OIVs)	R

Tourism Working Group

1. Improper application of Immigration Act, Article 99-3 of (Joint Penalty Provisions)	R

List of 'Low-hanging fruit' Issues

'Low-hanging fruit' refers to "sweet and easy-to-reach fruit at the lower end of a tree's branches", and it can be interpreted as "task that is relatively easy to solve". ECCK has selected 'low-hanging fruit' issues among the 145 issues and recommendations included in the ECCK White Paper 2020 that can be improved relatively easily with a high probability of implementation. The list of the issues are as follows.

Automotive Committee

10. Revision of Unnecessary Testing Methods Related to Emission/Noise Certification of Manufactured Motor Vehicles	p 74
11. Clarification of Subject for Reporting and Management on Defects of Emission Related Components	p 75
14. Clarification of the Calculation Methods for the Achievement Result on the Distribution of Low Emission Vehicles	p 78

Beer, Wine & Spirits Committee

3. Allowing Smart Order for Gifts	p 83
4. Deregulation of Digital Marketing Guideline on Smart Order	p 84

Chemical Committee

1. Technical Barriers to Trade (TBT) Notification on the Amendment and Establishment of Regulations Related to Chemicals	p 89

Cosmetics Committee

Food Committee

Healthcare Committee

Insurance Committee

Intellectual Property Rights Committee

Logistics & Transport Committee

In 2019, the ECCK committees and working groups across 20 different sectors have raised 180 key industry issues and suggestions to the Korean government. The government's feedback and ECCK's future actions per issue raised by each committee are listed as below.

Automotive Committe

A total of 13 issues from the ECCK Automotive Committee were raised in the 2019 White Paper and 5 issues received responses from the Korean government, with the committee's recommendations on those issues being accepted or partially accepted. ECCK readdressed some of the recommendations this year, reflecting the feedback from the government and the industry's additional opinions.

2019 Key Issues List

1. Condition and Subject of Vehicle Exchange/Refund Regulation
Government Feedback: Not Accepted
ECCK Future Action: Readdress

2. Test Standards of Traction Battery for EV/PHEV
Government Feedback: Not Accepted
ECCK Future Action: Need to Monitor

3. Harmonization of Identification of Hand Controls, Tell-tales and Indicators
Government Feedback: Partially Accepted
ECCK Future Action: Need to Monitor

4. Stipulation of Alteration Report in Law
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

5. Clarification of Calculation Method of Average Fuel Economy for High Fuel-Efficient Vehicles
Government Feedback: Accepted
ECCK Future Action: Readdress

2019 Review

6. Condition and Subject of Vehicle Exchange/Refund Regulation
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

7. Enhancing Flexibility on Regular Inspection
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

8. HS Code of Semitrailer-Towing Tractors
Government Feedback: Not Accepted
ECCK Future Action: Readdress

9. Vehicle Width Standard
Government Feedback: Not Accepted
ECCK Future Action: Readdress

10. GHG Calculation Program for Heavy-Duty Vehicle
Government Feedback: Accepted
ECCK Future Action: Readdress

11. EU-Korea Noise Level Standard Harmonization
Government Feedback: Implemented
ECCK Future Action: Need to Monitor

12. The Timing for Indication of Tire Safety Certification Mark
Government Feedback: Implemented
ECCK Future Action: Readdress

13. Designation as Business Suitable for Livelihood for Used Vehicle Sales and Small Automobile Repair Business
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

Beer, Wine & Spirits Committee

Beer, Wine & Spirits Committee presented 3 issues in the ECCK White Paper 2019. The issue which hasn't received yet the reply will be monitored continuously, and it is requested that the 'National Health Promotion Act' to be revised to allow the promotional and marketing activities for promotional items of alcoholic beverages. The use classification labeling requirements

2019 Review

for bottled beer will be abolished. Regarding the liquor sales via mail order and online, Smart Order makes possible to make online payments, but consumers still have to go to the store to pick up the products they have paid for.

2019 Key Issues List

1. Allowing Digital Marketing for Provision of Liquor Promotional Items
Government Feedback: Deadline Extension
ECCK Future Action: Need to Monitor

2. Revision of Use Classification Labeling Requirements for Bottled Beer
Government Feedback: Long-Term Review
ECCK Future Action: Closed

3. Allowing Liquor Sales via Mail Order and Online
Government Feedback: Long-Term Review
ECCK Future Action: Closed

Chemical Committee

While it was a positive outcome that the recommendation related to the designation of toxic substances has been accepted, however, continuous monitoring is needed to see whether the industry can secure a sufficient period and reasonable procedure for additional opinion submission until the relevant regulation is amended. In addition, it is encouraging that many suggestions regarding K-BPR have been amended or will be reflected in the revision, and the research project is underway in line with the acceptance. However, there are still existing redundant regulations among and within chemical laws, and we will readdress the standards that do not harmonized internationally by supplementing cases from overseas.

2019 Key Issues List

1. Reinforcement of Transparency on Legislation and Notification Revision
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

2. Redundant Regulations on Chemical Substances
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

3. Timing and Requirement of Notification and Submission of Change
Government Feedback: Not Accepted
ECCK Future Action: Need to Monitor

4. Exclusion of Chemical Substances for R&D Use From Composition Submission
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

5. Exclusion of Consumer Biocidal Products From 'CCA' and Complementary Measures on the Matter in 'K-BPR'
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

6. Substance Subject to Intensive Control (SSIC): Designation and Notification of Contained Products
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

7. Threshold of Annual Domestic Combined Volume of Imported and Manufactured Chemical Substances
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

8. Quantitative Structure–Activity Relationship (QSAR) Data Submission
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

9. Simplification of Exemption Confirmation for R&D Use Chemicals
Government Feedback: Not Accepted
ECCK Future Action: Need to Monitor

10. IT System: Confidential Business Information (CBI) Protection for Exempted or/and Registered Substances by Proxy
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

11. Commenting Period before Public Notice of Toxic Substance Designation
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

12. Issue on Registration of Indirectly Imported Chemical Substance by OR
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

13. Notification by OR of Registered Substance Under 'Toxic Chemicals Control Act (TCCA)'
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

14. 'ARECs' Guideline for Exempted Article from Registration
Government Feedback: Not Accepted
ECCK Future Action: Need to Monitor

15. Registration and Notification of Change under 'ARECs' (Update of Submitted Dossiers)
Government Feedback: Partially Accepted
ECCK Future Action: Need to Monitor

16. Polymer Registration
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

17. Deletion of SSIC Requirement in Polymer Low Concern (PLC) and Polymer Notification
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

18. Data Exemption for Biocidal Product Registration
Government Feedback: Implemented
ECCK Future Action: Closed

19. Criteria of Recognition for Imported Treated Article
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

20. Additional Notification for Existing Active Substance
Government Feedback: Accepted
ECCK Future Action: Closed

21. Labeling Requirement for Household Chemical Products
Government Feedback: Partially Accepted
ECCK Future Action: Need to Monitor

22. Global Harmonization of Safety Standard for Household Chemical Products
Government Feedback: Partially Accepted
ECCK Future Action: Need to Monitor

23. Duplicated Control of Hygiene Products
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

24. Universal Chemical Tracking System (UTCN) and Duplicated Submission of Chemical Information
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

25. Notification of Chemical Substance Identification by Representative Appointed by Overseas Manufacturer
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

26. Configuration of Chemical Substance Identification Number
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

27. Notification of Change for Chemical Substance Identification
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

28. Subject to Exemption from Investigation of New Chemical's Harmfulness and Hazardousness
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

29. Submission of Material Safety Data Sheet
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

30. Submission of Changes in Material Safety Data Sheet
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

31. Requirements for CBI Approval in Material Safety Data Sheet
Government Feedback: Not Accepted
ECCK Future Action: Readdress

Cosmetics Committee

The issues that are accepted or responded with a 'long-term review' in the White Paper 2019 will be monitored continuously. Also, the practical problems of the issues regarding manufacturing information, customized cosmetics, the human application test data, and the Korea Fair Trade Commission (KFTC) will be further identified. The Sun Protection Factor (SPF) indication issue is recognized as being required additional evidence. Some of the issues will be updated in the White Paper 2020 to reflect the current situation and comments from the industry.

2019 Key Issues List

1. Package Recycle Classification Regulation
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

2. Labeling & Advertisement of Cosmetics Using Natural Related Claims
Government Feedback: Not Accepted
ECCK Future Action: Readdress

3. Improvement of Free Sale Certification (FSC) Submission Requirements
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

4. Improvement of Documents for Submission of Preliminary Report for Customs Clearance
Government Feedback: Not Accepted
ECCK Future Action: Need to Monitor

5. Improvement of Entry Item of Preliminary Report for Customs Clearance
Government Feedback: Not Accepted
ECCK Future Action: Need to Monitor

6. Recognition of Electronic Documents for Preliminary Report of Customs Clearance
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

7. Manufacturers Information
Government Feedback: Not Accepted
ECCK Future Action: Closed

8. Customized Cosmetics
Government Feedback: Not Accepted
ECCK Future Action: Closed

9. Sun Protection Factor (SPF) Indication
Government Feedback: Not Accepted
ECCK Future Action: Closed

10. Human Application Test of Functional Cosmetics
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

11. Adding "Actors" to the Sanction List of Unfair Labeling or Advertising Forbiddance
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

12. Establishing the Warrant System for Corporate Investigation by the Korea Fair Trade Commission (KFTC)
Government Feedback: Not Accepted
ECCK Future Action: Closed

13. Establishing the Scope and Format Limit of Data Requests from Korea Fair Trade Commission (KFTC)
Government Feedback: Not Accepted
ECCK Future Action: Closed

Fashion & Retail Committee

ECCK is pleased that since mentioning the challenges related to the importation procedure of infant clothing, Korea Customs Service has created guidelines for its Alleviated Customs Procedure, allowing for reduced inspections and exempting import requirements for applicants that have high compliance rates. ECCK looks forward to foreign companies benefitting from such measure.

ECCK further notes the plans by the Ministry of Trade, Industry and Energy (MOTIE) to hold an industry meeting to discuss the price labeling system.

ECCK does note that challenges related to direct shipment, pH restriction level and safety testing of infant textile products persist.

2019 Key Issues List

1. Direct Shipment Requirement
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

2. Price Labeling Requirement
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

3. pH Restriction Level under the Safety Quality Labeling Standard
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

4. Import of Infant Textile Products
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

5. Safety Testing of Infant Textile Products
Government Feedback: Not Accepted
ECCK Future Action: Readdress

6. Consultations in Advance of Regulatory Amendments
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

Food Committee

Regarding the 'natural flavor' issue, it is recommended that the standards will be reviewed in harmony with the international standard. Moreover, the issues regarding the Non-GMO labeled products from overseas and the revision on labeling requirements are subject to be readdressed by reflecting the situation and opinions of the industry. ECCK will also continue to monitor the situation on implemented issues.

2019 Key Issues List

1. Definition and Specifications on 'Natural Flavor'
Government Feedback: Accepted
ECCK Future Action: Readdress

2. Equity is Required Between Good Overseas Manufacturer System and Good Overseas Importer System
Government Feedback: Implemented
ECCK Future Action: Need to Monitor

3. Non-GMO Labeled Products from Overseas
Government Feedback: Not Accepted
ECCK Future Action: Readdress

4. Improvements on Food Import Clearance Process
Government Feedback: Implemented
ECCK Future Action: Need to Monitor

5. Discussion Needed on the Revision of Labeling Among Government Agencies
Government Feedback: Not Accepted
ECCK Future Action: Readdress

Healthcare Committee

It is positive for the revision efforts such as expanding the scope of risk sharing agreement to include severe and incurable diseases, and latecomers, introducing a face-to-face review system, and planning to start a research for signing a mutual recognition agreement on GMP with the EU.

The long-term review or accepted issues will be monitored for the progress and non-accepted agenda will be readdressed to reflect the industry's opinions and to ensure recognition of innovation and rationalization of regulations.

2019 Key Issues List

1. Revising the PE Guideline for New Drug Patients Access Improvement
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

2. Expanding the Scope of PE Exemption System to Secure New Drug's Patient Access
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

3. Reforming the Formula Pathway for Fixed Dose Combination Drugs
Government Feedback: Not Accepted
ECCK Future Action: Readdress

4. Revising the New Requirements Imposed Through Drug Price Agreement
Government Feedback: Not Accepted
ECCK Future Action: Readdress

5. Making the Premium Pricing Policy for Global Innovative Drugs Realistic and Eligible
Government Feedback: Not Accepted
ECCK Future Action: Readdress

6. Expanding the Scope of Risk Sharing Agreement (RSA) For Better Patient Access
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

7. Eliminating the Value-Added Tax (VAT) Over-Burden (Or Double-Taxation) of RSA Refund
Government Feedback: Not Accepted
ECCK Future Action: Readdress

8. Introducing an Accelerated Listing Pathway to Save Patient Lives ('Pre-Reimbursement and Post-Evaluation' System)
Government Feedback: Not Accepted
ECCK Future Action: Readdress

9. The 4th National Cancer Care Plan
Government Feedback: Not Accepted
ECCK Future Action: Readdress

10. National Health Insurance (NHI) Coverage Expansion for Severe and Rare Disease
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

11. Reforming the Price-Volume Agreement (PVA) System
Government Feedback: Not Accepted
ECCK Future Action: Need to Monitor

12. Maintaining the Current Pricing System for Loss of Exclusivity (LoE) Drugs with Less Than three Generics (Surcharge System)
Government Feedback: Not Accepted
ECCK Future Action: Closed

13. Optimization of Planned Drug Control System E.G. Re-Evaluation, Drug Cost Control (Price Control Per Drug Class)
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

14. Improving the Predictability of Health Care Policies by Enhancing Transparency in Committee Decisions
Government Feedback: Not Accepted
ECCK Future Action: Readdress

15. Improving Transparency on Actual Transaction Price (ATP) Based Price Decrease
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

16. Allowing Foreign-Invested Companies to Keep the License of Their Locally Manufactured Drugs Through a Consignment Manufacture Process
Government Feedback: Not Accepted
ECCK Future Action: Closed

17. Adding a New Option of Multi-Regional Clinical Trial (MRCT) Data for a New Drug Registration
Government Feedback: Accepted
ECCK Future Action: Closed

18. Creating an Expedited Process for Clinically Urgently Needed Innovative Drugs
Government Feedback: Implemented
ECCK Future Action: Need to Monitor

19. Simplifying the Product Registration Renewals
Government Feedback: Not Accepted
ECCK Future Action: Closed

20. Creating a Mutual Recognition Agreement (MRA) with EU
Government Feedback: Accepted
ECCK Future Action: Readdress

21. Creating a More Favorable Conditional Approval for Innovative Medicines
Government Feedback: Accepted
ECCK Future Action: Readdress

22. Reducing the Tendency to Request Additional Data During the Investigational New Drug (IND) Review Process for Early Phase Trials
Government Feedback: Not Accepted
ECCK Future Action: Closed

23. Reforming the Post-Marketing Surveillance (PMS)
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

24. Revisiting the Repacking Requirements
Government Feedback: Not Accepted
ECCK Future Action: Closed

25. Innovative Pharmaceutical Company Designation Criteria to Be Fair to Foreign-Invested Companies
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

26. Simplification of Importing & Post-Usage Reporting Process of Ancillary Supplies (Medical Device, Electronic Equipment, Lab Supplies Etc.) Used for Clinical Trials
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

27. Simplifying the Quarantine Process Required for the Customs Clearance of QC Testing Reagents of Animal Origin
Government Feedback: Not Accepted
ECCK Future Action: Closed

28. Removing the BSE Free Statement for Every Batch and Shipment with COS Number
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

29. Implementing the Tariff Exemption for Investigational Medicinal Products (IMP)
Government Feedback: Not Accepted
ECCK Future Action: Closed

30. Improving the Vaccination Fee Scheme to Support Vaccination
Government Feedback: Not Accepted
ECCK Future Action: Readdress

31. Eliminating the Double Testing (Local QA Testing) for Vaccines and Medicines
Government Feedback: Not Accepted
ECCK Future Action: Readdress

32. Cancelling the New Regulation Imposing the Full Testing for Vaccines
Government Feedback: Not Accepted
ECCK Future Action: Need to Monitor

33. KC Certification for The Service/Maintenance Components of Medical Devices
Government Feedback: Accepted
ECCK Future Action: Closed

34. Import Prices for Reimbursement Pricing Cut
Government Feedback: Not Accepted
ECCK Future Action: Need to Monitor

Insurance Committee

In ECCK White Paper 2019, total of 5 items had been addressed to Financial Services Commission (FSC) Insurance division, Ministry of Land, Infrastructure and Transport (MOLIT), etc. As a result, item regarding 'Release of Standardized Repair Cost and Hours of Imported Cars' has been positively reviewed. The committee looks forward to substantive discussion and specific announcements through the insurance maintenance council, therefore will readdress reflecting the government's previous feedback. In order to request further review and open discussion for part of other not accepted items, it is readdressed through the White Paper 2020.

2019 Key Issues List

1. Cancellation of Protections to Drivers Driving Under the Influence of Alcohol
Government Feedback: Not Accepted
ECCK Future Action: Closed

2. Prior Notice and Disclosure of Increase in Automobile Parts Price
Government Feedback: Not Accepted
ECCK Future Action: Closed

3. Simplification of Identity Verifying Process in Quotation of Premiums
Government Feedback: Not Accepted
ECCK Future Action: Closed

4. Release of Standardized Repair Cost and Hours of Imported Cars
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

5. Requesting a Supportive Review on the Proposal for Revision of Insurance Law for the Purpose of Prevention of Inheritance of Debts
Government Feedback: Not Accepted
ECCK Future Action: Readdress

Intellectual Property Rights Committee

The ECCK is pleased to recognize initiatives that are aimed at establishing a more supportive IP environment in Korea. We would like to particularly highlight the preparations to increase the maximum amount of statutory damages for trademark infringements, as well as new regulations on liability of online service providers for the distribution of counterfeit products, both of which were included in the ECCK White Paper 2019. Various recommendations of the IPR chapter of last year's White Paper that went unanswered are readdressed in this year's White Paper.

2019 Key Issues List

1. Studies about Economic Impact of Counterfeit Industry
Government Feedback: Long-Term Review
ECCK Future Action: Closed

2. Lack of Cooperation on IP Enforcement
Government Feedback: No Response Received
ECCK Future Action: Readdress

3. Ineffective Sentencing of IP-Related Crimes
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

4. Border Seizures
Government Feedback: No Response Received
ECCK Future Action: Readdress

5. Parallel Importation
Government Feedback: No Response Received
ECCK Future Action: Readdress

6. Investigations at Free Trade Zones
Government Feedback: Partially Accepted
ECCK Future Action: Need to Monitor

7. Open Sale of Counterfeit Products
Government Feedback: No Response Received
ECCK Future Action: Readdress

8. Enforcement Against Similar Marks
Government Feedback: No Response Received
ECCK Future Action: Readdress

9. Pro-Active Measures by Online Intermediaries
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

10. Stakeholder Cooperation on Online Enforcement
Government Feedback: No Response Received
ECCK Future Action: Readdress

11. Copyright and Royalties
Government Feedback: Not Accepted
ECCK Future Action: Readdress

12. Standard Essential Patents
Government Feedback: No Response Received
ECCK Future Action: Readdress

13. Ambiguity as to Interpretation of Legislation Related to Control of Technology Export
Government Feedback: No Response Received
ECCK Future Action: Readdress

14. Damage Calculation Methods
Government Feedback: No Response Received
ECCK Future Action: Readdress

15. Statutory Damages
Government Feedback: Partially Accepted
ECCK Future Action: Closed

16. Consultations in Advance of Regulatory Amendments
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

Kitchen & Home Appliances Committee

Regarding easing test standards for household scales, a meeting was held in July 2020 to collect opinions from stakeholders on deregulation of formal approval and to discuss follow-up management measures. The issues of the adoption of the latest version of the technical regulation standard and the internationalization of the Korean technical regulations shall be closed.

2019 Key Issues List

1. Easing Test Standards for Household Scales
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

2. Latest Version Needs to be Adopted for the Technical Regulations
Government Feedback: Accepted
ECCK Future Action: Closed

3. Internationalization of the Korean Technical Regulations
Government Feedback: Accepted
ECCK Future Action: Closed

Logistics & Transport Committee

2019 Key Issues List

1. Tonnage Tax Regime
Government Feedback: Accepted
ECCK Future Action: Closed

2. Coastal Cabotage Exemption
Government Feedback: Not Accepted
ECCK Future Action: Closed

3. Sustainability & Environmental Legislation & Challenges
(1) – Inclusion in National Council of Clean Air and Climate Change
Government Feedback: Not Accepted
ECCK Future Action: Closed

4. Sustainability & Environmental Legislation & Challenges
(2) – Ship Scrapping
Government Feedback: Not Accepted
ECCK Future Action: Closed

5. Sustainability & Environmental Legislation & Challenges
(3) – Sulfur Tax
Government Feedback: Not Accepted
ECCK Future Action: Closed

6. Direct Shipment – General
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

7. Direct Shipment via Transit Hubs/Change of Mode of Transportation
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

Marine & Shipbuilding Committee

ECCK notes that the Korea Fair Trade Commission (KFTC) includes the use its standard subcontract agreements as a factor in rating companies in its Fair Trade Agreement Performance Evaluation

and is pleased that the KFTC will continue to make efforts to expand the practical use of standard subcontracting agreements.

ECCK is further pleased that through the revision of the Enforcement Decree of the Ballast Water Management Act products that have already obtained an approval type in a foreign country can be exempted from Korean tests. A wider acceptance of products that have already undergone overseas testing, as well as harmonization of Korean standards with international standards will further facilitate trade from and to Korea.

2019 Key Issues List

1. Localization Policy for Marine and Shipbuilding Industry
Government Feedback: Partially Accepted
ECCK Future Action: Need to Monitor

2. Harmonization of Standards
Government Feedback: Not Accepted
ECCK Future Action: Need to Monitor

3. Unfair and Impractical Purchase Terms and Conditions
Government Feedback: Partially Accepted
ECCK Future Action: Need to Monitor

4. Practice of the Lowest Price Bidding System in Domestic Shipyards
Government Feedback: No Response Received
ECCK Future Action: Readdress

Aerospace and Defense Working Group

Aerospace & Defense Working Group raised total 5 issues: Facility Security Clearance (FSC) for Korean Small and Medium-sized Enterprises, Offset Project Process, White List for Compliance of Korean Industries, Inconsistent Application of Evidence, Documentation Required to Prove Eligibility to Attend Explanatory Sessions, Requirement of CEO Signature. Among them, the recommendation of White List for Compliance of Korean Industries was accepted by the Korean government.

2019 Key Issues List

1. Facility Security Clearance (FSC) for Korean Small and Medium-sized Enterprises
Government Feedback: No Response Received
ECCK Future Action: Closed

2. Offset Project Process
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

3. White List for Compliance of Korean Industries
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

4. Inconsistent Application of Evidence / Documentation Required to Prove Eligibility to Attend Explanatory Sessions
Government Feedback: No Response Received
ECCK Future Action: Closed

5. Requirement of CEO Signature
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

Energy & Environment Working Group

It is expected to establish a safe environment for use and harmonize with the global standards as the recommendation for the revision of electric vehicle charging system standards was accepted. There were also positive achievements that the increase in the rates of biofuel mandate and additional cuts in the LNG import tariff will be partially reviewed. However, we plan to supplement opinions regarding the REC grants for self-consumption and G-SEED certification system and readdress them.

2019 Key Issues List

1. Electric Vehicle Charging System Standard
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

2. Consistency of Renewable Energy (RNE) and Recycling Policies: Biofuel Mandates in Liquid Fuel
Government Feedback: Partially Accepted
ECCK Future Action: Need to Monitor

3. Favor Gas Power Plant Development
Government Feedback: Partially Accepted
ECCK Future Action: Need to Monitor

4. Financial Support for RNE: Limit of Current REC(Renewable Energy Certificate)
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

5. Energy Efficiency in Building: G-SEED Certification for Green Buildings
Government Feedback: Implemented
ECCK Future Action: Readdress

6. Third Party Access to Domestic Electricity Market
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

7. Third Party Access to Domestic Water Market
Government Feedback: Implemented
ECCK Future Action: Need to Monitor

8. Accelerating Smart, Sustainable Cities Around the World Together
Government Feedback: Partially Accepted
ECCK Future Action: Need to Monitor

Human Resources Working Group

The ECCK is pleased to note the various plans to alleviate pertinent challenges in the labor market through incorporation of (part of) the recommendations contained in its White Paper 2019. These include the planned publication of a casebook on standards for Workplace Harassment, preparation of guidelines on comprehensive wage system, consultations with relevant ministries to establish support programs for private enterprises on applying public holidays as well as the legislative debate on

the establishment of a system of a flexible working hours period of up to six months. ECCK is looking forward to seeing the above plans materialize in concrete results.

2019 Key Issues List

1. Annual Leave Entitlement
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

2. Exclusion from Benefits to Small and Medium-Sized Enterprises
Government Feedback: No Response Received
ECCK Future Action: Readdress

3. 52-Hour Working Week
Government Feedback: Partially Accepted
ECCK Future Action: Need to Monitor

4. Workplace Harassment
Government Feedback: Partially Accepted
ECCK Future Action: Closed

5. Comprehensive Wage System
Government Feedback: Partially Accepted
ECCK Future Action: Need to Monitor

6. Public Holidays for Private Companies
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

7. Flexibilization of Labor Legislation
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

Taxation Working Group

In the ECCK White Paper 2019, total of 8 items out of 14 raised have either been accepted or is on-going under cautious review. The ECCK Taxation Working Group positively views the Korean government's such active review and effort for improvement, and look forward to further continuous and open discussion. Items which have been accepted yet seem incomplete, which are not accepted or is undergoing review yet need to re-address will be included in the White Paper 2020 with added global cases and more detailed description.

2019 Key Issues List

1. APA Completion Process
Government Feedback: Not Accepted
ECCK Future Action: Closed

2. Request for a Deadline Extension of Corporate Tax Return Filing
Government Feedback: Not Accepted
ECCK Future Action: Readdress

3. Request for Clarification of the Reporting Criteria of Simplified Payment Statement
Government Feedback: Accepted
ECCK Future Action: Closed

4. WHT Issue When the Down Payment Paid to a Foreign Corporation is Substituted With Penalty/Compensation
Government Feedback: Not Accepted
ECCK Future Action: Readdress

5. Application of Transfer Pricing Regulations Under the Law for the Coordination of International Tax Adjustment to Domestic Related Party Transactions
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

6. Deadline for Country-by-Country Reporting Notification Form
Government Feedback: Not Accepted
ECCK Future Action: Readdress

7. Guidelines for Preparation of Local Files for Financial Companies
Government Feedback: Long-Term Review
ECCK Future Action: Closed

8. Inclusion of Expenses Occurred Overseas as Global Income Tax Filing Deductible
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

9. Exclusion of Over par Purchase Bond Cost From Global Income Tax Calculation
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

10. Clarification of Conditions for Deferment of Collection
Government Feedback: Accepted
ECCK Future Action: Readdress

11. Public Notice of a List of Foreign Corporations by Category
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

12. Amendment of Tax Laws to Allow Companies to Participate Efficiently in Group Cash Pooling Arrangements
Government Feedback: Not Accepted
ECCK Future Action: Closed

13. Allow Deduction for Bonus Payment to Officers Provided Paid in Accordance With Employment Contract
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

14. Requirement for Government to Publish List of Territories that Provide Similar VAT Treatment as Korea on Professional and Business Support Services to Enable Companies to Determine Whether Services Eligible for Zero-Rate
Government Feedback: Not Accepted
ECCK Future Action: Closed

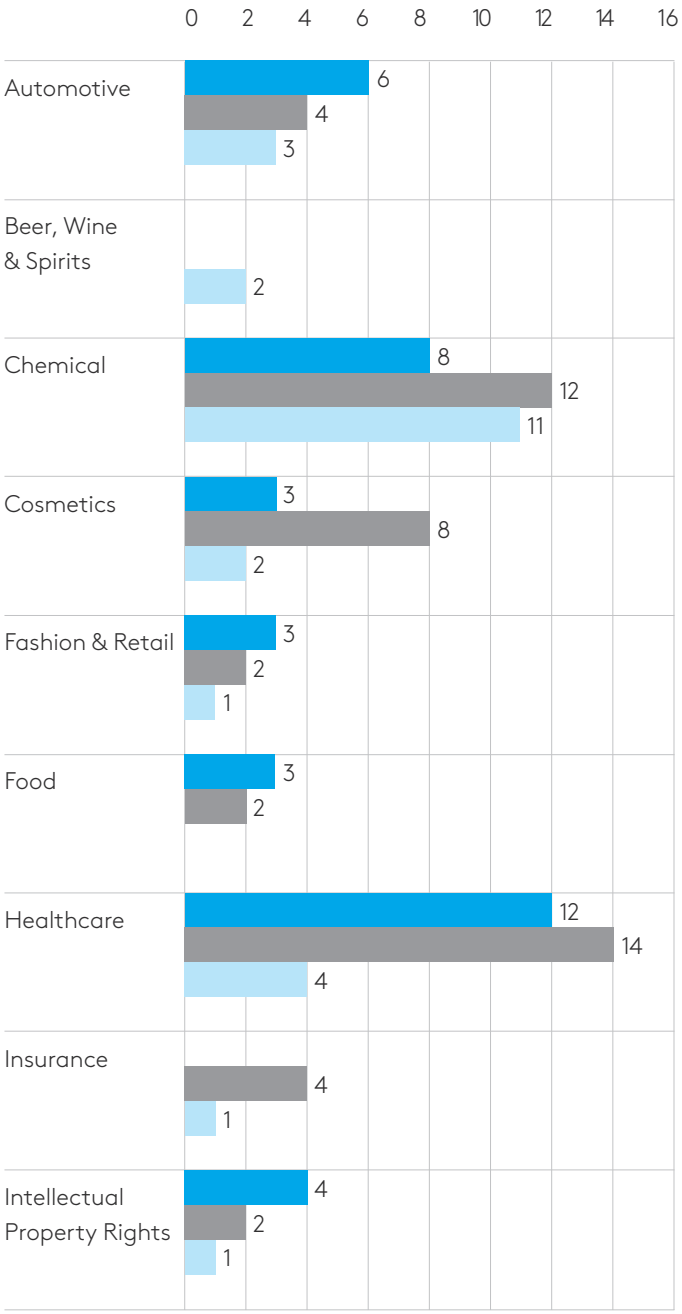
Tourism Working Group

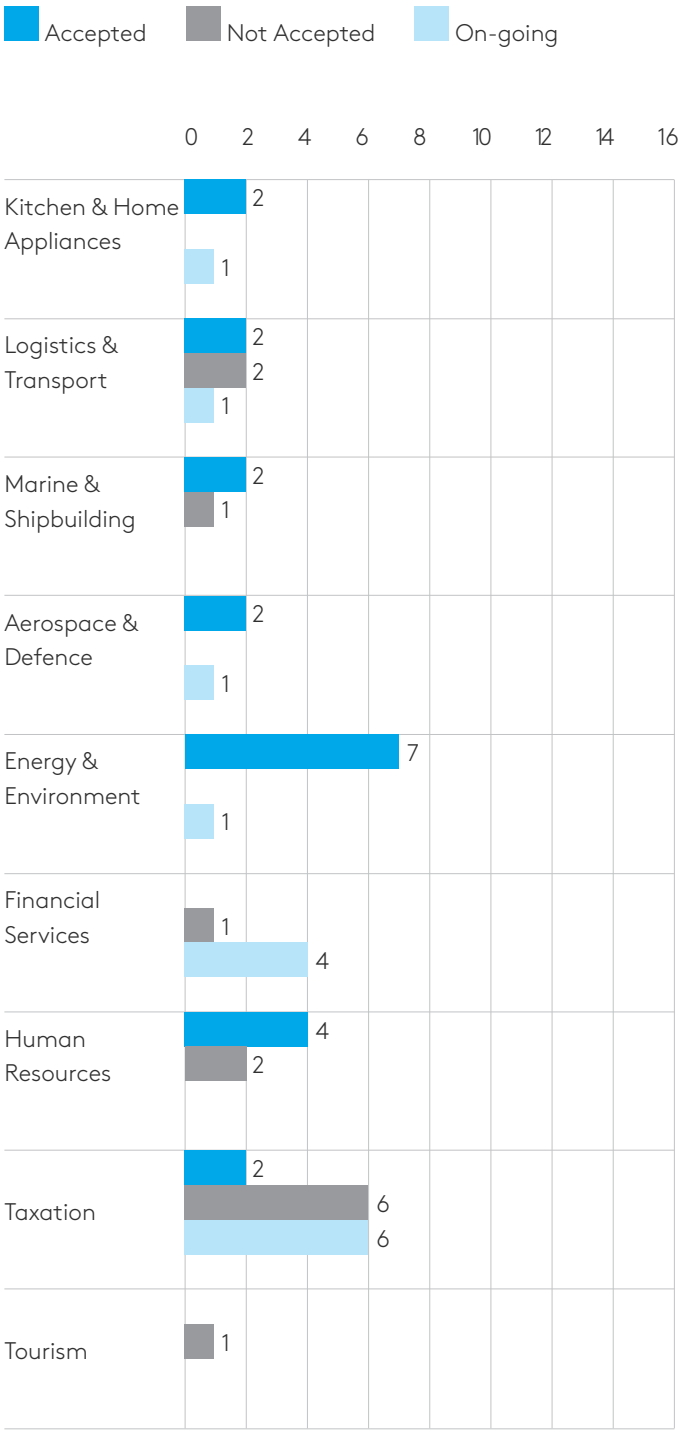
ECCK Tourism Working Group has raised the issue of Improper application of Immigration Act, Article 99-3 (Joint Penalty Provisions). However, the recommendation of the issue has not been accepted. The Tourism Working Group will raise this issue again in the White Paper 2020.

2019 Key Issues List

1. Improper application of Immigration Act, Article 99-3 (Joint Penalty Provisions)
Government Feedback: Not Accepted
ECCK Future Action: Readdress

ECCK White Paper 2019 Government Feedback (by Committe/Working Group)





ECCK Committee Reports

Automotive

Changhoon Rim
Head,
Automotive
Industry

Overview of the Industry

In 2019, the market share of imported motor vehicles in the domestic passenger vehicle market decreased by 6.1% compared to the previous year, but the market share of European automobile manufacturers in the imported passenger vehicle market rose to 75.2%. In the commercial vehicle market, the market share of European automobile manufacturers was 73.5% in tractor sector, 76.9% in dump truck sector, and 29.8% in large cargo sector. In the tire market, sales of imported tires showed a steady upward trend on the back of an increase in the ratio of imported tires installed in domestic motor vehicles.

In the regulatory field, the low emission vehicle supply target, which requires motor vehicle sellers to sell a certain percentage of low emission vehicles, has been implemented from 2020. In addition, the tire noise report and labeling regulation, which requires tire manufacturers to report the noise level of tires and include such on tires, have been implemented in 2020 to reduce traffic noise and to increase the distribution of low noise tires.

Currently, Korea and the EU continue to proceed for mutual recognition of technical regulations and harmonization with international standards based on the EU-Korea FTA, and are believed to have had very positive results so far. On the other hand, there is an opinion that improvement is needed in the procedures to collect opinions from the industry when revising domestic regulations. For automobile manufacturers whose headquarter is located overseas, it is difficult to analyze the impact and make decisions within a short period of time, considering the time required for discussions with headquarter and translation of relevant regulations. Therefore, it would be desirable to allow at least a 3 to 6 months discussion and review period when introducing new regulations or guidelines. Particularly in case of the target on greenhouse gas emission or low emission vehicle supply, it is recommended to be notified with medium-to-long term plan in advance to let manufacturers to have enough time of preparation. Also, it is expected that consultation with a panel of foreign manufacturers will help the government to prepare the trend of international standards and resolve concerns over trade barriers in the FTA.

Key Issue & Recommendation

1. Improvement of the System of Imposing Penalty Surcharges on Voluntary Recalls

Currently, automobile manufacturers are fined for non-compliance with safety standards when they take corrective measures for defects (recalls). However, there have been instances in which penalty surcharges have been imposed without reduction even if the automobile manufacturer voluntarily took corrective measures. Meanwhile, there also have been cases where penalty surcharges have been reduced even when the manufacturer took corrective measures following an order from the government , thus it is necessary to consider the equity in such cases. In case an automobile manufacturer is ordered to take corrective measures following an inspection by the government, those that actively cooperate with the investigation are subject to a reduction in penalty surcharges, while those that take corrective measures voluntarily are not, even though such could be considered as an extenuating circumstance. Since voluntary recalls can be initiated quickly, which can be considered to be a case where corrective measures are taken immediately, and it is necessary that the government take lenient measures for the case.

In addition, the current standard for imposing penalty surcharges is based on the number of vehicles subject to corrective measures. If the correction of manufacturing defects is taken by means of the replacement of parts, after an investigation on the total vehicles subject to corrective measures, the penalty surcharge should be calculated based on the number of "individual motor vehicles that do not actually meet the standards for automobile safety" and the number of vehicles that are found to be in compliance with the actual safety standards should be excluded from the calculation method.

Recommendation

It is recommended to revise the 'Standard for Imposing Penalty Surcharges under Article 74(2) of the Act' in Table 1-2 attached to the Enforcement Decree of the Motor Vehicle Management Act. Voluntary recalls should be exempted from the imposition of penalty surcharges or be amended to reduce the amount by at least 80%.

In addition, if the recall is taken by means of replacement of parts after an investigation on the total number of vehicles subject to corrective measures, it is recommended that the penalty surcharges should be calculated based on the number of "individual motor vehicles that do not actually meet the standards for automobile safety" and the number of vehicles that are found to be in compliance with the actual safety standards should be excluded from the calculation method.

Relevant Act/Regulation Motor Vehicle Management Act / Enforcement Decree of the Motor Vehicle Management Act

Responsible Authority & Division Ministry of Land, Infrastructure and Transport (MOLIT)

Recommendation Status New

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2. Improvement of Scope of Recalls

Under the current Motor Vehicle Management Act, automobile manufacturers are required to take corrective measures if a motor vehicle that has been manufactured is found to be defective. However, imported motor vehicles are considered manufactured once they are imported to Korea and are considered to be subject to manufacturing defects even before being sold. As a result, motor vehicle manufacturers are required to send notifications through mail and make announcements in newspapers on motor vehicles that are not owned by anyone yet, such as those before being taken out of the warehouse after import. This does not meet the purpose of the notification of defects to vehicle owners, and it is causing unnecessary cost and time for manufacturers.

Recommendation

It is recommended that the relevant regulations are revised so that the subject of recalls are limited to the motor vehicles that have already been sold.

Relevant Act/Regulation Motor Vehicle Management Act

Responsible Authority & Division Ministry of Land, Infrastructure and Transport (MOLIT)

Recommendation Status Updated

3. Flexibility for the Application of Total Repair Period of 30-days in Vehicle Exchange/Refund Regulations

Article 47-2 of the current Motor Vehicle Management Act stipulates that if a motor vehicle has been repaired at least once and the total period of repair exceeds 30 days, the owner of the motor vehicle may claim replacement of such motor vehicle with a new motor vehicle or the refund of the purchase price of such motor vehicle from the motor vehicle manufacturer. Currently, the total period of repair is interpreted as the period from the date the vehicle owner requests the repair to the date the automobile manufacturer notifies the owner of the completion of the repair. There is no exception clause to take into account delays in repairs due to unavoidable reasons. This may lead to undesirable situations, such as an application for a motor vehicle replacement or refund of the purchase price due to the fact that the repair period exceeded 30 days, even though the actual motor vehicle is free of defects. Accordingly, the definition of the total repair periods needs to be supplemented. In particular, there have been problems in the supply of motor parts in 2020 due to the shutdown of plats for motor vehicles and parts due to COVID-19, which cannot be solved by the automobile manufacturers and is hardly related to defects of motor vehicles.

Recommendation

It is recommended that an exception clause is prepared for the total repair period of 30 days. It is suggested to exclude the period of legal holidays, weekends, and delays caused by inevitable circumstances such as natural disasters from the total repair period.

Relevant Act/Regulation Motor Vehicle Management Act

Responsible Authority & Division Ministry of Land, Infrastructure and Transport (MOLIT)

Recommendation Status Updated

4. Expansion of Authority of the Secretariat of the Committee for Deliberation on Safety and Defects of Motor Vehicles

The implementation of the motor vehicle exchange and refund system (Lemon Law) allows motor vehicle owners to request exchange or refunds if certain requirements set out in the relevant laws are met. Such requests are subject to arbitration. However,

there are a growing number of cases in which vehicle owners apply for arbitration despite not satisfying the requirements for vehicle exchange/refund set forth in the relevant laws.

In order to prevent unnecessary administrative work and cost loss, it is necessary to institutionalize authority over the decision whether motor vehicle owners meet the requirements for the exchange the application from or the refund by expanding the authority of the Secretariat of Committee for Deliberation on Safety and Defects of Motor Vehicles. It should be necessary to specify the reasons for the apparent rejection in the regulations and, if applicable, the Committee for Deliberation on Safety and Defects of Motor Vehicles should make decisions. Examples of obvious reasons for rejection may be the cases where the owner did not notify the reoccurrence of a defect to the manufacturer or the owner did not provide the manufacturer a chance to repair the vehicle after the owner notified the reoccurrence of a defect to the manufacturer.

Recommendation

It is recommended to specify obvious reasons for the rejection on the application for an exchange or a refund of motor vehicles, and to authorize the Secretariat of Committee for Deliberation on Safety and Defects of Motor Vehicles to decide rejections without organizing an arbitral tribunal in cases where it is obvious that the application for an exchange or a refund of motor vehicles should be rejected.

Relevant Act/Regulation Motor Vehicle Management Act

Responsible Authority & Division Ministry of Land, Infrastructure and Transport (MOLIT)

Recommendation Status New

5. HS Code of Semitrailer-Towing Tractors

During the EU-Korea FTA negotiations, the HS Code of semitrailer-towing tractors was erroneously stated in the Annex 2-C-1 of the EU-Korea FTA. This has 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 semitrailer-towing tractors not subject to technical standard equivalence stipulated in Annex 2-C. The EU

safety standard of seat belt anchorage for semitrailer-towing tractors in particular, is currently not recognized to satisfy Korea's safety standard as per the EU-Korea FTA although the seat belt anchorage safety standard is included as an item for safety standard equivalence recognition according to Annex 2-C of the EU-Korea FTA. This leads to additional costs for the EU's automobile manufacturers to develop vehicles that meet Korea's safety standards separately, and manufacturers are restricted to import vehicles with more diverse specifications of the European market to Korea. Because of this, it is deemed that EU automobile manufacturers and Korean customers are not fully benefiting from the FTA.

Recommendation

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

Relevant Act/Regulation EU-Korea FTA Annex 2-C (Motor Vehicles and Parts)

Responsible Authority & Division Ministry of Land, Infrastructure and Transport (MOLIT) & Ministry of Trade, Industry and Energy (MOTIE)

Recommendation Status Retained

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6. Update of Annex of the EU-Korea FTA and UK-Korea FTA

In Table 1 of the Appendix 2-C-3 of the EU-Korea FTA and Table 1 of the Appendix 2-C-3 of the UK-Korea FTA, it is stipulated that the UNECE Regulations, can be recognized as complying with Korean safety standards for products originating in the EU or the UK . However, in case the provision number of Korean safety standards is amended, these amendments are not reflected in the tables in the applicable appendixes of the FTA, which makes it is unclear whether the UNECE standards can be recognized according to the FTAs.

Recommendation

It is recommended to update Appendix 2-C-3 of the EU-Korea FTA and the UK-Korea FTA reflecting the revisions of relevant regulations in Korea and EU to ensure that UNECE standards are recognized

in Korea as stipulated in the EU-Korea FTA and the UK-Korea FTA. Or else, it is recommended to prepare separate guidelines to clarify mutual recognition and equivalence of safety standards still after the change in clause number of Korean/European regulations.

Relevant Act/Regulation EU-Korea FTA Annex 2-C (Motor Vehicles and Parts) / UK-Korea FTA Annex 2-C (Motor Vehicles and Parts)

Responsible Authority & Division Ministry of Land / Infrastructure and Transport (MOLIT) & Ministry of Trade, Industry and Energy (MOTIE)

Recommendation Status New

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7. Recognition on Korean Motor Vehicle Safety Standards for EU Type Approval Vehicles

In Korea, when new safety standards are introduced, vehicles that are being manufactured, assembled, or imported at the date of entry into force can be recognized as existing types of vehicles and granted a certain grace period for the application of new safety standards. In Europe, in a similar way, existing types of motor vehicles are given a grace period on the application of new safety standards. However, in case vehicles that were recognized as an existing type of vehicle and given a grace period for application of safety standard in Europe and are imported to Korea later than the effective date of a particular new safety standard, such vehicles should satisfy the new Korean safety standard because they cannot be recognized as an existing type of vehicle in Korea. Even if the same effective date is applied in Korea and the Europe to the same safety standards, the importation of vehicles from Europe to Korea can be delayed due to the additional time required for Korean certification and delivery. Considering the basic principles and objectives of the FTA, it is recommended to seek measures that allow market access to Korea for European type approval vehicles.

Recommendation

It is recommended to recognize the compliance of Korean safety standards for the safety standard items on Table 1 of the Appendix 2-C-3 of the EU-Korea FTA or Table 1 of the Appendix

2-C-3 of the UK-Korea FTA (Safety Standards Equivalence Recognition Items) if the imported motor vehicles have received the type approval in Europe as existing types of vehicles.

Relevant Act/Regulation EU-Korea FTA Annex 2-C (Motor Vehicles and Parts) / UK-Korea FTA Annex 2-C (Motor Vehicles and Parts)

Responsible Authority & Division Ministry of Land, Infrastructure and Transport (MOLIT) & Ministry of Trade / Industry and Energy (MOTIE)

Recommendation Status New

8. Flexibility on Vehicle Width Standards

Article 4 of the current 'Rules on the Performance and Standards of Motor Vehicles and Parts' stipulates that the width of a motor vehicle cannot exceed 2.5m. Meanwhile, since the vehicle width standard in Europe is set at 2.55m, buses and some trucks built on a 2.55m-width standard from Europe cannot be imported into Korea. The motor vehicle width standard needs to be examined in connection with the road width standards, and the 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 an additional flexibility of 0.05m to the current vehicle width standard of 2.5m, permitting a 2.55m standard which is equivalent to the vehicle width standard of Europe. In particular, the flexibility for expanding the distribution of environment-friendly vehicles, such as electric buses, can be considered in accordance with the recent policy for 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 limited vehicle categories such as freight/special motor vehicles, double-decker buses, and environment-friendly buses/trucks, etc.

Recommendation

It is recommended to permit a 2.55m vehicle width standard for limited vehicle categories such as trucks/special motor vehicles, double-decker buses and environment-friendly buses/trucks, etc.

Relevant Act/Regulation The Rules on the Performance and Standards of Motor Vehicles and Parts

Responsible Authority & Division Ministry of Land Infrastructure and Transport (MOLIT)

Recommendation Status Retained

9. Stipulation of the Modification Report in Law

Article 48, Paragraph 2 of the 'Clean Air Conservation Act' requires automobile manufacturers to obtain certification for modification when they modify significant matters in the certification of emissions. However, the 'modification report' for the minor modifications that do not influence the emission is not regulated in the 'Clean Air Conservation Act' directly. For this reason, automobile manufacturers that did not report the modification for the minor modification are deemed to have violated the modification certification and can be subjected to criminal punishment. Moreover, unlike domestic manufacturers, imported vehicle manufacturers are exposed to the risk to be subject to additional punishment under the Customs Law for violating their duty to report modifications. Since the subject of the modification report is a change that has no impact on the environment, it seems that the proportionality and justification of punishment should be reflected in the punishment standard . On the other hand, other legislations similar to the 'Clean Air Conservation Act' clearly classify the 'modification approval/permit' of important modification and 'modification report/registration' of minor modification, and sanctions are differently regulated applying punishment for the violation of the former and fine imposition for the violation of the latter.

Recommendation

It is recommended to regulate the modification report for minor changes separately in the 'Clean Air Conservation Act' and differentiate the modification certification and modification report in its punishment referencing other legislation examples. When no modification certification is made, a penalty should be given and for violation of modification report, fines or measures other than criminal punishment should be given.

Relevant Act/Regulation Clean Air Conservation Act

Responsible Authority & Division Ministry of Environment (ME)

Recommendation Status Retained

10. Revision of Unnecessary Testing Methods Related to Emission/ Noise Certification of Manufactured Motor Vehicles

Because of the reinforcement of the emission standard, the Ministry of Environment (ME) revised the applicable testing methods in the relevant test notification accordingly. However, the current test notification includes test methods which were applied in the previous standard and this is causing confusion. For instance, there are cases in which the application for certification submitted by the manufacturer requires information about the weight of a motor vehicle according to the previous test methods, although the definition of the weight for motor vehicles has been changed due to the change in emission testing methods of diesel vehicles (NEDC→WLTP). In addition, the CVS-75 mode measurement method for the testing of emissions for gasoline vehicles also includes currently invalid testing methods for diesel vehicles, and in the test method for the exhaust noise and horn noise, the ISO 362 test method which is for the accelerated running in the previous standard is remained.

Recommendation

It is recommended to amend the currently invalid test methods of the notification for the clarity of the regulations on testing methods for emission/noise certification of manufactured motor vehicles.

Relevant Act/Regulation Notification for Test Inspection and Procedure of Manufactured Motor Vehicles

Responsible Authority & Division Ministry of Environment (ME)

Recommendation Status New

11. Clarification of Subject for Reporting and Management on Defects of Emission Related Components

In January 2020, the Ministry of Environment (ME)/National Institute of Environmental Research published a guide for reporting defects of emission related components and requested industry to input the relevant reporting requirements via Korea Emission & Noise Certification Information System (KENCIS) from the first quarter of 2020. However, it is not clear whether some parts are subject to reporting, and it is causing confusion in the industry. Remark 2 in Table 2 of the Enforcement Rules of the Clean Air Conservation Act stipulates 'other parts' related to the operation and control of major emission related components, but it is not clear whether the 'other parts' prescribed herein are also subject to reporting. Those 'other parts' are replaced together with major emission related components during warranty repairs, so they account for a significant portion of the number of requests for the correction of defects although the parts themselves do not have defects.

Currently, the input page for submitting the number of requests for the correction of defects and the analysis status for the correction of defects on KENCIS is designed to select items from the list based on the parts submitted during the basic certification and the certification for modification or to input other items directly. Because of this system environment, it will require significant administrative work in manufacturers to input 'other parts' mentioned above. In addition, there is a possibility of errors in input information because manufacturers should input 'other parts' which could be hundreds of cases individually.

Recommendation

It is recommended to limit the parts subject to reporting of defects of emission related components as parts , which were submitted in basic certification and modification certification. Also, it is recommended to exclude parts which were prescribed in Remark 2 of Table 20 in the Enforcement Rules of the Clean Air Conservation Act from the subject to reporting because those parts are not collected and managed by the certification authority directly.

Relevant Act/Regulation Clean Air Conservation Act / Guide for the Operation of Reporting the Defect of Emission Related Components and the Plans for the Correction of Defects

Responsible Authority & Division Ministry of Environment (ME)

Recommendation Status New

12. Establishment of the Medium-and Long-term Roadmap for the Low Emission Vehicles Supply Target

A motor vehicle seller that is required to distribute low emission vehicles should submit a plan for the distribution of low emission vehicles for the following year by December 31 and obtain approval from the Minister of Environment. Also, the motor vehicle seller should distribute low emission vehicles in accordance with the approved plan, and report the achievement result to the Minister of Environment. In order for motor vehicle sellers to establish such a low emission vehicles supply plan, medium-to-long term supply targets need to be presented in advance. However, such medium-to- long term supply target have not been proposed yet, so it is difficult for industry to establish a management plan regarding the distribution of low emission vehicles. In addition, some established policies are being regarded to have been insufficient in consultation with industry for its enactment, so closer discussions with the industry are required to establish goals.

Recommendation

In order for the motor vehicle sellers to establish and implement a plan for the distribution of low emission vehicles in the medium-to-long term, it is recommended that the target for the supply of low emission vehicles is established and noticed publicly with a medium-to-long term plan of at least 3 years.

Relevant Act/Regulation Clean Air Conservation Act/Enforcement Rules of the Clean Air Conservation Act

Responsible Authority & Division Ministry of Environment (ME)

Recommendation Status New

13. Clarification of the Calculation Methods for the Achievement Result on the Distribution of Low Emission Vehicles

Under the annual supply target of low emission vehicles implemented from 2020, motor vehicle sellers are required to calculate the achievement result on the distribution of low emission vehicles and submit them to the Minister of Environment. However, it seems that the definition of 'zero emission mileage' and 'combined fuel efficiency' among the items in the notice which stipulates how to calculate achievement result is not clear, and it needs to be supplemented. Meanwhile, it is understood that the domestic system for the supply target of low-emission motor vehicles is designed in conjunction with the system for the average energy consumption efficiency and greenhouse gas emissions standard, and the measured fuel efficiency (not 5-Cycle corrected fuel efficiency) is used for calculation of the achievement result in average energy consumption efficiency and greenhouse gas emissions standard. With this being said, it is necessary to specify that the measured fuel efficiency should be used for 'zero emission mileage' and 'combined fuel efficiency' in the calculation method for the achievement result on the low emission vehicles supply target.

In addition, it regulates the ‘zero emission mileage’ for plug-in hybrid vehicle which is in class 2 low emission vehicles to be calculated in accordance with the ‘Notification for Test Inspection and Procedure of Manufactured Motor Vehicles’, however, it is difficult to measure the ‘zero emission mileage’ for plug-in hybrid vehicles according to the notification. Therefore, this also needs to be revised for the ‘zero emission mileage’ of plug-in hybrid vehicles to be measured in accordance with the 'Notification on the Test Method for the Energy Consumption Efficiency and Greenhouse Gas Emissions of Motor Vehicles'.

Recommendation

It is recommended to specify that the measured fuel efficiency is used for 'zero emission mileage' and 'combined fuel efficiency' in the Notification (2020 Annual Supply Target of Low Emission Vehicles). In addition, it is recommended to amend the measurement method of 'zero emission mileage' for the plug-in hybrids is to be measured in accordance with the 'Notification on the Test Method for the Energy Consumption Efficiency and Greenhouse Gas Emissions of Motor Vehicles’.

Relevant Act/Regulation Clear Air Conservation Act/2020 Annual Supply Target of Low Emission Vehicles

Responsible Authority & Division Ministry of Environment (ME)

Recommendation Status New

14. Flexibility in Utilization of Achievement Result in the Low Emission Vehicle Supply Target

The current system of the low emission vehicles supply target does not allow the carryover of exceeded achievement and reimbursement of shortage of the target, unlike the Systems for Average Energy Efficiency and Greenhouse Gas Emissions Standard of the same ministry in charge, the Ministry of Environment (ME). This lack of flexibility could place undue pressure on both of the ME and industry which operates and participates the target scheme, particularly in unforeseen circumstances, such as the spread of COVID-19 in 2020

As seen in other countries' policies on the distribution of low emission vehicles, the government's goal is to distribute low emission vehicles to a certain level in the medium-to-long term. A permission to carryover the exceeded achievement and reimburse shortage of the target will help motor vehicle sellers operate a low emission vehicle sales plan flexibly in accordance with their business plans, and may ultimately have the effect of inducing voluntary participation of the companies in achieving the government's medium-to-long term target for distributing low emission vehicles.

Recommendation

It is recommended to permit the carryover of the exceeded achievement and reimbursement of shortage of the target of the year, and regulate it in the Clean Air Conservation Act. It is also suggested to discuss with industry regarding the validity period of carryover/reimbursement and other methods of use (achievement result transaction methods).

Automotive
Committees

Relevant Act/Regulation Clear Air Conservation Act/2020 Annual Supply Target of Low Emission Vehicles

Responsible Authority & Division Ministry of Environment (ME)

Recommendation Status New

15. Examination of the Designating of 'Used Vehicle Sale Business' and 'Small Volume Automobile Repair Business' as Business Suitable for Livelihood

It is being reviewed to designate 'Used Vehicle Sales Business' and 'Small Volume Automobile Repair Business' as business suitable for livelihood. If those businesses are designated as business suitable for livelihood, it is expected that most European imported vehicle manufacturers cannot expand their business in those business area and it can have a negative effect on customer's satisfaction and sales of new vehicle of automobile manufacturers. It is considered that the used vehicle sales business and small volume automobile repair business are related with the safety of vehicles, and support from headquarter for specialized service and continuous investment is necessary. Also, it is indicated that the restriction for those business area is not corresponding to the market access provision which is stated in EU-Korea FTA, so in this regard, it needs to be considered that business restrictions on European and other imported motor vehicle companies on the businesses may cause a trade issue. Moreover, it is considered that the used vehicle sales business and small volume automobile repair business in imported vehicle are not largely engaged with small businesses because it requires the purchase of high-priced vehicle and the substantial investment.

Recommendation

It is recommended not to designate 'Used Vehicle Sales' business and 'Small Volume Automobile Repair' business as the business suitable for livelihood.

Relevant Act/Regulation Special Act on the Designation of Types of Business Suitable for Livelihood of Micro Enterprises

Responsible Authority & Division Ministry of SMEs and Startups (MSS)

Recommendation Status Retained

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16. Unification of Similar or Duplicated Regulations Related to Motor Vehicles

Currently, regulations related to motor vehicles are being managed by several ministries such as the Ministry of Land, Infrastructure and Transport (MOLIT), the Ministry of Environment (ME), and the Ministry of Trade, Industry and Energy (MOTIE). However, there are cases in which the relevant statutes are duplicated or conflicting each other and relevant authorities have different interpretations of the regulations. For example, there are cases of different interpretations of the definition of the weight or the fuel efficiency depending on authorities. In the emission test, there could be confusion for manufacturers if the manufacturer should refer the joint notification of 3 ministries as well as the notification of the ME. In the facility confirmation inspection, the duplicated inspections shall be conducted for the identical test equipment depending on the relevant ministries.

In this case, it is deemed advisable for a single institution to take overall control of related tasks, such as facility confirmation and issuance of certificates, by determining the suitability of equipment in accordance with the Notification of the National Institute of Environmental Research (NIER).

Even if the jurisdiction of each administrative department is limited and the purpose of the policy is different, it would be desirable for ministries to make consistent and systematic voices from the perspective of the government as whole. If there are overlapping and conflicting opinions among ministries on the same behavior, it may be deemed redundant regulations for companies and lead to management difficulties such as cost increase. Hence it is desirable to prepare relevant measures to prevent those problems.

Recommendation

It is recommended to clarify and unify the interpretation of the regulations for similar or duplicated regulations related to motor

vehicles. In addition, it is desirable to consolidate the relevant statutes on similar or duplicated regulations for the long term.

Responsible Authority & Division Ministry of Land, Infrastructure and Transport (MOLIT) / Ministry of Environment (ME) / Ministry of Trade, Industry and Energy (MOTIE)

Recommendation Status New

Beer, Wine & Spirits

Eunhye Baek
Manager,
Beer, Wine &
Spirits
Committee

Overview of the Industry

With the revision of the Liquor Tax Act in 2020, Smart Order has become possible for consumers to order alcoholic beverages online and pick up the products directly from the stores. In addition, as part of the 'Improvement Plan for Liquor TRegulations' announced by the Ministry of Economy and Finance and the National Tax Service, companies that hold liquor manufacturing licenses will be able to use third-party manufacturing facilities (OEM), and the classification labeling requirements 'for hypermarket' for beer and takju will be abolished.

The import of wine and spirits decreased by 5.1% to 4.65 million liters in 2019 comparing to 2018. And the cost deduction rate was 2.2%, the first decline in imports of alcoholic beverages that have shown the positive growth rate over the past decade.

Key Issue & Recommendation

1. Improvement of the Standard of Allowance of Testing

The current standard of serving size for tasting of liquor set by the National Tax Service's 'Guideline on the Affairs of the Liquor Tax Act' is inconsistent. The allowed serving size for beer, soju, and whisky are 18,000 liters, 12,960 liters, and 900 liters, respectively, and when the serving sizes are converted into alcohol volume, the gap is huge as it turns into 576 kg of beer, 1,752 kg of soju, and 288 kg of whisky. Also, permissible amount of tasting for whisky is only 288kg which is 10 times smaller compared to the general distilled liquor (2,880kg) with the highest permissible amount of tasting.

Recommendation

Two criteria for determining the social impact of alcohol use by WHO are alcohol consumption and drinking patterns. IConsidering the social cost of alcohol use, it is more reasonable to set the allowed serving size for tasting of each type of liquor based on the amount of alcohol rather than the current bottle/liter standard Thus, it is recommended to limit the total amount based on the same amount of alcohol for all types of alcoholic beverages.

Beer, Wine &
Spirits
Committee

Relevant Act/Regulation Notification of Order Delegation on the Establishment of Liquor Transaction Order Guideline on the Affairs of the Liquor Tax Act

Responsible Authority & Division Excise Tax Division/National Tax Service (NTS)

Recommendation Status New

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2. Offering Precise and Detailed Data of RFID System

It has been over ten years since it became mandatory for whisky to attach RFID tags since 2011, and this provided positive effects such as eradicating counterfeit whisky and contribution to transparent distribution. However, as there have been various changes in the situation, it is time for an overall review of the RFID system. The RFID tag, the only one of its kind to be applied only to whisky, continues to be a burden on the whisky industry due to additional costs and procedures.

Recommendation

Due to the nature of the whisky industry, it is difficult to understand responses from consumers and market. If return information and sales information by product level are shared through RFID system, it is expected to contribute to the development of the whisky industry with products and services that meet the market and consumer needs.

Relevant Act/Regulation Notice of delegation of orders concerning the offering and getting of alcoholic beverages/the other party and others

Responsible Authority & Division Excise Tax Division/National Tax Service (NTS)

Recommendation Status Updated

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3. Allowing Smart Order for Gifts

Smart Order, which is the online sales of alcohol permitted since April 2020, has been receiving positive responses from consumers and market. However, especially with the outbreak of COVID-19, it

is difficult for consumers to order and receive alcohol directly, and the National Tax Service has banned smart orders for purchases where orderer and receiver are different which limits the use of smart orders for gift purposes.

Recommendation

To increase the convenience of consumers and the efficiency of the business of the Smart Order, it is recommended to allow smart orders through using adult verification for purchases where orderer and receiver are different.

With that, it is considered that the illegal delivery of alcoholic beverages through delivery companies can be sufficiently screened out according to the current procedure for verifying the personal information of the orderer and the recipient.

Relevant Act/Regulation Notice of Delegation of Commands on the sale of alcoholic beverages by mail order

Responsible Authority & Division Excise Tax Division / National Tax Service (NTS)

Recommendation Status New

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4. Deregulation of Digital Marketing Guideline on Smart Order

The online ordering and sales of liquor is now possible through Smart Order, which was implemented in April 2020. Accordingly, companies need to advertise and promote the benefits of using smart order to consumers. However, under the current law, it is prohibited to advertise free gift promotions online, which hinders marketing activities for companies and have negative effect on consumer benefits.

Recommendation

In line with the purpose of the Smart Order, it is recommended to allow online gift promotions and discounts, which are commercial activities permitted under the Liquor Tax Act, to increase consumer convenience and business efficiency and encourage online orders to minimize face-to-face contact in the COVID-19 era.

Relevant Act/Regulation National Health Promotion Act

Responsible Authority & Division Ministry of Health and Welfare (MOHW)

Recommendation Status New

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5. Reinforcing Regulation on Safety Management by Parallel Importers, Protecting Brand Equity and Clarifying Responsibility

Safety management on imported foods by parallel importers is significantly important as the foods can affect customers' health directly. Currently, parallel imports are allowed to induce customers' rational consumption, but the parallel imported foods are in the blind spot of consumer safety management. Also, in the event of consumer complaints or safety issues of parallel imported foods due to insufficient management in distribution, it is difficult to protect brand assets and there is a concern that negative perceptions of the brand may increase. Furthermore, it is necessary to clarify the responsibility for parallel imported foods as distinguishing responsibility can be unclear.

Recommendation

It is recommended to strengthen 'The Special Act on Imported Food Safety Control' and to conduct regular checks on whether the importers are reporting overseas production locations properly. Also, the regulation on safety management of parallel imported goods during customs clearance should be strengthened.

In particular, regulations clarifying responsibility should be introduced, such as reinforcing the duty to protect brand assets when distributing parallel imported products in Korea, and directly asking the parallel importers to be held liable in case of consumer complaints or safety issues for parallel imported products.

Relevant Act/Regulation Fair Trade Commission 'Public Notice on Unfair Trade Practices for Parallel Importation' / Korea Customs Service 'Certification of Customs Clearance on Parallel Imported Goods' / Ministry of Food and Drug Safety 'The Special Act on Imported Food Safety Control'

Responsible Authority & Division Fair Trade Commission (KFTC) / Korea Customs Service (KCS) / Imported Food Safety Policy Bureau, Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

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6. Change 'Limits on Consumer Prize by Liquor Types' into 'Limits on Consumer Prize by Taxation Types' Based on Sales of the Previous Year

According to paragraph 10 of article 2 of the 'Delegated Orders on Establishment of Liquor Trade Order', "Liquor prize should be under 1.5% of the previous year's tax base by liquor types and provided at the licensed premises only." However, it is difficult for companies that handla large variety of liquor to follow the order. Also, using the previous year's tax base as a standard brings little benefit for customers as the price limit is low.

Recommendation

Taxation has changed into specific tax for beer. Therefore, for liquors subject to the ad valorem tax, it is recommended to remove the classification of liquor type and operate as a whole regardless of the classification. Also, sales of the previous year should be adopted rather than tax base of the previous year to strengthen customers' benefit.

Relevant Act/Regulation Delegated Orders on Establishment of Liquor Trade Order

Responsible Authority & Division Excise Tax Division / National Tax Service (NTS)

Recommendation Status New

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7. Sufficient Grace Period And Reasonable Introduction Of The Revision Of Packaging Related Regulations

The revision of the regulations on packaging materials has a significant impact on the design and development stage of the products. It also takes a lot of time when change is required. Nonetheless, only a very short grace period was given to the industry

to reflect the revised regulations which makes it difficult for industries to take appropriate measures within the given time. In particular, it is more difficult for importers, which need a relatively longer preparation period compared to local manufacturers.

(Example 1, "Simplified Measurement Methods for Product Packaging Materials and Packaging Methods" (revised on Nov 18, 2019 and enforced from Jul 1, 2020) → need to change packaging within seven months)
(Example 2, "Rules on the Standards of Product Packaging Materials · Packaging Methods" (revised on Jan 29, 2020 and enforced from Jul 1, 2020): prohibition of repackaging → The details of the regulation have not yet been finalized although the enforcement date is set to be Jan 2021.)

In addition, in accordance with the Article 11 of the 'Product Packaging Rules' (Prohibition of Repackaging of Packaged Products) which specifies that 'Repackaged products shall not be manufactured·imported·sold', imported products that have already been packaged when manufactured in the exporting country are essentially prohibited from packaging after import. Therefore, importers are far more disadvantaged than local manufacturers which can do additional packaging at their local facilities. Moreover, by prohibiting the packaging by importers after import and encouraging packaging in exporting countries, it can cause negative effects such as reducing the domestic packaging industry (job losses).

Also, according to the Resources Recycling Act, EPR (Extended Producer Responsibility) system which specifies packaging materials subject to recycling obligations (paper packs, glass bottles, metal cans, synthetic resin packaging materials) is being operated and recycling charges or contributions are paid. Nonetheless, the prohibition of all repackaging regardless of packaging materials could be considered inconsistent in regulations.

Recommendation

It is recommended that at least two years of grace period to be given in order to take appropriate measures for the revision of packaging related regulations.

Also, in line with the Article 11 of the 'Product Packaging Rules' (Prohibition of Repackaging of Packaged Products) "repackaged

Beer, Wine & Spirits Committee

products shall not be manufactured·imported·sold", repackaging exception criteria for importers should be established taking into account the fairness with local manufacturers that additional packaging is possible at local manufacturing factories. Furthermore, the prohibition of repackaging should be introduced gradually depending on packaging materials. To minimize confusion between consumers and industry and to comply with the regulation, it should be introduced to film sheets packaging materials first and gradually implement to easily recyclable materials such as paper after reviewing the result.

* This issue is also included in the Beer, Wine & Spirits / Cosmetics / Food Committee chapters.

Relevant Act/Regulation Act on the Promotion of Saving and Recycling of Resources / Rules on the Standards of Product Packaging Materials · Packaging Methods / Simplified Measurement Methods for Product Packaging Materials and Packaging Methods / Other packaging related regulations

Responsible Authority & Division Resource Circulation Policy Division / Ministry of Environment (ME)

Recommendation Status New

Chemical

Taeyang Kim
Coordinator, Chemical Committee

Overview of the Industry

The chemical industry, as the key national industry, is widely linked with other industries and provides endless scope of products depending on the chemical reaction, process, and formulation for daily life. The chemical industry's total global revenue reached USD 3.94 trillion in 2019. In the same year, chemicals were the 3rd most important commodity after machinery and transportation equipment in the total EU-Korea trade, and it accounts for 17% of export to and 16 of imports from Korea. Korea exported USD 26.1 billion worth of chemical products and ranked 7th in the world in 2019.

Korean chemical laws have continued strengthening to protect the public Safety and environment and are the highest regulatory level in the world. Industry upholds the purpose to enact and amend the chemical laws related to environment, health, as well as safety, however, it is important to harmonize internationally with the revision process and regulatory degree.

The chemical industry faced many difficulties as the human and materials resources have been restricted to move worldwide, including Europe and the US, due to the pandemic of COVID-19. Therefore, it is necessary to review the current chemical substance management system considering the highly advance supply chain around the world. It is also crucial for the Korean government to provide active policy supports and substantial deregulation to encourage the industry to smoothly implement and comply with the chemical regulations.

Key Issue & Recommendation

1. Technical Barriers to Trade (TBT) Notification on the Amendment and Establishment of Regulations Related to Chemicals

When enacting or amending relevant regulations occur TBT notification are made without being delayed for domestic cosmetics, pharmaceuticals and electronic products, and opinion collection period is accordingly given at least 60 days. However, the TBT notification is not distributed well for chemical products despite the regulations are affecting the import procedures, labeling and test standards. As a result, foreign manufacturers who are the direct stakeholders of imported products are frequently left behind in the

official channels to submit their opinions towards the amendment.

Furthermore, the WTO members must ensure the technical regulations, standards, and conformity assessment procedures to be non-discriminatory and do not interfere with the trade environment. With being said, it is obligated to accommodate predictable trade conditions by informing TBT matters in advance to other members.

Recommendation

We recommend the Ministry of Environment (ME) and Ministry of Employment and Labor (MOEL) to carry out TBT notifications so that the domestic and foreign stakeholder can secure to grasp the revision contents and submit opinions for the sufficient period in the case of amendment of laws or regulations affecting imported chemical products, such as the MSDS submissions to the MOEL before importing which amended in the early this year. The TBT notifications related to chemical products will increase the predictability of the trade environment for the domestic market of chemical industry and enhance the transparency of regulatory environment.

Relevant Act/Regulation N/A

Responsible Authority & Division Ministry of Employment and Labor (MOEL) / Ministry of Environment (ME) / National Institute od Environmental Research (NIER) / Ministry of Trade, Infrastructure and Energy (MOTIE)

Recommendation Status Updated

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2. Redundant Regulations: Chemical Accident Prevention Plan vs. Process Safety Report (PSR)

When a Process Safety Report is completed according to the OSHA, the Chemical Accident Prevention Plan (former the Off-Site Consequence Analysis) that is required under the CCA is simplified but not completely exempted. Even though the laws are different, the intention cannot be fundamentally different that result in redundant regulations.

Recommendation

If a Process Safety Report according to the OSHA is completed, the Chemical Accident Prevention Plan and facility standards required by the CCA should be exempted from the compliance. If the Chemical Accident Prevention Plan is completed by the CCA, the Process Safety Report according to the OSHA should be exempted.

Relevant Act/Regulation Chemical Control Act (CCA) / Occupational Safety and Health Act (OSHA)

Responsible Authority & Division Ministry of Environment (ME) / Ministry of Employment and Labor (MOEL)

Recommendation Status New

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3. Redundant Regulation of Import Procedures for Prohibited Substances

In order to import prohibited substances, the importer must obtain approval from the Ministry of Employment and Labor (MOEL) under the OSHA and submit them to the Ministry of Environment (ME) to obtain additional permission under the CCA. Permission procedures must be carried out for individual import cases, and it takes up to two months to reach the end-users. Given the fact the prohibited substances are already legally restricted for research purposes, the time and cost of overlapping regulations are becoming burdens for researchers who are the end-users as well as importers and sellers.

Recommendation

We recommend that the procedures to be consolidated into one competent department or the review period to be shortened to half of the current (20 days from the MOEL, 15 days from the ME) level.

Relevant Act/Regulation Chemical Control Act (CCA) / Occupational Safety and Health Act (OSHA)

Responsible Authority & Division Ministry of Environment (ME) / Ministry of Employment and Labor (MOEL)

Recommendation Status New

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4. Test Data Regeneration for Existing Chemical Substances

The Ministry of Environment (ME) and Korean Environmental Corporation (KECO) have been continuously conducting new studies for existing chemical substances since 2017 and a considerable number of studies are already existing in the EU or other countries. The process of selecting existing chemical substance to produce studies is not transparent and violates the OECD's principle of minimizing vertebrate animal testing. As the Korean authority produces cheap acute data, registrants still need to purchase expensive chronic data from data owner in other countries.

Recommendation

We recommend the Ministry of Environment (ME) to consider that target chemical to be tested is a polymer with no data both inside and outside of Korea. In addition, the selection process for existing chemical to be tested should be transparent. The lead registrant could request new study to Korean authority after data gap analysis is completed if needed. The existing chemicals to be tested shall be announced before the test is conducted and Korean authority shall investigate the possibility of exemption and the existing data.

Relevant Act/Regulation Act on Registration, Evaluation of Chemicals (K-REACH)

Responsible Authority & Division Ministry of Environment (ME) / Korean Environmental Corporation (KECO)

Recommendation Status New

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5. Deletion of Tonnage Limits for Quantitative Structure–Activity Relationship (QSAR) Data Submission

Currently, QSAR data is accepted only below 10 tpa registration, therefore there is no opportunity to submit alternative analysis data for high tonnage band registration which requires several toxicological studies (up to a maximum of 47). For this reason, it is inevitable to perform additional tests if there are no toxicity data generated internationally. In reality, it is difficult to utilize QSAR under the K-REACH due to the frequent supplementary order from the administrative agency and insufficient guidance. The regulation to produce additional test data even though the alternative analysis data are available does not coincide with the international trends to minimize animal testing.

Recommendation

It is realistically impossible to create toxic/eco-toxic data within the remaining grace period (approximately 13 months) in the situation to register the substances until 2021, in the case of inevitable testing due to the limitation of 10 tpa on QSAR data. Therefore, we encourage the Ministry of Environment (ME) to eliminate the limitation of volume for QSAR data. EU REACH encourages to use and accept the QSAR data without limitation of volume according to annex 7~11, so there are many substances registered by alternative sources.

Relevant Act/Regulation Act on Registration, Evaluation of Chemicals (K-REACH)

Responsible Authority & Division Ministry of Environment (ME)

Recommendation Status Retained

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6. Detailed Proof for Notification of Hazardous Substance Designation

Under the current Notice on Designation of Toxic Substance, only the results of identification and classification of toxic chemical substances are notified. In this case, those who hold test data for the substances designated as a toxic substance can inquire detailed proof to the National Institute of Environmental Research (NIER) based on the data if necessary, however downstream users have no choice but to accept the notification results without specific proof due to no possession of test data.

Recommendation

We recommend the Ministry of Environment (ME) and National Institute of Environmental Research (NIER) to notify the detailed proof such as “test items and results” clearly when announcing the Notice on Designation of Toxic Substance.

Relevant Act/Regulation Act on Registration, Evaluation of Chemicals (K-REACH) / Notice on Designation of Toxic Substances

Responsible Authority & Division Ministry of Environment (ME) / National Institute of Environmental Research (NIER)

Recommendation Status New

7. Individual Submission of Application Documents for Substance Approval

According to Article 19, Paragraph 4, Item 1 of the Act on Safety Control of Household Chemical Products and Biocides (K-BPR), the applicant would be able to submit the application materials for substance approval separately upon confirmation of the Minister of Environment when it is expected that joint submission would disclose the company's trade secret, resulting in a significant loss. Nonetheless, even if a company applied for confirmation of individual submission of application documents for substance approval due to occurrence of commercial loss from disclosing trade secret during the joint registration process, the National Institute of Environmental Research (NIER) ordered the supplementation for other reasons not directly related to the ground for individual submission that the applicant claimed. As such the individual submission is not available in fact which causes undue delay in the application process for substance/product approvals.

This is a basis of the European Chemical Agency (ECHA), which does not enforce the joint submission for EU BPR approval, and most of the submission takes place individually. Keeping a solid position to turn down the application for individual submission triggers undue delay in overall K-BPR registration process, substance/product approvals and serious damage to the industry as a result of disclosing trade secret.

Recommendation

We recommend the authority to enhance the flexibility to evaluate the application for individual submission to avoid unfavorable situation. It may give the serious impact to biocidal products or treated articles from undue delay in substance approval or withdrawal of application for substance approval as well. When it comes to data sharing, it takes place between the data owner and registrant(s). Therefore, even a data owner does not participate in joint submission, data owner as non-substance information exchange forum (SIEF) member would be able to cooperate with registrant(s) for data sharing. The SIEF may ask the consultation from a 3rd party trustee as to facilitate the data sharing process as a neutral person

to secure confidentiality of information collected from registrants in the SIEF.

Based on the guidance from EU and Korea on technical equivalence, the data can be shared in the consortium when the sources of each registrants have been evaluated as equivalent. Otherwise it implies to share confidential business information with 3 parties which would not be acceptable.

Relevant Act/Regulation Act on Safety Control of Household Chemical Products and Biocides (K-BPR)

Responsible Authority & Division Ministry of Environment (ME) / National Institute of Environmental Research (NIER)

Recommendation Status New

8. Technical Standard for Approval of Quasi-drugs Transferred from Ministry of Food and Drug Safety (MFDS)

The Ministry of Environment (ME) and the National Institute of Environment Research (NIER) did not accept the storage stability study which has been fully evaluated and accepted for product approval under EU BPR and Australian APVMA as to consider the potential complaint from industry in interim period of transferring the product registration from the Ministry of Food and Drug Safety (MFDS) to ME. This case would conflict with Annex 3 to the NIER Notice 2019-69 which stipulates the validity of stability study approved in OECD countries.

With regard to the new additive (co-formulant), never used in quasi-drugs (Household Chemical Products subject to Safety Confirmation under the K-BPR) before, the NIER requested the physicochemical properties, toxicity study reports (animal health, ecotoxicity and environmental fate), development background, origin and manufacturing process for the application of product approval as the Household Chemical Products subject to Safety Confirmation, even the applicant submitted the product data including toxicity studies. The request from the NIER on new additive would be much heavier than data requirements for biocidal product registration under EU and K-BPR regulations and scientifically unjustified.

Recommendation

We recommend that the authority to recall scientific justification to evaluate the test studies for substance/product approvals which needs to be aligned between quasi-drugs classified as the Household Chemical Products subject to Safety Confirmation and biocidal product registrations under the K-BPR.

Relevant Act/Regulation Act on Safety Control of Household Chemical Products and Biocides (K-BPR) / Regulation on Approval of Household Chemical Products subject to Safety Confirmation

Responsible Authority & Division Ministry of Environment (ME) / National Institute of Environment Research (NIER)

Recommendation Status New

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9. Delay the Due Date of Active Substance Approval or Reduce Review Period

Biocidal substances used in disinfectants, algicides, pesticides and repellents have grace period of 3 years, which is until December 31, 2022, for the approval. Industries have been recommending to submit the required documents 18 months before the due date by June 30, 2021 considering the review period of the National Institute of Environmental Research (NIER).

In order to receive the approval notice until the approval grace period, data must be submitted within the next year, but currently forming a consultative group is also being delayed as well as detailed guidelines for substance equivalence check, risk assessment, and effectiveness and efficacy data are not being prepared. As the impact of COVID-19 is not only affecting Korea but also around the world, preparation of data for registration is not going smoothly. In reality, the recommended deadline for data submission is approaching, but it is difficult to prepare them properly.

Recommendation

Even if the grace period is not as sufficient as in Europe, the grace period for approval of biocides, such as disinfectants, etc., which is currently 3 years, is needed to be extended for an additional 2 years.

Or, in the case of active substances such as disinfectants with a very short approval grace period of 3 years, the review period for the submitted data should be reduced to 6 months, or the submitted data is submitted by 2022. We request that the approval notice based on the 'completeness check' to be preceded and the 'compliance check and supplementary notice' be reviewed later.

In the case of EU BPR, there was a period of more than 10 years from the BPD implemented in 2000 to BPR in 2013, and in the case of active disinfectant, the Competent Authority Report (CAR) was submitted by 2018. And it is expected that ECHA's Biocide Committee (BPC) will prepare by 2019 and final approval will take more time. EU started BPR earlier than Korea, but EU has a sufficient grace period despite the experience of BPD, but in reality many active substances are not approved yet.

Relevant Act/Regulation Act on Safety Control of Household Chemical Products and Biocides (K-BPR)

Responsible Authority & Division Ministry of Environment (ME)

Recommendation Status New

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10. Guideline of Effects and Efficacy Success Criteria for Biocidal Product

It is unclear what effectiveness and efficacy data will be specifically required for biocidal products under current regulations. It is expected to be specified through guidelines in the future. If excessive amount of efficacy data is required, it will be a barrier of biocidal products registration. Moreover, if the success criteria of approval for the efficacy of biocidal products is not fixed quickly, companies cannot even decide whether to proceed with approval for biocidal actives.

Excessive demand for higher level efficacy data than what industry claims may lead to excessive prescription of biocidal actives. And it could hinder the launch of various products and it will have a negative impact to the industry.

Recommendation

We request the effectiveness and efficacy data in line with what

companies claim to be accepted. Also, we recommend 3 log efficacy data (99.9%), which is widely used for household products, to be accepted.

Relevant Act/Regulation Act on Safety Control of Household Chemical Products and Biocides (K-BPR)

Responsible Authority & Division Ministry of Environment (ME)

Recommendation Status New

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11. Review of Designation and Management System for Hazardous Chemicals

There are many substances that are designated as hazardous chemicals even though they are not solid substance nor physically hazardous, but simply because of its environmental toxicity. These substances are often not related to chemical accidents, such as leaks, fires, explosion, etc. As a result of the Off-Site Consequence Analysis, these substances only impact few meters radius, so it was determined that there is no need to require the Off-Site Consequence Analysis and facility standards.

Recommendation

We request to establish reasonable hazard criteria for the Chemical Accident Prevention Plan (former Off-Site Consequence Analysis) by considering the substance's physical risks and state and classify risk assessment targets among designated hazardous chemicals. It is necessary to technically and correctly improve current system so that the substances subject to the classified risk assessment can acquire to comply with the Chemical Accident Prevention Plan and facility standards, and the other designated hazardous chemicals can acquire business license without complying with the Chemical Accident Prevention Plan and facility standards.

Relevant Act/Regulation Chemical Control Act (CCA)

Responsible Authority & Division Ministry of Environment (ME)

Recommendation Status New

12. Exclusion of Consumer Biocidal Products from Application under the Chemical Control Act (CCA)

There are cases that biocidal substances have been classified as toxic chemicals, and the relevant products have more than the designated level of the toxic substances. For this reason, the regulatory obligation of hazardous chemical management have been imposed to the consumer product (currently Household Chemical Products subject to Safety Confirmation) transferred from the quasi-drugs under the Pharmaceutical Affairs Act even though it should be approved by the ME in compliance with the K-BPR.

If finished consumer products are classified as toxic substances, manufacturing, storage, and retail stores also should newly have the permission for the business license and handling facilities for hazardous substances in compliance with the CCA. This is the unreasonable regulation without considering the seller's handling conditions for the finished consumer products.

Recommendation

It is necessary to exclude finished consumer products from the mandatory application of hazardous chemicals depending on the characteristics (how to use/hazardous classification/solid form, etc.), otherwise, they are regulated redundantly both under the CCA and K-BPR since being already approved and controlled by the K-BPR. Therefore, we recommend complementing the accident management and response related to consumer products to the K-BPR (i.e. to add first aids for chemical accidents on the labeling of the product and place MSDS of the product at the warehouse excluding retail stores).

Relevant Act/Regulation Chemical Control Act (CCA)

Responsible Authority & Division Ministry of Environment (ME)

Recommendation Status Retained

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13. Redundant Requirements Within the CCA: Chemical Statistic Survey Report vs. Designated Hazardous Chemicals Circulation Report

The fact that the circulation data of one hazardous chemical product handled, such as import, manufacturing, and sales, is required

for repeated submissions as 'Chemical Statistic Survey Report' and 'Designated Hazardous Chemicals Circulation Report' respectively, only with excuse of different purposes of the reports, is understood to be unreasonable and administrative convenience regulation.

Recommendation

We request to unify two respective reports into the 'Chemical Statistic Survey Report'. Also, we recommend to design an IT system to utilize the submitted statistical survey information for the designated hazardous chemicals circulation since the items of 'Designated Hazardous Chemicals Circulation Report' are included in the 'Chemical Statistic Survey Report'.

Relevant Act/Regulation Chemical Control Act (CCA)

Responsible Authority & Division Ministry of Environment (ME)

Recommendation Status New

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14. Trade Secret Claim on Materials Safety Data Sheet (MSDS)

Although the regulatory lists falling under 'Substances Excluded from the Alternative Data in MSDS' is stipulated with the criteria for mixture respectively, it is excessive disclosure request that any content less than the criteria of mixture is also excluded from the alternative data in MSDS.

Since highly hazardous substances already have been designated as 'Substances Excluded from the Alternative Data in MSDS', the approval process of alternative data should be streamlined for protecting the trade secrets of companies as much as possible and minimizing the costs and manpower resources of the government and companies.

The draft of Public Notice, Annex 7-2 (Standards for Judgement on Necessity of Substitution) requires detailed information extended from Annex 7-1 Data Proving Trade Secrets rather than providing a practical criterion of judgement.

Recommendation

When the content less than the criteria of mixture for the regulatory lists, it is recommended to be exempted from 'Substances

Excluded from the Alternative Data in MSDS'.

Furthermore, we recommend the data proving the trade secret required for non-disclosure approval (the draft of Public Notice, Annex 7-1) would be simplified to the extent that it can be objectively verified and allow companies to autonomously prepare the data in accordance with the Unfair Competition Prevention Act. Also, it is recommended to provide a fair, clear, and objective standards for non-disclosure approval by re-specifying 'Standards for Judgement on Necessity of Substitution' in the draft of Public Notice, Annex 7-2.

Relevant Act/Regulation Occupational Safety and Health Act (OSHA) / Standards on Material Safety Data Sheet and Classification·Labeling of Chemicals

Responsible Authority & Division Ministry of Employment and Labor (MOEL)

Recommendation Status Updated

Ansook Park
Director,
Cosmetics
Committee

Cosmetics

Overview of the Industry

The economic impact of the COVID-19 pandemic has severely affected many industries. The cosmetics industry is no exception in this regard due to untact way of life including travel bans and social distancing, and the change in the distribution channel has been accelerated due to decline in sales at offline stores including duty-free shops.

As a result, the cosmetics industry is experiencing heavy financial losses that needs the Korean government's support and continuous deregulation to minimize the damage. Particularly, the packaging regulations are strengthened continuously in response to environmental issues, and enough time for preparation is necessary for the industry to take appropriate measures.

Key Issue

1. Sufficient Grace Period and Reasonable Introduction of the Revision of Packaging Related Regulations

The revision of the Ministry of Environment (ME) regulations on packaging materials has a significant impact on the design and development stage of relevant products. Also, it takes a lot of time when such change is required. Nonetheless, a very brief grace period is given to the industry to reflect the revised regulations, so there are many difficulties in taking appropriate measures within the given time. In particular, importers who need a relatively longer preparation period compared to local manufacturers, becomes more problematic.

(Example 1, "Simplified Measurement Methods for Product Packaging Materials and Packaging Methods" (revised on November 18, 2019 and enforced from July 1, 2020) → need to change packaging within seven months.)
(Example 2, "Rules on the Standards of Product Packaging Materials · Packaging Methods" (revised on January 29, 2020 and enforced from July 1, 2020): prohibition of repackaging → The details of the regulation have not yet been finalized although the enforcement date is set to be January 2021.)

In addition, in accordance with the Article 11 of the 'Product Packaging Rules' (Prohibition of Repackaging of Packaged Products), which specifies that "repackaged products shall not be manufactured·imported·sold", imported products that have already been packaged when manufactured in the exporting country are essentially prohibited from packaging after import. So, importers are far more disadvantaged than local manufacturers which can do additional packaging at their local facilities. Moreover, by prohibiting the packaging by importers after import and encouraging packaging in exporting countries, it can cause negative effects such as reducing the size of domestic packaging industry and decreases of employment.

Also, according to the 'Resources Recycling Act', the extended producer responsibility (EPR) system that specifies packaging materials subject to recycling obligations (paper packs, glass bottles, metal cans, synthetic resin packaging materials) is being operated and recycling charges or contributions are paid. Nonetheless, the prohibition of all repackaging regardless of packaging materials could be considered inconsistent in regulations.

Recommendation

It is recommended that at least two years of grace period to be given in order to take appropriate measures for the revision of packaging related regulations.

Also, in line with the Article 11 of the 'Product Packaging Rules' (Prohibition of Repackaging of Packaged Products) "repackaged products shall not be manufactured·imported·sold", repackaging exception criteria for importers should be established taking into account the fairness with local manufacturers that additional packaging is possible at local manufacturing factories.

Furthermore, the prohibition of repackaging should be introduced gradually depending on packaging materials. To minimize confusion between consumers and industry and to comply with the regulation, it should be introduced to film sheets packaging materials first and gradually implement to easily recyclable materials such as paper after reviewing the result.

* This issue is also included in the Beer, Wine & Spirits / Cosmetics / Food Committee chapters.

Relevant Act/Regulation Act on the Promotion of Saving and Recycling of Resources / Rules on the Standards of Product Packaging Materials ·Packaging Methods / Simplified Measurement Methods for Product Packaging Materials and Packaging Methods / Other packaging related regulations

Responsible Authority & Division Ministry of Environment (ME) / Resource Circulation Policy Division

Recommendation Status: New

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2. Package Recycle Classification Regulation

To encourage recycling, headquarters use recycled glass bottles of various colors to equalize the quality. In this case, glass bottles other than certain colors (colorless, brown and green) are classified as 'difficult to recycle' according to the Korean regulation. Also, they are included on the list of additional surcharges on recycling expenses. This is contrary to the purpose of the 'Recycling of Resources Act', which aims to promote the recycling of packaging materials.

Recommendation

It is necessary to improve the system lowers the number of recycle classification evaluations and surcharges on expenses.

Relevant Act/Regulation Resource Recycling Act / Standards on the Packaging Materials Structure and Ease of Recycling

Responsible Authority & Division Ministry of Environment (ME) / Resource Circulation Policy Division

Recommendation Status Updated

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3. Labeling and Advertisement of Cosmetics Using Natural Related Claims

Even though natural/organic cosmetics products are certified base on international standards, if these products do not meet the Korean certification standards of the natural/organic cosmetics, the product's labeling will appear "we cannot claim". Such regulation

impedes the consumer's right to choose the product based on accurate information , manufacturers' product developmentand is contrary to international harmonization of standards.

Recommendation

It is recommended to allow labeling and advertisement of natural-related claims including international standards (i.e. ISO index, etc.), when the company can substantiate them according to the regulation on substantiation of cosmetic labeling and advertisement. Countries that allow ISO norm 16128 include the EU, US, Japan, China, Taiwan and Russia.

Relevant Act/Regulation Cosmetics Act / Regulations on the Standards of Natural Cosmetics & Organic Cosmetics/Regulation on Substantiation of Cosmetic Labeling and Advertising

Responsible Authority & Division Ministry of Food and Drug Safety (MFDS) / Cosmetics Policy Division

Recommendation Status Retained

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4. Recognition of Electronic Documents for Free Sale Certificate and Manufacturing Certificate

Under the 'Consolidated Public Notice and Cosmetics Act', cosmetics marketing authorization holders are required to prepare customs clearance documents including free sale and manufacturing certificates, and the relevant agencies usually require the documents in paper form. As electronic documents are being used in various sectors domestically and internationally in line with the development of electronic supplementary systems that the choice of both paper or electronic documents should be available according to the circumstances of individual companies. Through this process, unnecessary administrative work is expected to be reduced.

Recommendation

It is suggested that electronic documents to be also recognized as an eligible format for the requirements of manufacturing and free sales certificates.

Relevant Act/Regulation Consolidated Public Notice/ Enforcement Rule of Cosmetics Act

Cosmetics Committee

Responsible Authority & Division Ministry of Trade / Industry and Energy (MOTIE) / Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

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5. Expansion the Inclusion Criteria of Human Applications Test for Help Soften Red Lines Caused by Stretch Marks

According to the Ministry of Food and Drug Safety (MFDS) guideline of human applications test to prove the function of cosmetics that help soften the red line caused by stretch marks, it has accepted 'red lines' as a symptom to be only found in the early stages of stretch marks, which makes it difficult to recruit test users and apply the cosmetics to the old stretch.

Recommendation

The selection criteria applicable to old stretch marks without red lines should be considered.

Relevant Act/Regulation Enforcement Rule of Cosmetics Act/ Guidelines for Human Application Test of Cosmetics to Help Soften Red Lines Caused by Stretch Marks

Responsible Authority & Division Ministry of Food and Drug Safety (MFDS) / Cosmetics Policy Division / National institute of Food and Drugs Safety Evaluation (Cosmetics Evaluation Division)

Recommendation Status New

Fashion & Retail

Sven-Erik Batenburg
Director,
Fashion & Retail
Committee

Overview of the Industry

Fashion is in high demand amongst Korean consumers, who exhibit a positive attitude towards and high-level awareness of European brands and products. While the domestic fashion market has seen growth over the past years, COVID-19 has resulted in a forecast decrease of 5.3%p until the end of 2020 and 2%p drop in 2021.

European fashion products do enjoy a popular perception by Korean consumers, resulting in many European companies in the fashion and retail sector having entered the Korea market. Korean consumers tend to have a very high level of brand awareness, and are also relatively well traveled, both are factors that benefit European brands.

Since its entry into force more than nine years ago, the EU-Korea FTA has offered preferential treatments for a wide range of EU fashion products shipped directly from the EU to Korea. This has increased interest on the part of EU companies in conducting business in Korea.

ECCK is pleased that since ECCK mentioned the challenges related to the importation procedure of infant clothing, Korea Customs Service has created guidelines for its Alleviated Customs Procedure, allowing for reduced inspections and exempting import requirements for applicants that have high compliance rates. Such measure can decrease the import burden on foreign companies and ECCK looks forward to foreign companies benefitting from such measure.

ECCK further notes the plans by the Ministry of Trade, Industry and Energy to hold an industry meeting to discuss the price labeling system, following its explanation of the challenges related to such in the White Paper 2019.

A high number of regulations, nevertheless, remain in place, and these pose a hurdle to the actual import and sale of various products from overseas companies. In order to stimulate local purchases and increase government revenue following such, ECCK favors a re-assessment of particularly onerous restrictions on fashion products imported to Korea.

Key Issues

1. Labelling of Consumer Products

Products sold in Korea are subject to compliance with various labelling requirements. Some of these requirements stem from the 'Safety Standards of Consumer Products Subject to Compliance with Safety Standards', which exist for a wide range of products ranging from leather products to sunglasses and textile products.

The various Safety Quality Labelling Annexes provide a number of indication methods in order to allow for products to be easily recalled in case of certain deficiencies. The indication methods include manufacturing date, import date, season of first sale and lot number, all of which can be used to recall products in case necessary.

Unfortunately, the indication methods differ from Annex to Annex, increasing the regulatory burden on companies. Whereas the labelling for leather products can only indicate the manufacturing date, the labelling of sunglasses can include either the manufacturing date, the import date or the lot number and the labelling of textile products can contain either the manufacturing date, the season of first sale or the lot number.

Recommendation

By allowing indication of products' import date, season of first sale and lot number, it has been accepted that all these indication methods are suitable alternatives to products' manufacturing date.

It is recommended that the labelling requirements for products throughout the Safety Quality Labelling Annexes is harmonized by inclusion of products' import date, season of first sale and lot number for all products.

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)

Recommendation Status Updated

2. Safety Testing of Infant Textile Products

The 'Special Act on Safety for Children Products' governs the safety requirements for all children's products. Since November 2018, the enforcement practices for infant textile products (for children below the age of three) have been amended.

Under such change, infant textile products are subject to customs verification, requiring an individual safety test for each product. Previously a single safety test was sufficient for various products.

Moreover, it is not accepted to evidence the products' safety through overseas testing reports. A lack of alignment on the safety standards serves as a barrier to successful trade, making it difficult for foreign products to enter the Korean market while simultaneously frustrating Korean products from entering new markets.

Recommendation

It is recommended that overseas safety tests of infant textile products are accepted and that additional testing in Korea is avoided.

Additionally, it is recommended that companies that have a low failure rate for safety tests over an extended period of time are subjected to random tests, rather than having to conduct safety test for all their products.

Eunhye Baek
Manager,
Food Committee

Overview of the Industry

Regulations on grading and labeling of packaging materials became effective on December 25, 2019. The Extended Producer Responsibility (EPR) producers are subject to these rules to classify packaging materials and label it by dividing them into four categories: Excellent, Good, Normal, and Difficult.

The 'Rules on the Standards of Product Packaging Materials · Packaging Methods', which was supposed to take effect on July 1, 2020, was suspended for six months. During this period, the Ministry of Environment plans to discuss "repackaging" issues through multi-sectoral consultative bodies and revise problems to implement them from January 2021.

According to the 2019 statistics of the Ministry of Food and Drug Safety, the amount of food and etc. import reached at USD 28.1 billion, which has increased by 2.8% comparing with last year and its weight, 18.6 million tons, which has increased by 0.3%. In particular, the amount of agricultural, forestry and fishery products imports decreased compared to 2018, while livestock and processed foods increased.

Key Issues

1. Grace Period for Revised Food Labeling Standards

According to the food labeling improvement policy (2017) from office for government policy coordination, it was agreed that regardless of the date and frequency of amendment to laws and notices related to food labeling regulation by each department, ministry, or agency government bodies, it was decided to unify the effective date as January 1 of an even-numbered year with a grace period of at least one year from the date of revision.

Nonetheless, recent amendment to Korea Food Code (No. 2020-3) which establishes new food category (dairy containing food), requiring to modify food labeling accordingly was announced with validity from January 1st, 2022, without update to food labeling standard. The concerned department is prohibiting to use the new terms until Food Labeling Standard is newly released. It is considered not in accordance with the agreed principle of change in even-numbered year.

Food
Committee

For food importers, the minimum stock of packaging materials is large, and it takes a lot of time to proceed with business with the overseas headquarters in reviewing imported food labels and changing packaging materials such as copper plate production, printing supervision, and packaging material production. It is difficult to for food importers to follow such short/unpredictable grace period.

Recommendation

It is recommended that any changes to food labeling must be made with respect to the agreed rule of even numbered of the date and the numbers of revision. In line with Korea Food Code No 2020-3 (effective from Jan 1, 2022), the new terms must be allowed to be labeled from now, in advance of the effective date.

Relevant Act/Regulation Korea Food Code (No. 2020-3)

Responsible Authority & Division Ministry of Food and Drug Safety (MFDS)

Recommendation Status Updated

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2. Ease the Labeling Standard of 'Natural Flavor'

Since 2018, the Ministry of Food and Drug Safety has revised the classification system of food additives in harmony with international standard to clarify the purpose of use by specifying the main purpose of each product without distinction of natural additives and artificial additives.

The main purpose of the revision was to eliminate the distinction between chemical compounds and natural additives. In the EU, the United States, and Japan, food additives are not classified based on the natural and artificial additives.

However, when it comes to the flavoring, it is managed separately from natural flavor and artificial flavor, and even when it is marked, it shall be marked separately with natural flavor and artificial flavor. As a result, many consumers wrongly recognize that natural flavor is safe and beneficial to the body, and artificial flavor is unsafe.

In the case of Japan, products are only labeled "flavoring" to avoid

misunderstanding by consumers.

Recommendation

Just as the labeling of synthetic sweeteners and synthetic pigments has disappeared, it is recommended to ease and allow to state 'flavoring' only rather than to differentiate 'natural flavor' or 'artificial flavor'.

Relevant Act/Regulation Act on Labeling and Advertising of Food

Responsible Authority & Division Ministry of Food and Drug Safety (MFDS)

Recommendation Status Updated

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3. Review on Standard of 'Natural Flavor'

In Korea, flavoring is imported by foreign countries, and most Korean perfumers are supplied with flavoring from perfumers in overseas countries, and only partially modify it. In other words, it is extremely rare to create a new flavoring.

Therefore, Korean perfumers are highly dependent on the flavoring produced by foreign perfumers, and the flavorings in overseas countries have already been proven safe and are listed in IOPI and FEMA.

However, according to MFDS's Regulation No. 2018-53, '3) Flavoring substances...Codex, FEMA (Flavor and Extract Manufacturer's Associations), or IOFI (International Organization of the Flavor Industry) can be used based on the flavoring substances of international common use' of which clause was removed, but positive list of artificial flavor substances was newly established.

As a result, there is confusion in determining the flavorings contained in the product, and it is difficult for the Regional Office of Food and Drug Safety to confirm whether only the flavorings in the positive list are available and safe. For your information, the perfumers of overseas countries do not disclose details of the flavoring for confidentiality reasons.

Recommendation

It is recommended that adding the clause in the existing regulation

that states, "If it is used internationally as a food flavor, such as CODEX, FEMA, and IOPI, it is also recognized in Korea" will prevent confusion in the handling of the work by the industry and the Regional Office of Food and Drug Safety.

Relevant Act/Regulation Food Additive Code

Responsible Authority & Division Ministry of Food and Drug Safety (MFDS)

Recommendation Status Updated

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4. Non-GMO Labeled Products from Overseas

Japan does not apply legal sanctions against Non-GMO labelled by foreign countries, even if a product on sale in an exporting country is labelled as Non-GMO so long as Japanese sticker is not labeled as Non-GMO.

However, due to the strict Korean regulations, if Non-GMO labelled products on sale in overseas countries are imported, there are many difficulties such as attaching a sticker for covering Non-GMO labeling.

Recommendation

It is recommended to establish an escape clause, allowing that all the requirements in domestic regulations would not need to be met, for international coordination, only if Non-GMO labelled products on sale in foreign countries are imported.

Only if Non-GMO labelled products on sale in foreign countries are imported:

- Non-GMO labeling on products from foreign countries can remain the same.
- But Non-GMO or "non-genetically modified food" cannot be indicated on Korean labelling.
- To avoid misunderstanding by consumers, make sure to clearly state on the Korean labeling, which the labeling in foreign languages (e.g. English, Japanese) is not in accordance with the domestic regulations.

Relevant Act/Regulation Standards and Specifications for Utensils, Containers and Packages

Responsible Authority & Division Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

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5. Extension of the Scope of Permissible Recycled Plastic Resins for Utensils, Containers and Packages of Food

There are no limitations of usage of various recycled plastics (i.e. rPP, rPE) in other major jurisdictions such as the EU, US, and Japan, and the actual usage volume of those recycled plastics is growing fast. In the EU, Commission Regulation (EC) 282/2008 stipulates for the materials on recycled plastic materials in direct contact with food. According to the regulation, monomers and oligomers resulting from chemical depolymerization should not be treated differently from monomers manufactured by chemical synthesis.

In 2006, US FDA issued the guidance for the use of recycled plastics in food packaging. According to the guideline, manufacturers are responsible for ensuring that recycled material meets all existing specifications for the virgin material and the guidance requires evaluation by the FDA. There are already many businesses that acquired no objection letters (NOL) for the recycled plastic materials like polypropylene and polyethylene.

In Japan, the recycled plastics are ruled by the 'Guidelines Related to Recycled Plastics in Utensils and Food Packaging'. According to the guideline, it must be scientifically demonstrated that the chemical contaminants are adequately removed during the recycling process and will not eventually permeate into the food. The guidance suggests manufacturers and importers of utensils and food packaging can request the Japanese authorities' concurrence regarding the safe use of recycled plastics in the applications.

However, Korea is only allowing rPET and rPEN as food contacting material and other recycled plastics cannot be used for the same purpose, even if they are recycled through scientifically proven safe method.

Recommendation

It is recommended to expand the scope of recycled plastic, which can be used as food contacting material to other various recycled plastics such as rPP and rPE like other major jurisdictions.

Relevant Act/Regulation Standards and Specifications for Utensils, Containers and Packages

Responsible Authority & Division Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

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6. Sufficient Grace Period and Reasonable Introduction of the Revision of Packaging Related Regulations

The revision of the ME regulations on packaging materials has a significant impact on the design and development stage of relevant products. It also takes a lot of time when change is required, but very short grace period is given, which makes it difficult for the industry to take appropriate measures and reflect the revised rule within the given time. In particular, for importers, which need a relatively longer preparation period compared to local manufacturers, the short grace period becomes more problematic. (Example 1, "Simplified Measurement Methods for Product Packaging Materials and Packaging Methods" (revised on November 18, 2019 and enforced from July 1, 2020) → need to change packaging within seven months)), (Example 2, "Rules on the Standards of Product Packaging Materials · Packaging Methods" (revised on January 29, 2020 and enforced from July 1, 2020): prohibition of repackaging → The details of the regulation have not yet been finalized although the enforcement date is set to be January 2021.)

In addition, in accordance with the Article 11 of the 'Product Packaging Rules' (Prohibition of Repackaging of Packaged Products) which specifies that 'repackaged products shall not be manufactured·imported·sold', imported products that have already been packaged when manufactured in the exporting country are essentially prohibited from packaging after import. Thus, importers are faced with more difficulties than local manufacturers that can allow additional packaging to be done at their local facilities. Moreover, by prohibiting the packaging after import by importers

Food Committee

and encouraging packaging in exporting countries, it can cause negative effects such as reducing the domestic packaging industry (job losses).

Also, according to the Resources Recycling Act, Extended Producer Responsibility (EPR) system which specifies packaging materials subject to recycling obligations (paper packs, glass bottles, metal cans, synthetic resin packaging materials) is being operated and recycling charges or contributions are paid. Nonetheless, the prohibition of all repackaging regardless of packaging materials could be considered inconsistent in regulations.

Recommendation

It is recommended that at least two years of grace period to be given in order to take appropriate measures for the revision of packaging related regulations.

Also, in line with the Article 11 of the 'Product Packaging Rules' (Prohibition of Repackaging of Packaged Products) "repackaged products shall not be manufactured·imported·sold", repackaging exception criteria for importers should be established taking into account the fairness with local manufacturers that additional packaging is possible at local manufacturing factories.

Furthermore, the prohibition of repackaging should be introduced gradually depending on packaging materials. To minimize confusion between consumers and industry and to comply with the regulation, it should be introduced to film sheets packaging materials first and gradually implement to easily recyclable materials such as paper after reviewing the result.

* This issue is also included in the Beer, Wine & Spirits / Cosmetics / Food Committee chapters.

Healthcare

Ansook Park
Director,
Healthcare
Committee

Overview of the Industry

As the overall economy and social structure of the society is going through a rapid change due to the outbreak of the COVID-19, the attention of healthcare-related industries has increased with its focus on the development of 'untact' (non-face-to-face) digital healthcare businesses.

Healthcare industry will create new innovations with continuous development in medical technology in response to rapidly changing economic and social environment. Appropriate recognition of these innovative values need to be made, and regulatory flexibility should be increased.

Key Issues

1. Reforming HTA Guidance to Ensure Better Access to New Medicine for Patients

Current HTA guidance of HIRA does not reflect the burden of disease, patient's needs and the value of innovative medicine properly. In particular, the ICER threshold update is needed considering that the guidance is till based on the GDP value in 2013. GDP per capita for 2013 was USD 23,000 and GDP per capita for 2019 is USD 31,940.

Also, updating HTA guidance that has been published over 10 years ago is needed such as discount rate, EQ-5D tariff etc. in consultation with industry.

Recommendation

It is recommended to reflect disease severity, alternative medical intervention, survival rate, QoL, value of innovation and societal demands for ICER threshold.

Also, more flexible approach is needed in basic assumption of the cost utility analysis model. (e.g. time horizon, utility, waning effect, discount rate etc.)

With that, adoption of EQ-5D tariff is needed which is a more flexible approach than looking at the value of HRQoL.

Adapt real ICER threshold when the value of innovative medicine is underestimated, or it cannot meet the unmet medical needs.

Relevant Act/Regulation Regulation for Evaluation Criteria and Procedure, etc. for Reimbursement Eligibility, etc. of Drugs

Responsible Authority & Division Health Insurance Medicine Department at Ministry of Health and Welfare (MOHW) / Pharmaceutical Benefit Department at Health Insurance and Review Assessment (HIRA)

Recommendation Status Retained

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2. Recognition of Value of Global Innovative Medicines Through New Drug Listing Policy

EU understands the current regulation has been set to ensure that all domestic and foreign pharmaceutical companies are applied fairly through due process. However, it is difficult to properly apply innovative drugs that have contributed to the development of Korea's public health care since the conditions of application of the regulations are very limited in reality, and the predictable benefits for the regulation is also unclear. Therefore, the relevant regulations continue to support the introduction or development of innovative new drugs that are important in domestic health care, and the recognition of the innovative value of innovation, which is an important factor for the sustainable introduction and supply of these drugs, is not adequately recognized.

Recommendation

A thorough and timely evaluation is important to see if the current regulation is playing an appropriate role for sustainable development in the public health care. It is recommended to have a more flexible approach for the application criteria for the regulation (e.g. applicable when 3 of the 5 conditions are satisfied), and create clear guidelines (e.g. increase the ICER threshold by 2 times) for the expected level of preferential drug price for the applied drug. We recommend rapid improvement so that it can play an important role in the sustainable development of domestic health care.

Relevant Act/Regulation Article 6, Clause 3 of Evaluation Standard and Procedure for Drug's Benefit in the National Health Insurance

Responsible Authority & Division Health Insurance Benefit for Drug Department at Ministry of Health and Welfare (MOHW)

Recommendation Status Updated

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3. Reforming Combination Drug Pricing Regulation

The combination drug pricing has been applied the sum of 53.55% of each ingredient price or adapting the highest price of the ingredients' based on the generic drug pricing guidance. This pricing method would be acceptable when the combination drug is made by ingredients that are off-patent. However, for combination drug with on-patent ingredient, it should be evaluated by taking clinical utility and cost effectiveness into consideration.

Currently, the calculation of the combination drug price of each ingredient without generic drugs (ingredients for which the patent is valid) deviates from this principle, and does not reflect clinical efficacy and cost effectiveness in the calculation of the upper limit amount, as well as the possibility of infringement on the patent. The launch of a combination drug that can improve patient compliance and expect a better treatment effect is being disrupted by the problem of the price calculation method.

Recommendation

It is recommended to reform evaluation criteria for combination drugs containing patented ingredients (without single-component generic drugs), and for this purpose, we propose a combination drug price calculation of the standard level (70%) for biological drugs.

Relevant Act/Regulation Article 14, Regulation for Drug Benefits of the National Health Insurance

Responsible Authority & Division Drug Benefit Department of Ministry of Health and Welfare (MOHW)

Recommendation Status Retained

4. Negotiation Target and Contents for the Agreement of Estimated Amount of Use to the Drugs which Accepted the Upper Limit Amount of Cost that are Excluded of Drug-Pricing Negotiation

According to the relevant regulations, it is needed to negotiate an expected amount of use even for the drugs that accepted the upper limit amount of cost that are excluded of drug-pricing negotiation. Accepting the upper limit amount of cost (e.g. a weighted average price) means to not affect to additional healthcare budget. The negotiation has caused a waste of administrative power without clear grounds of an expected amount of use the drugs. There is also the risk of inducing drug prices early due to excessive negotiations.

The main purpose of the current regulation of omission of drug price negotiation is to improve the drug listing process by minimization of unnecessary administrative process. But the negotiation of an expected amount of use for the drugs is contrary to the purpose.

Recommendation

In the case of the drugs that accepted the upper limit of the omission of the drug-pricing negotiation, the drugs are not affected to additional healthcare budget by accepting the upper limit price like an existing weighted average price.

Therefore, the negotiation of an expected amount of use for the drugs accepted the upper limit amount of cost should be abolished, and the negotiations should be replaced with the price-

Responsible Authority & Division Drug Benefit Department of Ministry of Health and Welfare (MOHW)

Recommendation Status New

5. Duplicated Price Containment System of the Drugs Which Can be Extended Scope of Use for National Health Insurance (NHI)

In the case of drugs with extended scope of use, their price should be reduced in advance with unclear assumption of expected amount of use.

There is no compensation system when an actual amount is not reached to the expected amount agreed with National Health

Insurance Service (NHIS) before an official announcement of the extension.

This can be the infringement of property rights to the companies.

Recommendation

The pre-price reduction system for extended scope of use should be abolished and a price adjustment of extended cope of use for a drug should be operated on the price volume linkage negotiation system.

Relevant Act/Regulation Standards for Decision and Adjustment for Drugs, Appendix 3

Responsible Authority & Division Drug Benefit Department of Ministry of Health and Welfare (MOHW)

Recommendation Status Updated

6. Predictability, Transparency and Flexibility of Risk Sharing Agreement (RSA) Operation

The Risk Sharing Agreement (RSA) is to share the insurance financial burden for insurer (payer) such as refunding between the gap of listed price and net price. It has improved patient access to innovative medicines which have been in difficulties to make patient access under the previous listing system. The NHIS's Detailed operation guideline on RSA price negotiation affects to company's business directly. No proper public hearing process for the NHIS's revised draft negatively affecting to industry which is high concerns in terms of transparency, predictability, and rationalization of RSA operation. Still the scope of RSA eligibility is limited, and the guideline expansion and contract period extension process should go through a complicated process with pharmaco-economics evaluation data & review process. It is not fair for RSA medicine compared with other drugs listed with PE listing pathway. The overburden of VAT creates the value erosion of innovative medicines since 2014 RSA introduced despite of no that of issue in overseas such as UK, Australia, France, and Italy, etc. The refunding to patients is processed by NHIS and each relevant company, which is the risk of information protection such as patient information, etc. So those operational issues should be improved.

Recommendation

For medicines with different therapeutic position regardless of substitution availability with high disease burden or patients' social needs, RSA can be applied on behalf of the request from company. The process of guideline expansion should be flexible and simplified. The NHIS's guideline revision should be processed with transparency and predictability in the principle of patient access improvement aligned with the purpose of RSA introduction.

The contract period should be secured until the generic is listed on. Through public-private RSA working group, the measures* to protect additional value erosion driven by VAT over-burden, the process improvement of refunding to patients through NHIS for full-patient payment etc. are recommended.

*Overseas or other industry cases: VAT exemption, VAT exclusion from refunding or Tax Receipt release process set-up

Relevant Act/Regulation Detailed Operation Guideline on Risk Sharing Agreement Price Negotiation/VAT Act Regulatory Enforcement

Responsible Authority & Division Ministry of Health & Welfare (MOHW) / National Health Insurance Service (NHIS) / Ministry of Economy and Finance (VAT related)

Recommendation Status Updated

7. Increasing the Drug Accessibility to Rare Disease and Rare Cancer Patients

A total 156 orphan drugs were approved in Korea from 2007 to 2019, and 88 of them (56%) were covered under NHI benefit. The expenditure on orphan drug against the overall pharmaceutical expenditure was insignificant, only at 1.44% in 2018.

Recommendation

In order to increase the drug accessibility for rare disease and rare cancer patients, it is recommended to shorten the reimbursement review period for '2021 Comprehensive National Health Insurance Implementation Plan'.

Also, it is recommended to make special accounts for the drugs using refunded budget and the main objective of the budget

should be described and spent the budget to drug including advanced innovative drugs.

Orphan drug expenditure ratio in the US, Canada, and Europe marked 2.5% to 8.9% in early 2010.

Relevant Act/Regulation 2021 Comprehensive National Health Insurance Implementation Plan

Responsible Authority & Division Drug Benefit Department of Ministry of Health and Welfare (MOHW)

Recommendation Status Updated

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8. Raising Fund for Severe Cancer Patients for Better Drug Access

To improve and accelerate innovative drug access to severe cancer patient, it is required to reduce financial burden before review period for reimbursement and seek developing the real world data (RWD) for refer to make a decision of reasonable price.

Recommendation

It is recommended to introduce a funding system like in the UK or Australia to ensure drug accessibility for patients prior to registration of benefits and to establish the scope of fund operation (data construction for the use of real world evidence (RWE), etc.) to be used to collect actual clinical data as a reference for cost-effectiveness evaluation when registering benefits.

The cancer drug fund, established in the UK in 2011 (revised in 2016), guarantees access to anticancer drugs whose benefits have not been determined.

Relevant Act/Regulation Cancer Management Act

Responsible Authority & Division Bureau of Health Insurance Policy Bureau of Ministry of Health & Welfare (MOHW)

Recommendation Status New

9. Organization of a New Committee Under MOHW to Improve Patient Access on Cell & Gene Therapy in Korea

Since the US FDA approved the first cell and gene therapy (CGT) such as CAR-T in 2017, in major developed countries, CGT is being reimbursed through various pay schemes and entering the market. In particular, since the CGT is an ultra-high-priced drug, it is expected that proper payment may be difficult with the existing health insurance payment principles and the existing drug payment registration system in Korea. On the other hand, these innovative new drugs are directly connected to the life of the patient and require prompt reimbursement, so a social consensus on the payment of these drugs is also required.

Recommendation

It is recommended that MOHW to organize its CGT committee or consultative body chaired by DG or assistant minister related to NHI in order to make social consensus on reimbursement of CGT and deal with improvement of P&R regulation including finding out appropriate P&R model for timely access of CGT in Korea.

The committee (or consultative body) should aim to come up with innovative reimbursement model and scheme for CGT in Korea by analyzing innovative reimbursement model of advanced countries for CGT and evaluating suitable model for Korea.

The committee needs to be composed of Pharmaceutical benefit division in MOHW. Pharmaceutical benefit department in HIRA, Benefits Strategy Department in NHIS, patient groups, external experts from academia and medical society, and pharmaceutical industry. Based on this composition, the committee will take a responsibility to make social consensus on early reimbursement of CGT.

Responsible Authority & Division Bureau of Health Insurance Policy Bureau of Ministry of Health & Welfare (MOHW) / Pharmaceutical Benefit Dept Department at Health Insurance and Review Assessment (HIRA) / Benefits Strategy Department of National Health Insurance System (NHIS)

Recommendation Status New

10. Introduction of Pre-Reimbursement and Post-Evaluation System for Anticancer Drug Benefits Review

For drugs treating rare and severe intractable diseases, it is difficult to prove the cost-effectiveness due to the characteristics of the disease. However, there are some drugs that do not fall under the system for rapid screening introduced by the Korea Review and Assessment Service even though they have been designated as rare by the Ministry of Food and Drug Safety (MFDS). we propose to establish a pre-approval and post evaluation system to ensure access to drugs for rare and severely intractable patients.

Recommendation

In the case of anticancer drugs and drugs for treatment of rare and intractable diseases, which the government has already announced that they plan to perform post-assessment, they are given the highest priority when deciding to register their benefits. It is recommended to determine the listing price according to the criteria at the time of ex-post evaluation.

Relevant Act/Regulation Regulation for Criteria for Providing Reimbursement Services under National Health Insurance

Responsible Authority & Division Dept. of Health Insurance Medicine Department at Ministry of Health and Welfare (MOHW)

Recommendation Status Updated

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11. Relaxation of the Requirements and Improvement of the Review Process for Innovative New Drug Substances with Expedited Reviews (conditional approval)

To obtain conditional approval as a result of a therapeutic exploration (phase 2) test subject to the submission of therapeutic confirmation (Phase 3) test results, it is interpreted that a phase 3 clinical trial in the same treatment group as that of Phase 2 is essential.

The expedited review should be able to absolutely shorten the 'actual review and approval period', but it is interpreted as a clause that is currently ineffective except for conditional permission because the exemption requirements and the expedited review period in the relevant regulations of the MFDS are not specified.

Accordingly, the introduction of innovative drugs or new drugs and new indications with high demand for medical unmet in Korea is delayed.

Recommendation

1) Relaxation of requirements for conditional approval.
Request for the revision of the relevant regulations or guidelines (e.g. Guideline for application of expedited reviews) in order to flexibly apply the requirements when the case is reasonable. (e.g. For oncology products, when it is difficult to conduct phase 3 with the same treatment group (same order, etc.) of the phase 2 trial.)

2) Improvement of the process for expedited reviews.
It is necessary to clearly state in the corresponding regulation or guidelines that which requirements can be exempted in the expedited review process compared to general process, and how long the review timeline can be shortened.

The current provisions do not clearly define the scope of possible exemptions and the timeline. (e.g. The Article 58 (Expedited reviews, etc.) in the regulation states "may allow applicants to submit sections of data after their marketing", "may grant approval by conducting expedited reviews preferentially")

Relevant Act/Regulation Article 58 (Expedited reviews, etc.), Regulation for Pharmaceutical Approval, Notifications and Reviews / Article 41 and 41-2, Regulation for Biopharmaceutical Approval, Notifications and Reviews

Responsible Authority & Division Pharmaceutical Authorization Coordination Team/Ministry of Food and Drug Safety (MFDS)

Recommendation Status Updated

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12. Drug Price Agreement and Execution Terms During Price Negotiation

Drug Price Agreement has been introduced in 2019, to secure stable supply of medicine and patient protection. However, the agreement include immoderate and unfair conditions into the agreement. For example, regardless of the medicine supply report has already been reported to the Medicine Management & Information Center, the agreement imposed additional obligations and penalty

on delaying report. It is apparently duplicated regulation on medicines listing on the National Health Insurance System.

The Drug Price Agreement, which was introduced in early 2019 for the stable supply of medicines and patient protection, is now adding more and more relevant provisions, adding to the contents that may appear to be excessive and unfair obligations to pharmaceutical companies with many redundant or unnecessary provisions. For example, in the case of supply reporting, even though it has already been reported to the Drug Administration Comprehensive Information Center according to the relevant regulations, the agreement imposed additional obligations on reporting and penalty in case of delayed report.

Recommendation

It is critical to establish a standard agreement that omits duplicated and non-feasible conditions with regards to original purpose of the Drug Price Agreement, ensuring patient protection and stable supply of medicine. In addition, the process to make standard agreement, it should be consulted with pharmaceutical industry to avoid forcing unfair terms and conditions to pharmaceutical companies.

Relevant Act/Regulation Evaluation Criteria for Drugs Subject to Negotiation Include New Drugs

Responsible Authority & Division National Health Insurance Service (NHIS)

Recommendation Status New

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13. Enhancing Transparency and Clear Role Sharing for National Health Insurance Committee Decisions

It is important to establish a system for several healthcare committees in which various stakeholders can maintain transparent decision-making based on evidence. Healthcare policy decisions are comprehensive decision-making such as accessibility to new drugs, insurance policies and regulations. Although there has been improvement in transparency with the meeting minutes disclosure of the evaluation results of the Drug Reimbursement Evaluation Committee, but the minutes and evaluation results from Severe

Disease Review Committee, Health-Economic sub-committee and Risk Sharing Agreement sub-committee are still not disclosed.

In addition, the review process between the committees and drug reimbursement evaluation committees on cost effectiveness and fiscal impact in recent years is redundant and repetitive, and it is unreasonable for pharmaceutical companies to go through the process of collecting opinions on the same content several times.

Recommendation

All review results at sub-committees under the HIRA should be informed to the applicant company at least. The MOHW should take an important role of mediation and consultation in all committee processes to ensure policy predictability and evidence-based decision making. Several sub-committees and DREC in HIRA should be clearly defined their role and responsibility to ensure expert review and to avoid duplicated and repeated review process.

For the contents reviewed by each subcommittee of the HIRA, it is recommended that the minutes of the meeting are shared with the pharmaceutical company that has submitted the evaluation, and the MOHW to legally consult and exercise the right to arbitrate in the decision making process by the committee to ensure policy predictability and evidence-based decision-making. By clarifying the division of roles of sub-committees and Drug Reimbursement Evaluation Committee under HIRA, a professional review should be made, and duplicative and repetitive reviews should be minimized.

Responsible Authority & Division Ministry of Health and Welfare (MOHW) / Health Insurance and Review Assessment (HIRA) / National Health Insurance System (NHIS)

Recommendation Status Retained

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14. Improving the Transparency on ATP Based Price Cut

Currently, the actual transaction price (ATP) survey uses health insurance claims every two years in order to calculate a weighted average price and lowers the drug price. However, despite the fact that supply of less than the actual purchase price of wholesalers is a violation of the distribution order under the Pharmaceutical Affairs Act, the ATP survey is driving pharmaceutical companies to excessive drug price cuts.

In addition, since the details of the weighted average price calculation method are not shared, pharmaceutical companies have difficulty in evaluating price reduction decisions and preparing plans to mitigate price cuts, which hinders policy transparency and policy predictability.

Recommendation

It is recommended to exclude the claims that have been made to health insurance that are distributed through wholesalers at a price below the lowest price supplied by the company. In addition, the ATP calculation method and details should be shared with the company, and sufficient opinions should be collected on the weighted average price calculation result.

Relevant Act/Regulation Criteria for Decision and Adjustment for Drugs

Responsible Authority & Division Health Insurance Review & Assessment Service (HIRA)

Recommendation Status Retained

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15. Fair Certification Standards for Selection of Innovative Pharmaceutical Companies

Innovative Pharmaceutical Companies (IPC) that are selected by the MOHW receive tax credit, R&D support, and drug pricing benefits in accordance with the Pharmaceutical Industry Promotion Act. The Act aims to foster the pharmaceutical industry by giving benefits to the companies that have contributed to the development of Korea's medical R&D environment. However, as of January 2019, only 4 of the 47 companies certified as IPCs are multinational pharmaceutical companies.

The evaluation criteria are unfairly applied to multinational companies because there are many items that are advantageous only to local pharmaceutical companies. In particular, the various activities that multinational companies are contributing to Korea's pharmaceutical industry are not properly reflected in the evalu-

ation. For example, only overseas exports, technology transfer/cooperation with foreign companies are included as criteria for evaluating activities of multinational companies, and domestic R&D expenses paid directly by the head office through CRO are not included in the evaluation.

Recommendation

In order to facilitate foreign companies' contribution to R&D environment in Korea and ensure a level playing field in pharmaceutical industry between domestic and multinational companies, it is critical to make objective R&D activity evaluation standards in IPC regulation. It is recommended to modify current IPC designation criteria for foreign companies to accurately capture the activities of foreign-invested companies such as variety of business and R&D partnership with domestic companies.

Relevant Act/Regulation Special Act for Pharmaceutical Industry Promotion and Support/Regulation on Accreditation for Innovative Pharmaceutical Company

Responsible Authority & Division Health Industry Development/Ministry of Health and Welfare (MOHW)/Korea Health Industry Development Institute (KHIDI)

Recommendation Status Retained

16. Participation of Multinational Pharmaceutical Companies in the National Health Insurance Policy Deliberation Committee

The National Health Insurance Policy Deliberation Committee has been established based on Article 4 of the National Health Insurance Law and reviews and makes decisions on reimbursement guideline, reimbursement cost and premium, etc. of the National Health Insurance. The committee consists of 25 members from public sector, employer group, labor group, civic group, consumer group, and a group representing the medical and pharmaceutical sector can commission 8 members to the committee. However, even though multinational pharmaceutical companies have been account of over 40% of ethical pharmaceutical distribution to Korea (Note: based on members of the Korea Research-based Pharma Industry Association), organizations that can represent the opinions of multinational pharmaceutical companies operating in Korea are not participating as members of the pharmaceutical group, so they do not have the opportunity to officially convey their opinions on health insurance policy decisions.

Recommendation

It is recommended that organizations of multinational pharmaceutical companies operating in Korea will also be given a fair opportunity to participate as members of the National Health Insurance Policy Deliberation Committee along with the Korea Pharmaceutical and Biopharma Manufacturers Association (KPBMA).

Relevant Act/Regulation Article 4, National Health Insurance Law

Responsible Authority & Division Department of National Health Insurance Policy/ Ministry of Health and Welfare (MOHW)

Recommendation Status New

17. Criteria for Judging Patentability for Selective Inventions in Korea

Patents on "selective inventions" commonly have been found valid in most other countries, yet either has been rejected for registration in Korea due to the unusually strict requirements, or even if it has been registered as a patent after much difficulty only to be invalidated as soon as it is challenged.

Because the new drug development process can take 12-13 years after the genus patent application is filed, it is very common to file one or more species patents and additional subsequent patents for isomers, crystalline forms, salts, formulations, and compositions. However, out of the major IP jurisdictions in the world, Korea is unique in that species patents as well as patents for isomers, crystalline forms, salts, etc., are subject to being classified as "selective inventions" with stricter patentability standards than inventions in general, and therefore easily refused or invalidated, regardless of the effort and cost involved in developing such inventions.

Recommendation

In order to ensure that the patent system in accordance with international harmonization can be operated in Korea, it is recommended to establish reasonable criteria for judging selective inventions.

Responsible Authority & Division Korean Intellectual Property Office (KIPO)

Recommendation Status New

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18. Mutual Recognition Agreement for GMP and QC Test Requirement with the EU (priority application of vaccines and biological products)

Pharmaceutical companies from the European Union (EU) member nations welcome the MFDS's movement to pursue exemption of GMP inspection and local QC test through mutual recognition agreement (MRA) with the EU, and to initiate related policy research in 2020~2023.

This topic is not a simple issue but requires continuous and multi-dimensional approach to accommodate a solution even before the policy research outcome. Furthermore, Korea possesses a high level of pharmaceutical quality as a PIC/S member and the European Commission (EC) already has made MRA with several non-EU countries that have comparable quality standards with Korea (e.g. Australia, New Zealand, Israel, Japan, Switzerland, Canada, and the US, etc.) for more than 10 years. Therefore, it is legitimate to find a way to include Korea as a mutually recognized country.

Recommendation

It is recommended to apply exemption from local testing through mutual recognition of QC standards between Korea and the EU to drugs that require prompt supply and advanced testing methods, (e.g. biologics, DTP-containing vaccines (Tdap, combination vaccines)) as an initial step EU companies will do their best to support this initiative in cooperation with the MFDS and the EC as needed.

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)

Recommendation Status Updated

19. Reforming National Lot Release System for Imported Influenza Vaccine and its Hazardous Level Evaluation Standards

For domestically produced Influenza vaccines, the national lot release inspection procedure proceeds at the same time as the production site's own quality inspection process. However, imported influence vaccines can enter into the national lot release inspection procedure and the review process for biologics summary protocol when they complete both the self-quality tests at their production process and the customs clearance in the country, which makes the market release for imported influenza vaccines inevitably later than the domestic influenza vaccines.

In addition, the hazardous level evaluation for vaccines is determined by how many batch number vaccines have passed the national release system over a year. Consequently, despite the fact that much more imported vaccines are being vaccinated globally, imported vaccines are receiving higher hazardous rating due to their small production units.

Recommendation

It is recommended that the hazardous level evaluation standards reflect global vaccine distribution data and introduce a fast track review process for imported influenza vaccines for national lot release review can be carried out simultaneously with the production site (overseas) quality testing.

Relevant Act/Regulation Pharmaceutical Affairs Act / Rules on the Safety of Pharmaceuticals, etc./Regulations on Approval and Review of Biological products. / Regulations on the Designation, Approval Procedure, and Method of Biological Products Subject to National Lot Release

Responsible Authority & Division Biopharmaceuticals and Herbal Medicine Evaluation Department / National Institute of Food and Drug Safety Evaluation (NIFDS) / Biopharmaceutical Quality Management Division, Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

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20. Improving the Vaccination Fee Scheme

The combo vaccines developed to prevent multiple infectious di-

seases have been vaccinated in various countries including European countries and the US since the 1990s. They can reduce the number of vaccinations to reduce the pain caused by injections of infants and toddlers and improve the complete vaccination rate. However, in order for the combo vaccines to be more widely vaccinated in Korea, it is necessary to improve the regulations on the costs. One of the most important is the doctor's calculation of vaccination fees. The current vaccination fee scheme receives a lower inoculation fee when inoculated with combo vaccines in hospitals and clinics than when inoculated with a mono vaccine multiple time. In other words, the vaccination fee is not designed based on the entire vaccination schedule, but is paid according to the number of vaccinations, which hinders the introduction of the new improved combo vaccines into the national vaccination program.

Recommendation

It is recommended to set the vaccination fee according to the number of ingredients(antigens) for the continuous development and introduction of combo vaccines that improve the overall vaccination rate of infants and toddlers. In addition, it is recommended to provide additional incentives to hospitals and clinics that have contributed to the improvement of the vaccination rate, and calculation of vaccination fees for all vaccines should be based on the vaccination schedule instead of the number of vaccinations.

Relevant Act/Regulation Regulations on Consignment of Vaccination

Responsible Authority & Division Regulations on Consignment of Vaccination

Recommendation Status Retained

21. Recognizing the Value of Innovative Vaccine Technologies for Public Health

Vaccines are inherently difficult to improve the efficacy of vaccines because they can expect sufficiently high immunity even with traditional vaccine development methods in which viruses are cultured, attenuated, and then inoculated. However, the development of innovative vaccines is still needed to prevent new diseases, improve immunity, minimize potential risks, and improve convenience/compliance.

Unfortunately, vaccine pricing is focused on attaining lower price level rather than the value of innovation in clinical improvement or newly developed technology to promote it.

There is a pricing guideline that states that a differentiated price can be given when improving efficacy, safety and convenience, but in fact, it is difficult to find a vaccine with a differentiated price in recognition of a new technology. In addition, even the guidelines for innovation, the criteria for price differentiation, are limited to continuously encourage the development of new technologies in consideration of the uniqueness of vaccines.

Recommendation

Recognizing the value of innovative vaccine would lead companies to keep putting efforts to develop improved vaccines for better public health and it can ensure introduction of innovative vaccines to Korea and minimize supply shortage issues.

Therefore, it is recommended that the overall policy for pricing and introducing vaccines to be reviewed in consideration of the developmental difficulties peculiar to the vaccine. In addition, it is required to improve related regulations and policy direction so that the efficacy, safety, convenience and technological innovation of vaccines can be fully recognized for vaccine pricing.

Responsible Authority & Division Ministry of Health and Welfare (MOHW)

Recommendation Status New

22. Grace Period for Post-approval Changes for Pharmaceuticals, etc.

For imported drugs, when the change of permission is completed, the changed permission must be reflected for the product to be cleared afterwards. In other words, there is no grace period for changes after permission. Thus, it is difficult to match the timing of the change of the license with the timing of the applied finished product. Also, the existing inventory that was produced prior

to the change of permit cannot be used, which can lead to supply and demand disruption.

To prevent supply disruption to Korea, companies are building safety stocks while the license change is in progress or changing the license according to the time of application. However, it is practically difficult to stock up sufficient amount of stocks in a short period of time and to accurately predict when stocks will be exhausted and the expected duration of change in license.

Especially, vaccines are complex biological products characterized by often composed of multiple antigens derived from various strains and multiple manufacturing steps from working cell to products. Also, vaccines are produced in large-scale volume to supply millions of patients worldwide, and production cycles span months to years. After approval, quality-related changes are made continuously due to the improvement of the reliability and efficacy of the production process, and the development of quality control technology, and changes must be approved by regulatory agencies in more than 100 countries.

In Korea, permission before/after the change is temporarily approved at the stage of the raw material (e.g. seed), but the level of permission is very limited and additional administrative procedures are required, and if it contains various antigens, the permission process gets more complicated. Consequently, immediate implementation of permit changes leads to product loss, increased cost, reduced supply flexibility and ultimately delayed patient access.

Recommendation
Changes to medical products are approved based on appropriate requirements and supporting data after review by health authority, so both products pre/post changes have appropriate quality unless there are adverse impact to patient safety and efficacy. A key element to help address this complexity is related to the time allowed in any given country once a post approval change or variation has been approved so that products produced before/after the license change. (*The grace period is 6 months in the US and the UK and up to 12 months in Switzerland (or from the next batch of production after the change of permission))

Relevant Act/Regulation Regulation on Safety of Pharmaceuticals, etc.

Responsible Authority & Division Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

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23. Replacement of Animal Testing Methods Used for Quality Testing of Biological Products

There is a trend to do quality testing by developing new models that can refrain from and replace testing using animals worldwide. Overseas manufacturers export medicines to many countries including Korea, and each country performs quality control using alternative test methods. Although a review was requested for the application of an alternative test method, the potency test using animals is maintained due to lack of resources, making it difficult to supply the product.

Recommendation
A positive review is requested when pharmaceutical companies develop a test method or a model to replace a potency test using animals and submit variation to change the specification and test method.

Relevant Act/Regulation Regulation on MA Approval and Review for Biologics, etc.

Responsible Authority & Division Biopharmaceuticals and Herbal Medicine Evaluation Department / Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

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24. Review of Necessity for Test Items of the Specification and Analytical Procedures of Drug Products that are Additionally Established in Korea

Although the test items are not established by the original manufacturer for imported drugs, some test items are mandatorily

added depending on the formulation of the product at the time of product approval in Korea. (e.g. For injectable formulation, the following test items are added: uniformity of Dosage Units test: set according to KP for powder formulation; foreign Insoluble Matter test: set according to KP, except for suspension formulation; insoluble Particulate Matter Test for Injections: set according to KP, except for suspension formulation; abnormal toxicity test: set according to Specification and test method for biological products.

This leads to a situation in which test items recognized to be no longer necessary based on technological developments are set unnecessarily due to regulations. For example, for abnormal toxicity test, the need for the test has been reduced with the introduction of GMP and development of process validation and strict quality control measures, and has been removed from the European Pharmacopoeia. In addition, if a specific test item is well-managed by in-process control or real time monitoring, depending on the product or test characteristics, it should be reviewed whether it is necessary to establish a double standard.

Recommendation

It is recommended that the abnormal toxicity test deleted in the European Pharmacopoeia to be removed from the specification and analytical procedures of biological products or needs to be set as necessary. In addition, it is recommended to clearly mention and specify the test items in the Korean Pharmacopoeia so that the test items can be set in consideration of the characteristics of each product.

Relevant Act/Regulation Specification and Test Method for Biological Products, Korean Pharmacopoeia (KP)

Responsible Authority & Division Biopharmaceuticals and Herbal Medicine Evaluation Department

Recommendation Status New

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25. Improving the Level of Supplementary Requests Related to CMC Review

Although the company submits the risk assessment and discussion data regarding CMC, unnecessary supplementary data such

as raw data other than CTD are requested by the MFDS. For example, there was an unnecessary request for raw data for 'all items' of the validation. Among the validation parameters, linearity and accuracy are evaluated based on the spiked amount only for 'identified' impurities. Even if a discussion data was submitted regarding unidentified impurities, the raw data for unidentified one, which are difficult to create and unnecessary was requested.

For DMF review, even if risk assessment is submitted for starting material, data such as upper materials, manufacturing process, and manufacturer are requested. Unnecessarily requesting for additional data despite risk analysis for the material has been completed is a big burden to the industry.

Recommendation

It is recommended to exclude the submission of raw data other than the CTD that can be replaced by risk assessment data and discussion data, from the requirements for CMC review. In addition, when reviewing DMF, it is recommended to establish the regulation for starting material and direction of review by consulting with the industry. The revision of the regulations will improve the submission/review of unnecessary data, such as physicochemical characteristics of already registered DMF. It is expected to consider the addition of DMF site of registered substance as DMF 'variation', not 'registration', and review only the site-related data.

Relevant Act/Regulation Article 7 (2) of the provisions for drug product approval, notification and review 4) / Article 4, Paragraph 1, Subparagraph 4 of the Regulation on the Registration of DMF

Responsible Authority & Division Pharmaceutical Quality Division / Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

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26. Separation of the Release Specification and Shelf-Life Specification for Drug Products

Due to the lack of detailed regulations for the establishment of standards and test methods, many pharmaceuticals are permitted to apply one standard to the entire expiration date from the time of release of the product in a form different from that of the

international common technical document.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the EU has a separate regulatory requirement for distinct specifications for release and for shelf-life. Due to the difference between Korean and ICH and/or regulations of other countries, not only disruptions in supply from overseas manufacturing plants are caused, but standards that are not the most appropriate for each stage of drug product lifecycle is set.

Recommendation
It is recommended to set specification that is the most appropriate for each stage of a drug product's lifecycle – release/stability/end of life – via amendment of relevant regulations and/or guidelines, to ensure continuous supply and safety of patients.

Relevant Act/Regulation Regulation for Pharmaceutical Approval, Notifications and Reviews/Regulation on Safety of Pharmaceuticals, etc / Regulation on Good Manufacturing Practice (GMP) for Medicinal Products

Responsible Authority & Division Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

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27. Harmonization of International Standards for Pharmaceutical Equivalence Testing Standards

Since the current Korea comparative dissolution test method and equivalence criteria are different from the international standards, it is difficult for importers to submit the results of the comparative dissolution test conducted at the manufacturer and required to retest in Korea.

In the US and Europe, tests are conducted at pH 1.2, 4.5 and 6.8 dissolution media, while there are additional "water" dissolution conditions in the Korea. If the drug is relatively unstable in 'water' rather than in the body's environment, it is difficult to conduct the dissolution test.

In the US and Europe, the time required for dissolution similarity comparison using a similarity factor is not specified, whereas in Korea, the comparison time is additionally limited to 15 minutes, 30 minutes, and 45 minutes.

According to Korea regulations, it is required to submit comparative dissolution test or bioequivalence test data when excipients are changed. For example, when the coating additive is changed, the level of change is classified only according to weight ratio of the content of the 'coating layer', and is excessively regulated compared to the regulations of other countries (weight ratio of 'total weight' of the formulation).

For the change level which requires comparative dissolution tests according to the international guideline, biological equivalence test is additionally required in Korea which makes it difficult to manage registration details.

Recommendation
It is recommended to conduct a comprehensive review of the drug equivalence study criteria. Establishment of more reasonable and clear criteria for determining drug equivalence through international harmonization of comparative dissolution test methods and acceptance criteria are required. Also, it is recommended to review the criteria for classifying pharmaceutical equivalence studies according to the level of change, such as the level of change for excipient changes.

Relevant Act/Regulation Regulation on Standards of Pharmaceutical Equivalence Testing

Responsible Authority & Division Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

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28. Deletion of Regulations on the Implementation of Re-Evaluation of Drugs

The introduction of a 5-year renewal system replacing re-evaluation of drugs was to continuously secure safety and efficacy of the drug by reflecting the latest scientific standards, because re-

evaluation of drugs has a problem that the evaluation cycle has been prolonged from 17 to 21 years.
The purpose of re-evaluation of drugs is also to re-evaluate drugs that have already been approved and need to be re-evaluated for safety and efficacy at the latest scientific level or to prove equivalence.
With the introduction of the renewal system, the question about the necessity of a re-evaluation system that seems to be a duplicate regulation with the renewal system has been continuously raised in a situation where safety and efficacy of drugs can be periodically evaluated by the 5-year renewal system.

Recommendation
It is recommended to review the effectiveness of the Notice on the 'Regulation on the Implementation of Re-evaluation of Drugs' including deletion.

Relevant Act/Regulation Pharmaceutical Affairs Act/ Enforcement Regulation on the Safety of Drugs/Regulation on the Implementation of Re-Evaluation of Drugs

Responsible Authority & Division Drug Safety and Evaluation Division/Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

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29. Unharmonized Clinical Trial Amendment Process and Inconvenience for Applying Variation Separately in the Current Clinical Trial Management System
In recently designed oncology studies, one asset is on several studies as an Investigational product, pharma needs to submit the same substantial amendment (e.g. IB update, CMC variations for each study) for each study.

In Korea, submission categories for substantial amendment are different from the FDA or EMA. The MFDS manages updates by study number, so there is inconvenience for applying similar variations separately, and there is no official guideline on parallel submission. It is partly accepted by attaching formal letter, but it cannot be applied to variation reporting.

This increases the procedural and institutional burden compared to other countries, which is an obstacle to attracting global clinical trials in Korea.

Recommendation
An official guideline and the regulatory processes should be established for managing parallel substantial amendment to help streamline updates for variations to harmonize the process with global health authorities. For the US, almost all studies within one indication are submitted under one IND [parent IND], all protocol amendments, program updates (IBs, DSURs) and CMC amendments are submitted and can be done in parallel.

Different from other countries, the FDA does not provide approval of amendment and those changes can be implemented immediately after regulatory submission. For the EU, each study is filed under its own Clinical Trial Application (CTA) within each country, but it categorizes substantial/non-substantial amendment and there is an official process for parallel application by specifying studies in application form.

Relevant Act/Regulation Regulation for approval of Investigational New Drug Application (IND)

Responsible Authority & Division Department of Clinical Trial Regulation/Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

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30. Categorizing Regulatory Process and Exemption of Supporting Documents Based on the Risk Assessment of the Regulatory Change
Supporting documents for the regulatory change are differentiated according to the regulatory change section. Regardless of the content of the change, the same level of supporting documents are required if the changed sections are the same.

In the EU, the US and Canada, they subcategorize the regulatory process based on the risk assessment of the registration change details. Regulatory change process depends on the risk of the registration change, whether it has major/moderate/minor effects on the safety, quality, efficacy of the products. Based on this as-

sessment, different supporting documents are required.

Recommendation

It is recommended to accelerate the introduction of the ICHQ12 and categorize the regulatory change process according to the risk assessment (major/moderate/minor) of the change. Also, to prevent supply issues caused by the delay of the registration change lead time, it is recommended to extend the scope of annual reporting and specify the details.

Relevant Act/Regulation Article 8 of Regulation on the Safety of Drugs, etc / Article 3 of Regulation on Marketing Authorization /Article 3 of Regulation on MA Approval and Review of Biologics

Responsible Authority & Division Drug Evaluation Department/ Biopharmaceuticals and Herbal Medicine Evaluation Department

Recommendation Status New

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31. Permitting E-Signature on the BSE Statement

In Korea, 'notarized' certificate from manufacturer is requested to verify that the BSE statement (for each batch of Vaccines) is genuine.

However, during lockdown in Europe due to the outbreak of the COVID-19, it was not possible to get the services of a notary. The MFDS have allowed the manufacturers to process batches during this exceptional time without notarization on the basis that notarized certificates will be provided eventually in the future.

Recommendation

Currently, the manufacturers have temporary waiver until the end of the year, however, it is on the basis that notarized certificates with wet ink signatures will be provided after for the batches supplied during the waiver period.

It is recommended to accept legally valid electronic signature (digital signature), rather than 'wet ink' signature and 'notarized' certificate.

Relevant Act/Regulation Pharmaceutical Affairs Law / Foreign Trade Act

Responsible Authority & Division Quality Department of Biopharmaceutical Product / Ministry of Trade, Industry and Energy (MOTIE)

Recommendation Status Updated

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32. Establishing a Separate Classification System to Clarify the Management Scope of the Filler

Currently, medical device fillers are only used for therapeutic purposes such as correcting wrinkles. However, in EU countries such as Italy, France and Germany, medical device fillers are recognized for aesthetic purposes such as improving skin elasticity and replenishing skin moisture. In Korea, there is no category of aesthetic filler, so it becomes off-label when it is used for aesthetic purposes. This can become a blind spot for safety management and limit the efficacy of fillers.

Recommendation

It is necessary to select categories including filler that claim to support aesthetic purposes and to revise the definition of the relevant statutes, and establish a classification system for the relevant products (e.g. revision of regulations on medical device items and grades by item, etc.).

Relevant Act/Regulation Medical Devices Act / Regulations on Medical Device Items and Grades by Item

Responsible Authority & Division Ministry of Food and Drug Safety (MFDS)

Recommendation Status New

Siyoon Kim
Coordinator,
Insurance
Committee

Overview of the Industry

The Insurance Committee of the ECCK represents the common voice of the insurance companies in Korea and acts as a communication channel between the industry and the government to enhance mutual understanding and facilitate co-operation to build a better business environment in Korea.

The ECCK Insurance Committee understands that the government has the responsibility to provide a regulatory framework, where clients of insurance products are adequately protected while insurance firms should be encouraged to develop diverse insurance services of good quality.

The ECCK Insurance Committee believes that the keys to having such an environment are:

- Strong regulation and supervision that does not impose unnecessary burdens to insurers
- Transparency and predictability. Regulations must be clear and appropriate to the financial market conditions and policy goals, while at the same time minimizing the "regulatory cost of compliance" arising from new regulations
- Predictable and smooth organization's structural changes and reshuffling at financial authorities that does not hinder regular business operations of insurance firms
- Close cooperation between the Financial Services Commission and the Financial Supervisory Service, in order to advance efficiency of supervision and monitoring
- Ensuring that all market participants compete on the same field under a fair competition environment
- Flexible rules with exceptions rather than a 'one-fits-all' rule to support product innovation

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Key Issues

1. Requesting a supportive review on the proposal for revision of insurance law for the purpose of prevention of inheritance of debts

The Insurance Business Act, in Article 100, prohibits lending financial institutions from demanding the borrower of a loan to purchase an insurance policy prescribing it as a forced-sale practice. This general provision practically prohibits the lending financial institutions from selling credit insurance products.

Insurance
Committee

Credit insurance is an insurance policy in which the insurer reimburses the debt to the lender for the borrower if the borrower dies or is otherwise rendered incapable of repaying the debts, thus prohibiting the inheritance of debts.

Benefits of credit insurance are as follows: (i) prevents inheritance of debts and promotes stability by improving loan quality, (ii) protects the most valuable assets (home), (iii) supports the most vulnerable households and prevents over-indebtedness, (iv) promotes financial inclusion, and (v) provides innovative growth engine in insurance company.

With the above stated benefits, credit insurance is used as a social safety net that promotes welfare of the society.

Recommendation

The Insurance Committee would like to request a positive review on the proposed amendment to the 'Insurance Business Act' to prevent inheritance of debts.

Relevant Act/Regulation Insurance Business Act, Article 100

Responsible Authority & Division Insurance Division, Financial Services Commission (FSC)

Recommendation Status Updated

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2. Release of Standardized Repair Cost and Hours of Imported Cars

ECCK Insurance Committee recommended that the Ministry of Land, Infrastructure and Transport (MOLIT) should prevent disputes between repair shops and insurance companies by promulgating a standard maintenance fee and time even for imported cars with more than 2 million registered vehicles in Korea in the same way as domestic cars. In response to the recommendation, the relevant division has answered that the maintenance fees for imported cars will be discussed when the insurance maintenance council is formed in accordance with the revision of the Act.

Recommendation

In accordance with the enforcement date of the applicable laws

and regulations (2020.10.8), the MOLIT needs to discuss the maintenance fee for imported cars, and announce specific standard maintenance fee and time.

Relevant Act/Regulation Insurance Business Act, Article 100

Responsible Authority & Division Insurance Division, Financial Services Commission (FSC)

Recommendation Status Updated

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3. Improvement of Full Payment System in Bodily Injury II for Medical Expenses

Article 3 of the current Enforcement Decree of the Automobile Damage Compensation Guarantee Act stipulates that the entire medical cost is paid only for 'Bodily Injury category I', which is a compulsory insurance. The standard terms and conditions for motor insurance however are extended to cover 'Bodily Injury category II'.

Compensating the full medical costs without allocating the negligence rate for 'Bodily Injury category II' will result in over-treatment and legal consistency problems.

Recommendation

It is necessary to abolish the current system that requires full payment for medical expenses that exceed the compensation limit or responsibility for 'Bodily Injury category I', and to amend the standard terms and conditions to compensate only for medical expenses calculated according to the negligence rate or comparative negligence. We request the amendment of "Standard Terms and Conditions <Attachment 3> comparative negligence, etc."

Relevant Act/Regulation Motor Insurance Standard Terms and Conditions

Responsible Authority & Division Insurance Division, Financial Services Commission (FSC) / Insurance Department, Financial Supervisory Service (FSS)

Recommendation Status New

4. Inclusion of Insurance Company to the Notification Subject of Repair Estimates

It is stipulated that automobile repair shop issue inspection/repair estimates and inspection/specifications to the person requesting repair and notify the follow-up management details., as prescribed by Ordinance of the Ministry of Land, Infrastructure and Transport (MOLIT).

In the case of repair due to an insurance accident, when the vehicle is normally received by a repair shop, the insurance company employee consults with the repair shop to determine the repair scope and repair method, and after the payment guarantee, the repair shop requests the repair cost, and the insurance company employee determines the damage and pays the repair cost. This is proceeded as a payment procedure.

However, even though some repair shops are aware that the repair is due to an insurance accident, using the ambiguity of the legal provisions, they arbitrarily repair the damage of the vehicle without notifying the insurance company and then charge excessive repair costs, or charge excessive repair costs to vehicle owners who do not have expert knowledge about vehicle repairs.

Recommendation

In order to protect the rights of insurance consumers by ensuring objectivity and transparency in the procedure for calculating repair costs, the insurance company responsible for paying insurance payments should be added to the notification subject to Article 58, Paragraph 4, 6 of the Automobile Management Act in case of repairs due to an insurance accident. It is suggested that the relevant Act is revised from " " to "the person who requested the maintenance and the insurance company".

Relevant Act/Regulation Vehicle Management Act Article 58, Clause 4, 6

Responsible Authority & Division Automobile Operation Insurance Division/Ministry of Land, Infrastructure and Transport (MOLIT)

Recommendation Status New

Intellectual Property Rights

Sven-Erik Batenburg
Director,
Intellectual Property Rights Committee

Overview of the Industry

Intellectual property rights (IPR) are the legal foundation through which ownership is provided over creations of the mind, better known as intellectual property (IP). Common types of IPR are copyrights (protecting literary and artistic works), trademarks (which serve to differentiate products or services and enable informed purchasing decisions), industrial designs (which promote innovation by protecting the visual appearance of (parts of) products, or their ornamentation) and patents (which reward technological innovation).

IP is of fundamental importance to the Korean economy. According to a Korea Institute of Intellectual Property (KIIP) study conducted in 2018, IP-intensive industries generated 43% of Korea's total GDP It further found IP-intensive industries to account for 6 million jobs, providing its employees a 50% wage premium.

In light of such importance, the ECCK has operated its IPR Committee since its establishment and has provided various recommendations throughout the years. The ECCK is pleased to recognize initiatives that are aimed at establishing a more supportive IP environment in Korea. The ECCK would like to particularly highlight the preparations to increase the maximum amount of statutory damages for trademark infringements, as well as new regulations on liability of online service providers for the distribution of counterfeit products, both of which were included in the ECCK White Paper 2019.

Challenges remain in particular as to the IP enforcement against counterfeit products, at Korea's borders, Free Trade Zones, within the country as well as online. COVID-19 has significantly impacted IPR protection, with decreases in enforcement at offline markets leading to increased sale of counterfeit products and the online sale of counterfeit products reaching new heights. Although there have been some improvements in awareness of IP in general, further understanding of importance of IPR amongst officials and citizens are still required[1].

The ECCK IPR Committee remains willing and ready to continue providing support to all parties involved in enhancing the Korean IP environment, ranging from increasing innovation by raising awareness of the importance of IP among all levels of society to enhancing enforcement of all types of IP In an effort to enable such improvements, a number of common challenges that could benefit from amendments in legislation or practice are listed below. The ECCK welcomes the openness to cooperation from all relevant stakeholders in order to obtain tangible and sustainable improvement.

1. In a consumer survey conducted by ECCK in 2019, 44% of consumers indicated to have purchased counterfeit products, ECCK (2019), Busan Consumers' Perception of Counterfeit Products 2019.

Key Issues

1. Lack of Cooperation on IP Enforcement

The scope of various enforcement officials' authority differs from one agency to the other, yet overlap in authority is very common. This can make it possible for large amounts of manpower to be dedicated to enforcing IP in general, as well as for specific investigations.

The reality however is that the number of joint activities, where the agencies pool their manpower to increase the efficiency and effect of the enforcement action, are limited. Moreover, information pertaining to an agency's seizures and observed market trends tends to be retained by the agency involved rather than shared with enforcement officials of other agencies, which hampers the efficiency of enforcement activities.

Recommendation

The ECCK recommends, in line with the OECD which has pointed to the importance of "strengthening cooperation and expanding the scope of international frameworks"[2], that regular exchanges of information and practices with domestic and foreign law enforcement officials, as well as industry representatives are organized.

Moreover, the establishment of specific units dedicated to IP enforcement outside of the Korean Intellectual Property Office would be welcomed.

Responsible Authority & Division Presidential Council on Intellectual Property (PCIP) IP Protection Policy Division

Recommendation Status Retained

2 OECD (2018), Governance Frameworks to Counter Illicit Trade.

2. Ineffective Sentencing of IP-Related Crimes

Effective enforcement of IPR is a basis for the fundamental aspect of potent IPR systems. Article 61 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to which Korea is a member holds that member countries "shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale [...] includ[ing] imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity".

In line with such provision the Korean Trademark Act, Design Protection Act and Patent Act allow for up to seven years of imprisonment or a financial penalty 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 indicated as a 'systemic deficiency'[3] as it was "considered insufficient to ensure adequate deterrence against IP infringements with regard to counterfeit and pirated goods"[4].

Particularly for actors involved in creating, distributing and selling counterfeit products "[p]enalties and sanctions are key deterrents [...], as these actors will prefer to trade in goods where the rewards are highest, and the risks are lowest"[5]. While in various countries counterfeiting is met with actual prison sentences, in Korea prison sentences are commonly handed down on a probation basis. Additionally, fines as low as a few hundred thousand KRW are still handed down to sellers of counterfeit products.

Recommendation

It is recommended that training programs are devised to inform all enforcement officials of the importance of IP in order to assure their understanding of the implications of IP infringements. Such understanding will drive in-depth investigations, which in turn enable vigorous prosecution and result in deterring sentencing.

In particular, enhanced understanding of the lucrative nature of the counterfeit industry will compel all involved to utilize the robust sentencing provided for in the respective legislation and issue truly deterring sentences, quelling the appeal of counterfeiting and curtailing repeat offenders.

3 European Commission (2018) COMMISSION STAFF WORKING DOCUMENT - Report on the protection and enforcement of intellectual property rights in third countries.

4 European Commission (2020) COMMISSION STAFF WORKING DOCUMENT - Report on the protection and enforcement of intellectual property rights in third countries.

5 OECD (2018), Governance Frameworks to Counter Illicit Trade.

Responsible Authority & Division Presidential Council on Intellectual Property (PCIP) IP Protection Policy Division

Recommendation Status Retained

3. Border Seizures

Customs offices are the first line of defense when it comes to contraband and counterfeit items. Detection and seizure of counterfeit items before entry into the country is an essential aspect of an effective anti-counterfeit policy as it directly decreases the number of counterfeit products available for circulation in the country. The enhancement seizure and destruction power of customs officials and the special project to seize counterfeit products sent as parcels are commendable developments.

Recommendation

It is recommended that an adequate shipment examination rate is maintained, as long as it does not unduly impede on trade activity.

It is also recommended that a sufficient number of officials are assigned to the examination of shipments.

It is further recommended that officials' skills to conduct investigations in a swift, yet thorough manner are developed through a sufficient number of capacity building seminars.

Responsible Authority & Division Korea Customs Service (KCS) Passenger & Simplified Clearance Division

Recommendation Status Retained

4. Annual Report on Seizure of Counterfeit Products at Customs

The ECCK is pleased that the Korea Customs Service (KCS) has started to publish annual reports on its counterfeit seizures as of 2015, following recommendations by the ECCK to such effect.

The yearly report provides the total number of seizures as well as information on how these seizures are made up, while utilizing three different indication methods to quantify the seized products (the

number of items, the total weight of the seized products, as well as the products' combined value).

Following a recommendation to that effect in ECCK's White Paper 2018, KCS' Passenger & Simplified Clearance Division indicated that it would improve its customs clearance procedure and review using the unified indication method.

Recommendation
We recommend that KCS counterfeit seizure publication aligns its indication of items seized, quantifying the total amount of item seized in terms of the total pieces.

Responsible Authority & Division Korea Customs Service (KCS) Passengers and Simplified Clearance Division

Recommendation Status Retained

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5. Enhancement of Effectiveness Korea Customs Service Express Mail Service (EMS) Project

For a number of years, the use of small consignments for the distribution of counterfeit products across borders has increased. In response to such, Article 8-2 of the Regulation of Customs Clearance of International Mail Items was amended providing officials with the authority to seize and store counterfeit products, rather than return these illicit products to their sender.

Following the regulatory amendment, an initiative was launched by the Korea Customs Service, rightsholders and industry representatives to cooperate on increasing the inspection of imports, the so-called Express Mail Service (EMS) project. On a designated day every week, relevant stakeholders assort parcels, conduct joint on-site authentications, and update the parcels database to allow for faster customs clearance.

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.

While the EMS project is a remarkable initiative that capitalizes on the cooperation of various stakeholders, there are certain structu-

ral challenges that keep it from reaching its full potential.

Firstly, a handful of customs officials are involved in the detection of all goods coming to Korea through postal customs. As the success of the project is determined by a high inspection rate, it is important that the number of officials involved in the detection is increased. Moreover, the storage designated for the parcels seized through the EMS Project is limited.

Recommendation
In order to allow the EMS project to reach its full capacity, we would like to recommend additional manpower to be designated to the detection of goods coming to Korea through postal customs as well as the allocation of additional warehouse space for the storage of parcels seized through the EMS project.

Relevant Act/Regulation Regulation of Customs Clearance of International Mail Items

Responsible Authority & Division Korea Customs Service (KCS) Passenger & Simplified Clearance Division

Recommendation Status New

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6. Designation of Special Judicial Authority to Local Government Officials

Through its IPR Committee, ECCK has consistently dedicated its efforts to curb the counterfeit industry in order protect consumers, businesses, and society at large. To this effect, ECCK established a joint initiative between Seoul local government officials and industry in 2013, aimed at rooting out the open sale of counterfeit products at Seoul's most popular tourist areas.

The presence of counterfeit products at street markets is not limited to Seoul. Of concern are also Busan's International Market as well as Daegu's Seomun Market.

Contrary to Seoul, local officials in neither Busan's nor Daegu's Central District Office have been provided with special judicial authority to investigate and take enforcement actions against the production, sale and distribution of counterfeit goods on the Inter-

national Market and Seomun Market. As a result of such, actions against counterfeit products are practically a matter for the various police units, for whom IP crimes are not of utmost importance.

Recommendation

It is recommended that local government officials of other large cities in Korea in general, and Busan and Daegu in particular, request the Prosecution Service to be assigned special judicial authority to investigate counterfeiting activities and seize illicit products on the basis of Articles 5 (38) and 6 (34) 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 & Daegu Central District Office

Recommendation Status Retained

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7. Open Sale of Counterfeit Products

Through its IPR Committee, ECCK has consistently dedicated its efforts to curb the counterfeit industry in order protect consumers, businesses, and society at large. To this effect, ECCK established a joint initiative between Seoul local government officials and industry in 2013, aimed at rooting out the open sale of counterfeit products at Seoul's most popular tourist areas.

A number of factors, including certain street markets' operating hours (approximately from 21:00 – 05:00), the covert operation of merchants and the sheer size of certain regions, have frustrated detection, making it practically impossible for a single agency to completely end the sale of counterfeit products.

The measures to curb the spread of COVID-19 throughout the country have resulted in a significant decrease in the enforcement activities. This has made it difficult, if not impossible for new members of the Counterfeit Crackdown Taskforce to receive proper training.

Recommendation

It is recommended to arrange proper handover processes and that

skills and insights are collected in the institutional memory of the team in case of rotation of employees.

Relevant Act/Regulation Act on the Persons Performing the Duties of Judicial Police Officers and the Scope of Their Duties

Responsible Authority & Division Seoul Central District Office

Recommendation Status Retained

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8. Enforcement Against Similar Marks

Over the past years, enforcement activities against counterfeit products have increased. In an effort to avoid seizure and destruction of their counterfeit products, the counterfeit industry has looked at alternate methods to free ride on famous brands' attractiveness and mislead consumers.

One of such ways is the creation of almost identical copies of branded products which contain slightly altered versions of the original brands. While the use of similar marks for the same goods does constitute trademark infringement, enforcement activities tend to revolve around the seizure of products containing identical marks.

A limitation of enforcement activities to merely identical marks, would incorrectly be perceived by the counterfeit industry to mean that the use of similar marks is acceptable.

Recommendation

It is recommended that enforcement officials include products containing marks similar to protected trademarks in their seizure activities. ECCK and its members stand ready to assist officials in their enforcement activities, for example by enhancing officials' awareness of the various intellectual property rights that protect members' products.

Relevant Act/Regulation Trademark Act

Responsible Authority & Division Seoul Central District Office

Recommendation Status Retained

9. Stakeholder Cooperation on Online Enforcement

The number of transactions made through online sources has been on an upward trend globally, and this has been further spurred by the outbreak of COVID-19 in 2020. The counterfeit industry has keenly followed such trend and has also expanded to the online space distributing its illegitimate products to unsuspecting consumers.

In an effort to curb the online sale of counterfeit products, the European Commission has facilitated dialogue between stakeholders (online intermediaries, rights owners and associations) that promotes collaborative approaches and voluntary, practical solutions. Such dialogue has resulted in the signing of a Memorandum of Understanding[6] between pertinent stakeholders.

6 Memorandum of Understanding on the Sale of Counterfeit Goods via the Internet.

In protecting consumers from malicious counterfeit products in the online space, rights holders actively monitor various online platforms and inform the respective operators of any offers to sell counterfeit products. Significant differences in online intermediaries' procedures and their willingness to cooperate with rights holders frustrate efficient take-down of counterfeit products.

In order to enhance cooperation between the various stakeholder, a Roundtable on Online IP Protection and Enforcement was organized in Korea in March 2019 and attended by online service providers, industry, the Korean Intellectual Property Office, the European Commission, the EU Delegation to Korea and the ECCK. During such meeting, participants agreed on the benefits of the creation of a Memorandum of Understanding between all relevant stakeholder in Korea.

While a Memorandum of Understanding aimed at decreasing the availability of counterfeit products at online platforms was signed between Korean Intellectual Property Office (KIPO) and online service providers, industry has not been included in any discussion in this regard.

Recommendation

As the online sale of counterfeit products is a global phenomenon, the ECCK recommends the exchange of information on best practices. This includes the exchange of information between online intermediaries, as well the creation of collaborative approaches that can lead to voluntary, practical solutions (such as the EU's Memorandum of Understanding on the Sale of Counterfeit Goods via the Internet).

In particular, ECCK recommends that a Memorandum of Understanding on the Sale of Counterfeit Goods via the Internet is prepared amongst all stakeholders in Korea (i.e. online intermediaries, rights owners, and associations) as such reflects the discussion at the Roundtable on Online IP Protection and Enforcement organized in March 2019.

Responsible Authority & Division Korean Intellectual Property Office (KIPO) IP Protection Policy Division

Recommendation Status Retained

10. Copyright and Royalties

Korea has signed various international treaties[7], as well as a Free Trade Agreement with the EU, under which it has committed itself to protect the rights of authors, producers and performers.

7 Including the WIPO Performances and Phonogram Treaty, the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") and the Berne Convention.

The Korean Copyright Act provides protection to various types of works, including phonograms or cinematographic works, as well as performances and broadcasts. Article 29(2) of the same Act provides a severe limit to the exercise of public performance rights by authors, producers and performers of sound recordings by providing an exemption to the requirement to pay royalties.

While the Enforcement Decree has set conditions under which this exemption applies, the applicable conditions are excessively wide and as a result the majority of Korean businesses qualify for such exemption.

While the compensation standards were established to help parties in receiving appropriate compensation, they have practically resulted in rights holders having to accept exceptionally low compensation, which cannot be considered a fair reflection of the value of their creations.

Recommendation

It is of high importance that a supportive environment for all types of IP is established in Korea. In order to establish an environ-

ment in which all authors, producers and performers of sound recordings are properly compensated for the use of their works, it is recommended that the scope of the exemption provided for in the Enforcement Decree is narrowed, taking account of the fact that business owners' decide whether or not to play music to increase the appeal of their business.

Additionally, it is recommended that a thorough re-assessment of the applicable compensation is being conducted, taking account of all relevant stakeholders' insights as well as practices in foreign countries, as well as the possibility for parties to practically reach an agreement on the applicable compensation through negotiation.

Relevant Act/Regulation Copyright Act

Responsible Authority & Division IPR Policy Division / Ministry of Culture, Sports and Tourism (MCST)

Recommendation Status Updated

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11. Standard Essential Patents

Global standards are fundamental to today's ubiquitous connectivity. The COVID-19 crisis of 2020 has further emphasized the importance of connectivity as it plays a crucial role in reducing the impact of necessary quarantine measures. The interoperability and performance provided by these global standards are the result of intensive research and development activity by companies in different parts of the world, brought together thanks to a performing standardization system, into an end-to-end solution.

The increasing importance of the cellular technologies has been demonstrated by the very rapid deployment and use of 5G technology in Korea, where more than 7 million 5G subscribers are already benefitting of the additional services this new technology brings.

Over the next decade, the importance of 5G and the further development of 5G standards, will address the needs of critical sectors including automotive, health, energy, agriculture and manufacturing. It will support the essential automation and data exchange required for the Internet of Things (IoT) and be at the core of societal functions like transport, public safety and defense.

To ensure that the enormous societal benefits of 5G and IoT are realized, it is critical that standards for mobile communications continue to be developed on the basis of cutting-edge technologies contributed by companies from all around the world, within a standardization framework that enables collaboration and competition.

Such a balanced approach will foster global markets and underpin a healthy and open technology ecosystem, enabling continued investments in R&D and ensuring access to state-of-the-art technologies for all.

Recommendation

It is vital that a market-led, open, balanced and sustainable ecosystem is preserved for the development and rollout of new communication standards. Key factors for success in such are the continued voluntary contribution of cutting-edge technology to open standards by industry and research centers in exchange for the right for those who contribute their technology to license the intellectual property covering such technology on fair, reasonable and non-discriminatory (FRAND) terms.

In particular, we would like to recommend that the Korea Fair Trade Commission and Korean Intellectual Property Office take account of the recent important developments in the US and EU, and evaluate whether these developments merit further action on their side.

Relevant Act/Regulation Review Guidelines on Undue Exercise of Intellectual Property Rights

Responsible Authority & Division IKorea Fair Trade Commission (KFTC) / Anti-Monopoly Division (Knowledge Industry) & Korean Intellectual Property Office (KIPO) / IP Creation Strategy Division

Recommendation Status Retained

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12. Ambiguity as to Interpretation of Legislation Related to Control of Technology Export

The existence of regulatory hurdles with regards to the export of technology and the ambiguity as to interpretation of such regulations have a stifling effect on the technology innovation and the creation of IP

In order to "prevent undue divulgence of, and protect, industrial technology in order to strengthen the competitiveness of Korean industries and contribute to national security and development of the national economy" and to avoid the "manufactur[e], development, use, or storage of weapons of mass destruction and missiles capable of delivering them" the Act on Prevention of Divulgence and Protection of Industrial Technology and the Foreign Trade Act have placed restrictions on the export of 'National Core Technology' and 'Strategic Technology/Material'.

A particular challenge as to the above is the ambiguity on the interpretation of 'National Core Technology' and 'Strategic Technology/Material', which are both designated by the Minister of Trade, Industry and Energy. Such restricts the possibilities for international collaboration for the innovation on a wide array of technologies.

While ECCK is pleased to note that Ministry of Trade, Industry and Energy (MOTIE)'s Market and Innovation for Industrial Technology Division has taken note of industry challenges related to the restrictions imposed by the aforementioned Acts, some guidance would be merited.

Recommendation

The ECCK recommends that clear guidance is provided on the scope and meaning of 'National Core Technology' and 'Strategic Technology/Material', including explanations and practical examples.

Relevant Act/Regulation Act on Prevention of Divulgence and Protection of Industrial Technology & Foreign Trade Act

Responsible Authority & Division Ministry of Trade, Industry and Energy (MOTIE) / Market and Innovation for Industrial Technology Division

Recommendation Status Updated

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13. Damage Calculation Methods

A number of calculation methods are available to claimants in order to calculate the damages stemming from the infringement of their IPR in Korea. These are calculations based on either: claimant's lost profit; the defendant's profit, or; what would have constituted a reasonable royalty.

In case it is difficult for the court to verify the facts necessary to prove the amount of such damages, the court can calculate a reasonable amount of damages based on its discretion, taking into account evidence provided in the case.

While in multiple countries (including Germany, Japan and the US) damages are typically calculated on the basis of what would constitute a reasonable royalty, damage compensation in Korea are most commonly rendered based on what the courts deem to be a reasonable amount[8].

Recommendation

In order to further increase the predictability of damage compensation it is recommended for the judiciary to deliberate ways to further utilize the reasonable royalty provision for example by setting standards to accept expert opinions on the quantification of reasonable royalties, in consultation with IP practitioners.

Relevant Act/Regulation Patent Act

Responsible Authority & Division Patent Court

Recommendation Status Retained

8 70% of the trademark infringements procedures from 2000 to 2013 saw a calculation of the amount of damages based on the court's discretion, Prof. Youngsun Cho (2013), Rethinking the Remedies for Trademark Infringement – Focusing on Simple Negligence Immunity.

Kitchen & Home Appliances

Eunhye Baek
Manager,
Kitchen & Home Appliances Committee

Overview of the Industry

The Kitchen & Home Appliances Committee handles food apparatus, containers, small home appliances, etc. The relevant authorities are: the Ministry of Food and Drug Safety (MFDS), which tests the food safety from using food apparatus and containers as well as packages, Korean Agency for Technology and Standards (KATS) under the Ministry of Trade, Industry and Energy (MOTIE), which hosts the safety verification of small household appliances, and National Radio Research Agency (RRA) under the Ministry of Science and ICT (MSIT), which is in charge of electromagnetic compatibility verification. The Korea Environment Corporation (KECO) under the Ministry of Environment (ME) is running Eco-Assurance System (EcoAS), a recycling system for electric and electronic goods.

Importers face high non-tariff barrier when entering the Korean market. Above all, when new food-service apparatus and containers are imported, the areas directly in contact with food must go through strict inspections by their material and color categories. Meanwhile, electronic goods must obtain electromagnetic compatibility (EMC) Registration/Certification and Electrical Appliances Safety Certification to be imported.

Key Issues

1. Improvement of the Labeling Requirement for Domestic Pressure Cooker

Pressure cookers for domestic-use is managed under the 'Electrical Appliances and Consumer Products Safety Control Act', but the labeling requirement for pressure cookers should be in-line with the 'Safety Standards for Domestic Pressure Pans and Pressure Pots'.

The requirement for safety labels used for domestic pressure cooker is similar to the one outlined in the 'Electrical Appliances and Consumer Products Safety Control Act', except for the labeling requirement for date of manufacture which requires to display manufacturing year and month on the product.

Even though the manufacturing week and year is already marked on the product surface in accordance with the labelling guide in

'Electrical Appliances and Consumer Products Safety Control Act', the indication of the manufacturing month and year is also required to be labeled on the packaging box separately in order to meet the 'Safety Standards for Domestic Pressure Pans and Pressure Pots' for domestic pressure cookers.

Recommendation

Therefore, for the products managed under the Electrical Appliances and Consumer Products Safety Control Act, we request permission to mark the time of production in accordance with the Operational Guide of Electrical Appliances and Consumer Products Safety Control Act even if there is a specific standards for each product category in place.

Relevant Act/Regulation Electrical Appliances and Consumer Products Safety Control Act–Operational Guide/Safety Standards for Domestic Pressure Pans and Pressure Pots

Responsible Authority & Division Korean Agency for Technology and Standards (KATS)

Recommendation Status New

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2. Converting KC Certificate into Electronic Document

KC certificate is issued by three test laboratories. The information on Electric safety certificate is shared through 'Safety KOREA' or UNI-PASS, etc, websites.

The companies are required to keep the original paper document of the safety certificate for renewal, cancellation and return of the certificate. Except these times, the original paper certificate is not used normally.

Registration of Broadcasting and Communication equipment document is issued by electronic document and it has made it easier to manage and renew the document. Thus, when KC Certificate is converted into electronic document, it will be easy to manage and keep efficiently.

Recommendation

It is recommended to issue KC Certificate electronically.

Kitchen & Home Appliances Committee

Relevant Act/Regulation Enforcement Decree of the Electrical Appliances and Consumer Products Act

Responsible Authority & Division Korean Agency for Technology and Standards (KATS) / Korea Testing Laboratory (KTL) / Korea Testing Certification (KTC) / Korea Testing & Research Institute (KTR)

Recommendation Status New

Christoph Heider
President

Logistics & Transport

Overview of the Industry

Logistic and transport services in Korea are and remain an important contributor to economic growth. 2019 was already a difficult year as shipments to and from Korea declined due to less exports and imports. The situation worsened in 2020 because of the COVID-19 pandemic; lockdowns including production halts in overseas markets and therewith challenges in container logistics management or also temporary suspensions of passenger and cargo flights had and still have a tremendous impact on this industry segment. The outlook for cross boarder shipments in the year 2020 is bleak. The Ministry of Ocean and Fisheries (MOF) published that Korean ports handled 8% less cargo in the period from January to June 2020 and a substantial recovery is not in sight. Total air cargo also experienced a certain dip as cargo capacity on passenger planes decreased considerably; instead capacity utilization in pure cargo carriers skyrocketed as the cargo fees did. As a consequence, airlines either used or even converted passenger jets into cargo planes as a temporary measure, mainly catering for the PPE sector. The domestic logistic & transport fared better due to a high demand for online sales as many people preferred to shop from home instead of physically visiting shopping malls, supermarkets or department stores.

Key Issues

1. Port-Mis Operational Secluding Reporting

All foreign vessels that call on Korean ports are required as from July 3, 2020 to report their operational schedules in the web-based filing system 'Port-Mis' (Article 28 Paragraph 4 of the Korean Marine Transportation Act). The reporting requires large data sets, therefore, creates an administrative burden for the companies; but especially the requirement to up-date changes in the shipping route is very time-consuming and cumbersome as there can be many changes in a shipping companies network at any single time causing significant administrative burden and cost.

Recommendation

It is recommended to critically review the data sets for the reporting via 'Port-Mis' and a potential elimination of non-critical reporting items to ensure that reporting can be conducted in an efficient and effective manner. Also, we suggest a change in the reporting

procedure about route respective vessel changes to ensure that reporting can be conducted in an efficient and effective manner.

Relevant Act/Regulation Marine Transportation Act Article 28 Paragraph 4 (Effective on July 3, 2020)

Responsible Authority & Division Ministry of Oceans and Fisheries (MOF)

Recommendation Status New

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2. Ocean Tariff Reporting for Korean Export/Import/Transit Cargo

Effective from July 1, 2020, the Ministry of Oceans and Fisheries (MOF) requires all ocean carriers to report – for fair ocean competition and open information in the market – Korean export, import and transit cargo rates.

The reporting requirement caused certain problems at shipping companies as the data definition at many shipping companies differs from the definition made by the Ministry of Ocean and Fisheries (MOF); such as company A is transferring short term rate offerings which pursues a more dynamic moving rate per point of booking, instead of the rates at the point of loading. Also, the determination of transit cargo rates is very difficult, and the reporting requirement presents a certain confidentiality risk from the industry point of view.

Recommendation

It is recommended to disclose and report only for shippers whose actual freight rates are discussed and contracts that are made in Korea; exclude transit shipments from the reporting. Furthermore, the declaration timeline to be 5-7 days prior to the effective date, to cover the reality of rate publish practice in the market to avoid multiple changes. Also, it is suggested to accept retro-active pricing for long-term contracts, to cover the reality of contract negotiation delay after contract effective date in Korea.

Responsible Authority & Division Ministry of Oceans and Fisheries (MOF) & Maritime Affairs

Recommendation Status New

3. Multimodal Transport Companies to Operate as Customs Brokers

Multimodal transport companies are allowed to operate as customs brokers at the same time in Korea. However, the qualifications to set up a customs house brokerage are realistically difficult to meet for the companies that only a few multimodal logistics companies could offer such services.

The Korea Customs Service (KCS) requires following qualifications for setting up a customs house brokerage business in Korea:

- Paid in capital of more than KRW 500 million
- For land transportation, more than 70 lorries or 30 tractors
- For air transportation, two cargo planes or more
- For a stevedoring company, the stevedoring equipment must cost over KRW 500 million

These conditions create difficulties for the logistics companies in pursuing customs clearance, furthermore become factors in the deterioration of logistics competitiveness due to the complexity of the Korean logistics process.

Recommendation

It is suggested to review and facilitate the different criteria to be fulfilled to set up and operate a customs handling brokerage business in Korea.

Responsible Authority & Division Korea Customs Service (KCS)

Recommendation Status New

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4. Direct Shipment Requirement – General

'Article 13 of the EU-Korea FTA' provides that "preferential treatment provided for under (the FTA) applies only to products ... which are transported directly between the Parties". For efficiency purposes, it is common for companies to use a regional hub when distributing their products globally. Based on the FTA, it is not allowed for companies to transport their products to regional hubs for subsequent repackaging and redistribution, however. The strict requirement of the FTA has proven to be an undue burden on companies and have led certain companies to decide not to utilize the FTA in doing business with Korea, or in the EU.

Logistics &
Transport
Committee

Recommendation
It is recommended for the EU and Korea to agree on a modernization of the FTA that would allow for repackaging and redistribution in appropriate circumstances.

Relevant Act/Regulation Article 13 of the EU-Korea FTA

Responsible Authority & Division Ministry of Trade, Industry and Energy (MOTIE)

Recommendation Status Readdress

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5. Direct Shipment via Transit Hubs / Change of Mode of Transportation

Goods are shipped in many different ways from Europe to Korea, such as via transit hubs for re-commissioning by a Logistics & Transport service provider (i.e. airline hub in a non-EU country like Qatar) or by train from Europe to an Asian port where is thenreloaded by a Logistics & Transport service providerto a vessel to be shipped to the final destination in Korea. It seems that in some cases, companies were informed by Korea Customs Service (KCS) that this is to be considered as indirect shipment and accordingly the shipment did not enjoy the preferential benefits of the EU-Korea FTA.

Recommendation
It is recommended that the above-mentioned cases to be considered as direct shipment by the originator of the shipment so they should be acknowledged by KCS as direct shipment without any exception. The choose of the shipping route and its mode of operation should not have any impact of determinationof direct or indirect shipment. The ECCK recommends that KCS drafts an internal communication to its employees to ensure that a common procedure is established.

Relevant Act/Regulation Article 13 of the EU-Korea FTA

Responsible Authority & Division Ministry of Trade, Industry and Energy (MOTIE)

Recommendation Status Readdress

Marine & Shipbuilding

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Shipbuilding
Committee

Overview of Industry

The global new shipbuilding order volume fell in 2019 by 11.6% on-year to 25.3 million Compensated Gross Tonnage (CGT). Korean shipbuilders took up the largest share of CGT orders, take up to 37.3% of all orders. Key to the Korean shipbuilders' performance has been the receipt of the global orders of Liquefied Natural Gas (LNG) carriers and Very Large Crude oil Carriers (VLCC).

Orders for new shipbuilding from January to July 2020 fell 40% year-on-year to 6.61 million CGT. The decline is due primarily to COVID-19 as well as the intensification of the regulation on limiting sulfur oxide (SOx) emissions by International Maritime Organization (IMO).

ECCK notes that the Korea Fair Trade Commission (KFTC) includes the use of its standard subcontract agreements as a factor in rating companies in its Fair Trade Agreement Performance Evaluation and is pleased that the KFTC will continue to make efforts to expand the practical use of standard subcontracting agreements.

ECCK is further pleased that through the revision of the 'Enforcement Decree of the Ballast Water Management Act' products that have already obtained an approval type in a foreign country can be exempted from Korean tests. A wider acceptance of products that have already undergone overseas testing, as well as harmonization of Korean standards with international standards will further facilitate trade from and to Korea.

The Korean government has continued a localization strategy under which it promotes the use of domestically produced products and parts. While this could serve as an opportunity for technological cooperation between foreign equipment companies (which hold original technologies) and domestic equipment manufacturers, foreign equipment manufacturers have been faced with the utilization of their technology without receiving any compensation.

Key Issues

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

Domestic shipbuilding equipment companies have adopted predatory bidding practices in bidding for orders by 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 and moreover result in maintaining of the status quo, decreasing investments in research and development, curbing innovation and leading to unsustainable business practices.

Recommendation

In order 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 price, in bidding processes.

Responsible Authority & Division Korea Fair Trade Commission (KFTC)

Recommendation Status Retained

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2. Scope of Suppliers Compensation for Consequential Damages

The Korea Fair Trade Commission (KFTC) provides information on standard subcontracting contracts intended to balance the terms of transactions between the parties and to protect the rights of subcontractors. These contracts and their stipulations have been (partly) adopted and incorporated in shipyards' own terms and conditions.

While the intention of the KFTC's creation of draft contracts is laudable, the draft contracts provision on consequential damages is a particular hindrance to subcontractors. Article 45 of the draft contract provides that "if the original business operator or the receiving business entity suffers damage due to the acts of the other party who violated this contract, the other party shall be liable for damages". This open-ended wording has resulted in the shipyards imposing an unlimited liability for consequential damages on their suppliers.

Such unlimited liability is not common within the industry, where the height of the liability is commonly part of the negotiation of the contract amongst both parties. The inclusion of such wording in the draft contract has resulted in reluctance of shipyards to agree to anything less than unlimited liability for consequential damages.

Recommendation

In order to align the practices in Korea with international practices, it is recommended that:

- The KFTC either removes the wording on the liability for consequential damages completely, or changes the wording of the draft contract from "the other party shall be liable for damages" to "the other party shall be liable for damages up to the height of [...]";
- The KFTC issues a communication to the effect that the wording of the draft contract is a draft contract intended to enhance the rights of the sub supplier and that any deviations in favour of the sub supplier are allowed and welcomed.

Responsible Authority & Division Korea Fair Trade Commission (KFTC)

Recommendation Status New

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3. Required Consent for Offshore Wind Projects

In July 2020 ,the Korean administration announced its Korean New Deal, of which the Green New Deal component is intended to change the Korean economy from a carbon-dependent economy to a green economy. A key aspect of such is the increased investment in eco-friendly infrastructure and renewable energy production, tripling the national capacity of solar and wind power generation to 42.7 GW by 2025.

In a speech on July 17, 2020 President Moon Jae-in noted that "offshore wind energy [...] has the greatest growth potential among green energy sources" and provides "more options for building sites, more feasible large-scale complexes and a higher capacity factor" compared to onshore wind farms. He went on to note that due to "offshore wind turbine towers [utilization of] maritime plant, shipbuilding and equipment technologies [...] expanding offshore wind

power generation will create new demand for our shipbuilding, steel and construction industries".

Foreign investors together with Korean companies have been working to develop floating offshore wind projects in Korea. A key hurdle to the efficient deployment of these projects is that while consent of local residents and fisheries is required at early stages of such projects (as early as the installation of a lidar sensor), no guidance from government is provided. As a result of such, developers are often involved in lengthy bilateral negotiations on a project-by-project basis as to whether compensation would need to be provided and what the height of such should be. These procedures cause significant delays in the project development.

Recommendation

In order to allow for the administration to achieve its goals, it is pertinent that delays in the construction of offshore wind farms are avoided. Therefore, we would like to recommend that:

- Clear guidance on the standards for compensation are jointly created by all government agencies involved. Such standards should take account of corporate compliance requirements, as well as indicate the procedures for identification of stakeholders involved, impact analysis and the type of compensation to be provided;
- Regional government support developers in approaching local residents and fisheries in receiving their consent for the project development.

Relevant Act/Regulation Fisheries Act

Responsible Authority & Division Ministry of Ocean Fishery (MOF) / Ministry of Trade, Industry and Energy (MOTIE)

Recommendation Status Retained

Aerospace & Defense

Bo Sun Kim
Vice President

Overview of Industry

In 2020, the Defense budget has increased by 7.4% from 2019 to reach KRW 50.15 trillion, exceeding KRW 50 trillion for the first time. Significant part (~33%) of this budget has been allocated to the procurement of equipment critical to the Korean national security, including important local development for which European companies are great contributors. 2020 have also seen major export contracts, further positioning Korea as a global aerospace and defense market, a trend that should continue in the years to come.

Despite the global COVID-19 pandemic and budget cuts, Korean defense activities have remained strong, with an important support from the Korean Government to the local industries, through a larger commitment to the indigenous development as well as the change of delivery schedules of several programs to benefit the Korean defense companies.

In this context, the Offset system may be a great tool to support the local industries to grow their capabilities and increase their impact globally. Over the past couple of years, DAPA has reviewed several times the Offset guidelines in the intent to make them more beneficial to Korean industries. Korea has also introduced a Banking system within its Offset policy to offer foreign defense industries more options to contribute to generating local values to fulfill their future obligations. This Banking mechanism is very important as it offers more time for foreign companies to identify offset activities that can be offered to Korea, and for Korean authorities to evaluate proposed activities.

If the European companies value the progress on Offset Guidelines, it seems that some changes or existing clauses increase the liabilities and obligations of the Foreign companies, what could be detrimental to the Korean defense equipment, Korean defense industries and the export activities. Moreover, it seems that the Banking mechanism could be adjusted to allow for more applications.

DAPA, European (Foreign in general) and Korean Defense industries would benefit from a collective and formalized dialogue on Offset Guidelines (including Banking) implementation. This

could be realized through a regular forum to share best practices and workshops with all Offset stakeholders (DAPA Offset team, local and foreign defense companies, the respective associations such as KDIA, ECCK, etc.), to exchange on the offset guidelines to identify conditions that would be more beneficial for every party.

Key Issues

1. DAPA Offset Policy Guidelines – Article 13 related to liabilities for extension

According to Article 13 of the DAPA Offset Policy Guidelines that have been newly revised in December 2019, legal liabilities of companies will increase if a project delivery deadline is not met.

The updated article states that an extension of the project period is subject to a 0.15% penalty per day, which results in penalties up to 54.75% per year. In comparison, those new liabilities are double the liabilities of domestic suppliers which are subject to a 0.075% penalty per day, up to 27.38% per year.

These conditions represent a significant increase compared to the previous guidelines which are subject to 20% increase of the remaining offset value in the first year and 10% on every subsequent year.

On top of the increase of the liability for extension of delivery deadline , the revised guidelines announced in December 2019 have also introduced an increase in companies' obligations should it be necessary to change the content of an already signed memorandum of agreement. This increase is defined at 10% of the remaining obligation, without extending the delivery deadline .

The new provisions mentioned above will severely impact the risk profile of the ROK Armed Forces' defense projects and bring significant challenges to the industry. In some cases, this can make a business engagement unfeasible due to the potentially unlimited financial risk liability that companies (obligors) would have to bear, or make the contractors include the risk as cost, leading to a higher price for the Korean government.

In addition, obligors may face difficulties such as prolonged negotiations and signature process of future obligations. All of this could

be detrimental to the Korean defense equipment, Korean defense industry and even export activities.

Recommendation

The new conditions in the revised guidelines are practically difficult for businesses (obligors) to execute. Therefore, it is recommended to revise article 13 to offer a more flexible system where obligors are not penalized when acting in good faith to implement their obligations.

In addition, it is recommended to organize a workshop with all offset stakeholders to exchange on the offset guidelines and the revision of article 13, to identify conditions that would be more beneficial for every party. Such workshop should include all related stakeholders from DAPA Offset team through to the local and foreign defense companies, including the respective associations such as Korea Defense Industry Association (KDIA) and ECCK.

Relevant Act/Regulation Article 13 of DAPA Offset Policy Guidelines

Responsible Authority & Division Defense Acquisition Program Administration (DAPA)

Recommendation Status New

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2. DAPA Offset Policy Guidelines – Article 14 related to Offset Performance Bond

Article 14 of DAPA Offset Policy Guidelines states that, should a foreign contractor fail to fulfill its offset obligation within the agreed implementation period of the agreement, DAPA shall be entitled to confiscate 10% of the unfulfilled portion of said obligation from the offset performance bond as a penalty for contract violation, without stating if such confiscation would release the company (obligor) of its offset obligation. Moreover, it does not give the company any opportunity to discuss about the decision.

The revised guidelines differ considerably from the previous guidelines that allowed foreign contractors to be exempt from offset obligations if they decided to confiscate performance deposits.

Moreover, the revised guidelines, in addition to other provisions that

Aerospace & Defense Working Group

require additional penalties for periods of performance extensions, represents a much more aggressive and punitive penalty structure than the previous guidelines. Indeed, the updated guidelines can be understood as imposing an unlimited and uncapped liability, representing a potentially unlimited financial risk liability for obligors.

The new provisions mentioned above will severely impact the risk profile of the ROK Armed Forces' defense projects and bring significant challenges to companies. In some cases, this can make a business engagement unfeasible due to the potentially unlimited financial liability that companies (obligors) would have to bear, or make the contractors include the risk as cost leading to a higher price for the Korean Government. In addition, obligors will face difficulties such as prolonged negotiations and signature process of future obligations. All of this could be detrimental to the Korean defense equipment, Korean defense industries and even export activities.

Recommendation

It is recommended to revise article 14 of DAPA Offset Policy Guidelines to allow foreign contractors to be exempted from the offset obligation if the performance deposit is confiscated due to failure to fulfill the offset obligation within the agreed period by returning to the pre-amendment conditions.

In addition, it is recommended to organize a workshop with all offset stakeholders to exchange on the offset guidelines and the revision of the article, to identify conditions that would be more beneficial for every party. Such workshop should include all related stakeholders from DAPA Offset team through to the local and foreign defense companies, including the respective associations such as Korea Defense Industry Association (KDIA) and ECCK.

Relevant Act/Regulation Article 14 of DAPA Offset Policy Guidelines

Responsible Authority & Division Defense Acquisition Program Administration (DAPA)

Recommendation Status New

Energy & Environment

Taeyang Kim
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Key Issues

1. Direct LNG Import Request from Companies Using City Gas NG

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. The customers' final products (TDI/MDI/PC) are exported mainly to overseas markets.

Under the 'Urban Gas Business Act (Article 10(9))', direct LNG import is allowed only for captive use purpose only or for new expansion or for fuel replacement. However, existing NG users who are supplied by City Gas companies are not entitled to directly import LNG, which weakens their market competitiveness compared to their new competitors that directly import LNG for their raw material.

Recommendation

It is recommended to change the Article 10(9) of the 'Urban Gas Business Act' and allow direct LNG import for those who are using City Gas NG.

In EU countries, NG/LNG market is completely deregulated. There is a full level playing fields between users (industrial users, power companies, etc.) and NG/LNG can be freely sourced from private retailers (international oil companies, traders, etc.). The terminal fee costs (regasification, storage, etc.) are regulated if they are owned and operated by a public company (i.e. KOGAS), but freely negotiated when the terminals are owned and operated by a private company. The inland pipeline transportation costs (capacity) are regulated.

Relevant Act/Regulation Urban Gas Business Act

Responsible Authority & Division Gas Industry Division, Ministry of Trade, Industry and Energy (MOTIE)

Recommendation Status New

2. Direct Contract Between KOGAS and Industrial Gas·Chemical Companies for NG Purchasing

Industrial gas companies produce H2/CO using Natural Gas (NG) as raw material and supply H2 and/or CO to customers who produce their final chemical products using CO/H2 as intermediate. The customers' final products (TDI/MDI/PC) are exported mainly to overseas markets.

According to the 'Urban Gas Business Act' (Article 2,3), wholesale business means supplying gas to massive consumers defined in the enforcement rule. In the enforcement rule, Article 2(2), users of power generation and power and heat generation whose capacity is bigger than 100 Megawatt are entitled to receive the NG directly from the wholesaler. Therefore, industrial gas companies should be added in the provision to receive the NG directly from the wholesaler (KOGAS) in order to increase their competitiveness in the overseas market.

Recommendation

Currently, the government allows power generation companies to directly trade with the KOGAS with access to the wholesale price. It is recommended to include "users for industrial gas production with NG consuming plants whose sum of design capacities at a designated business site is higher than 9400Nm3/h which is equivalent to 100 Megawatt" as an additional category in the Article 2(2) of Enforcement Rule. In EU, the NG market has already been fully deregulated.

Relevant Act/Regulation Urban Gas Business Act

Responsible Authority & Division Gas Industry Division, Ministry of Trade, Industry and Energy (MOTIE)

Recommendation Status New

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3. Measuring Instrument Verification of EV Charging Stations

The electric vehicle (EV) charger type approval system, implemented as of January 2020, requires that electric vehicle chargers be designated and managed as an electric meter, and such regulation exists only in Korea. As it becomes mandatory to install a display and seal the metering part in the charging type

charger, it is necessary to develop a product exclusively for the Korean market for foreign products.

Ministry of Trade, Industry and Energy (MOTIE) has given a grace period to allow local manufacturers and service provider to sell EV charging stations manufactured in 2019 until 2020. As a result, many local EV charger manufacturers have been selling their products without completing the Measuring Instrument Verification test. However, for foreign-made EV chargers, it is applied based on the customs clearance date, and products cleared after December 31, 2019 cannot be sold in Korea. It is a discriminatory measure to immediately apply the response process without a grace period to foreign products that naturally takes more time, which has increased the barrier to entry into the Korean market.

Recommendation

It is recommended to abolish or deregulate the new regulation, the articles related to LCD display on EV charging station. If it is impossible to delete the clause, it is recommended to allow foreign EV charging stations to be exempted from the regulation for 3 years.

Relevant Act/Regulation Article 14, 21, 23 and 24 of Measures Act, /Article 11, 17 and 20 of Enforcement Decree of the Measure Act

Responsible Authority & Division Metrology & Measurement Division /Korean Agency for Technology and Standards

Recommendation Status New

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4. Plug Type of EV Charging Station

The Korean government has decided to use higher power single phase based for AC charging from current one with single-phase based, 7kW(32A), to 17.6kW(80A) to shorten the charging time of EV.

However, single-phase 80A charger has disadvantage(s) as follows: (iv) High unbalanced load to power grid, (ii) 80A onboard chargers are heavy and costly, (iii) 80A charging cable is inconvenient due to heavy weight and less ability,

(iv) Expensive price of charging station, (v) Expensive cost for installation (Electric work), (vi) Inconvenient to additional EV charging stations.

Recommendation

It is recommended to approve 'IEC 62196 Type 2 (Europe Standard)' in addition to 'SAE J1772 Type 1 (Current one)' for the AC charger, and 'CCS 2 (Europe Standard)' in addition to 'CCS 1 (Current one) for the DC charger.

Relevant Act/Regulation KS R IEC61851-1, KS R IEC62196-3

Responsible Authority & Division Machinery & Materials Standards Division, Korean Agency for Technology and Standards/Korea Smart Grid Association

Recommendation Status New

5. Ease Regulations Regarding Licenses for Handling of Radioisotopes (RI License)

With the introduction of the New Deal stimulus plan, high growth in industries such as hydrogen, EV, battery etc. is expected to contribute to the Korean economy. Adjusting the threshold for radioisotope license operators along with other measures as described below, would remain within the reasonable margin of safety for the operation of lower voltage equipment while helping industry adapt high technology for growth.

Accordingly, the need for non-destructive X-ray testing in the fast growing industries such as hydrogen and batteries, is expected to increase, and demand for high-energy X-ray inspection equipment of 350kV or higher is also expected to increase due to the increase in R&D/production samples.

Under the current regulations, hiring a supervisor radiography isotope (SRI) license holder is mandatory when owning equipment of 350 kV or higher. However, unlike radioisotope (RI) licenses, there are only a few SRI license holders, and SRI license holders are paid relatively high, which increases the burden on employment.

Recommendation

It is recommended to raise the requirements for SRI license

holders to operate X-ray equipment to 1 MeV or more in order to promote the introduction of leading technologies in the growing industry and to harmonize regulations consistent with the international standards, permit own In addition, as a measure to ensure a reasonable level of safety, it should be supplemented with provisions of minimum experience and compulsory education.

Relevant Act/Regulation Article 53(2) and Article 84 of Nuclear Safety Act / Article 82-3 of Enforcement Decree of the Nuclear Safety Act

Responsible Authority & Division Radiation Safety Division, Nuclear Safety and Security Commission

Recommendation Status New

6. Clean Energy Production Through Fuel Flexibility and Enhanced Efficiency

There is an increase in need for cleaner, more efficient energy sources to fight climate change and reduce carbon footprint. Gas turbines applied in combined heat and power applications (CHP) is a great alternative energy source, especially for manufacturing sector and district heating/cooling. CHP solutions with gas turbines will enable fuel flexibility, allowing generators to switch from conventional fuels (diesel and natural gas) to next-generation 100% green fuels such as hydrogen, to bring CO2 emissions to zero without building an entirely new system.

In addition, CHP provides the most efficient way to use primary energy to minimize fuel imports, and to deliver predictable and reliable energy supply to manufacturing and process industries. The overall plant efficiency can reaches 90%, thus reducing CO2 emissions.

CHP could increase the competitiveness of Korean industries by enabling manufacturers to diversify and localize energy production by leveraging distributed power generation, while also obtaining a lower cost of energy and reducing the cost structure of domestic manufacturing. Furthermore, it can enhance Korea's competitiveness even if border-adjustment mechanisms like those being proposed in Europe are introduced which impose

tariffs or prohibit the importation of certain goods based on lifecycle emissions. However, even with the current carbon emissions trading scheme and existing subsidies, the economics for CHP are less attractive than alternative power source options which inhibits the sector's growth.

Recommendation

It is recommended to limit the CHP with gas turbine incentives to 50MW, which is the maximum capacity generally used in the production field. Also, it is recommended to limit the installation of new CHP with gas turbines to a case that provides energy savings of at least 10% compared with the audited baseline of factory energy profile and system efficiency.

Furthermore, it is recommended to establish incentive policy for CHP with gas turbines less than 50MW in manufacturing sector as follows: (i) investment tax allowance for capital expenditure, (ii) import duty and import tax waiver for imported equipment, (iii) favorable natural gas tariff compared to conventional use such as packaged boilers, (iv) pre-defined permitting and licensing procedures as well as one-stop application.

The incentive system began to evolve in Europe from the 1980s. Today, EU-15 CHP contributes about 18% of total power generation, and the share of total power generation that can be applied to CHP is about 20~25%.

Relevant Act/Regulation Article 15 of the Enforcement Rule of the Clean Air Conservation Act / Act on the Promotion of the Development, Use and Diffusion of New and Renewable Energy

Responsible Authority & Division Air Quality Management Division, Ministry of Environment (ME) / New and Renewable Energy Policy Division, Ministry of Trade, Infrastructure and Energy (MOTIE)

Recommendation Status New

7. Amendment of REC Price Scheme

In May 2020, the Ministry of Trade, Industry and Energy (MOTIE) reviewed the amendment of the fixed long-term contract for Renewable Energy Certificate (REC) as follows:

- Current: GENCOS guarantee a fixed price to project owner by compensating for the difference between fixed price and SMP (REC = Fixed Price – SMP) and the fixed price is determined at the time of REC contract and normally before project financing.
- Proposed Amendment: Contract for only fixed REC price, which is determined by Government's REC remuneration (settlement) price for the first REC production year (after Commercial Operation Date).

The reasons for the amendment are as follows: (i) Despite the quantitative growth of renewable energy, the decline in power generation cost is not as great as expected, (ii) Fixed long-term price for REC is much higher than the REC spot market price, (iii) GENCO's participation as a SPC shareholder affects the formation of high fixed price.

However, the reviewed amendment (draft) was confirmed to have the following effects on the renewable energy industry: (i) Difficulty in investment decision for the project development, (ii) Expose to uncertainty in revenue (fluctuation of SMP), (iii) Project finance is not possible due to uncertainty of price.

Recommendation

It is recommended to keep the current REC contract scheme as it is or to keep the SMP+REC fixed price method but apply an upper limit to the REC price.

Relevant Act/Regulation 18.5.1 Cost Assessment Detail Operation Regulations of KPX / Act on the Promotion of the Development Use and Diffusion of New and Renewable Energy

Responsible Authority & Division Electricity Market Division, Ministry of Trade, Industry and Energy (MOTIE)

Recommendation Status New

8. Differentiation of REC Price between Local and Imported WTGs

According to the interim reports of Levelized Cost of Electricity (LCOE) study for wind and solar, issued by Korea Energy

Economics Institute (KEEI) in June 2020, it suggests that the fixed price (SMP+REC) for wind business to be applied differentially depending on the origin of the Wind Turbine Generator (WTG).

<Suggested SMP+REC Price for Onshore>

- Domestic WTG: KRW 175.5/kWh
- Imported WTG: KRW 164.9/kWh

<Suggested SMP+REC Price for Offshore>

- Domestic WTG: KRW 175.3/kWh
- mported WTG: KRW 156.0/kWh

The study was conducted to establish an a guideline for fixed price contracts, however, the it does not provide adequate economic analysis of the utilization rate, power curve, etc. to evaluate business feasibility and focused on providing lower fixed price (SMP+1REC) for imported turbine. The impact of the study results will have on wind industry are as follows: (i) not in line with the aim to lower the fixed price especially for domestic turbine and (ii) it could be interpreted as hidden barriers for trade

Recommendation

It is recommended for REC price to be calculated by each project because the deviation of CAPEX is quite large due to factors such as civil engineering condition, grid connection option, number of towns nearby and so on. Also, for domestic turbine, project owner has to bear a high risk for long-term maintenance and repair for its operation. Furthermore, many wind farm owners who installed domestic turbines are suffering from difficulties with component supply and lack of technical support.

Responsible Authority & Division New and Renewable Energy Policy Division, Ministry of Trade, Industry and Energy (MOTIE) / New and Renewable Energy Research Team, Korea Energy Economics institute

Recommendation Status New

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9. Centralized Permit Process for Renewable Energy

Korea is aiming for 20% of its power source to be generated by renewable energy until 2030. Current development permits are provided through Ministry of Trade, Industry and Energy (MOTIE), Ministry of Environment (ME), local government, etc. Due to

many government parties involved with permits to develop renewable energy project, often the projects are delayed. In addition, there is no guideline or regulations regarding civil complains compensations which makes it even more difficult and costly as the Levelized Cost of Electricity (LCOE) of the projects often gets affected by those initial investment. Local government normally demands for 100% agreement from the locals to be able to proceed permit approval.

Recommendation

It is recommended to unify the permitting process to MOTIE, to eliminate local regulation since it differs by every country, and to create a guideline or regulation regarding civil complaint compensation.

In Denmark, Denmark Energy Agency is in charge of the renewable energy projects in terms of permits and support, and only private houses and facilities located within a radius of 500m from the turbine are paid compensation for civil complaints. .

Relevant Act/Regulation Act on the Promotion of the Development /Use and Diffusion of New and Renewable Energy/Local Regulation

Responsible Authority & Division Ministry of Trade, Infrastructure and Energy (New and Renewable Energy Policy Division) / Korea Energy Agency and Local Government

Recommendation Status New

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10. PPA (Power Purchase Agreement) Contract Discrimination

In order to increase the proportion of local turbine usage, when using overseas turbines, the power purchase agreement (PPA) can be progressed only by submitting the contribution to the domestic economy and the proportion of domestic parts.

In addition, different price for PPA is approved depending on the turbine manufacturer. Higher PPA price for local OEM and lower PPA price for foreign OEM to compensate and make up for loss in project Internal Rate of Return since local OEM CAPEX (Capital Expenditure) & OPEX (Operating Expenditure) is higher than foreign OEM.

Recommendation
It is recommended that the MOTIE to fairly treat developers who are requesting for PPA regardless of turbine's origin.

Relevant Act/Regulation Act on the Promotion of the Development /Use and Diffusion of New and Renewable Energy

Responsible Authority & Division Ministry of Trade, Infrastructure and Energy (New and Renewable Energy Policy Division)

Recommendation Status New

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11. Financial Support for Renewable Energy: Limit of Current REC
Currently, the REC is granted only to facilities producing electricity that is sold to power generation companies (GENCOs), directly or through an auction organized by the Korean Energy Agency (KEA) on behalf of those GENCOs.

Although the Korean government defined REC allocation for various types of renewable energy sources, bids organized by GENCOs or KEA are specifically targeting large photovoltaic (PV) solar projects, while such projects are difficult to develop in Korea. Also, GENCOs and KEA are reluctant to enter into long term power purchase agreement (PPA) for small and medium generation capacity (typically between 0.3 to 2.0 MW). The implementation of the REC policies is not consistent with the objective of fostering the development of a renewable and new energy source.

Recommendation
It is recommended to grant REC for self-consumption projects, to set clear rules for PPA, especially for private PPA (2B) and to extend applications to smaller capacity and more divers renewable and new energy technologies (i.e. fuel cell, heat pump, etc.).See Europe renewable energy directive (REDII) and the electricity market directive (EMDII) for reference.

Relevant Act/Regulation The Article 6, Management and Operation Guidance on the New and Renewable Energy RPS and Blending Obligation

Responsible Authority & Division New and Renewable Energy Policy Division / Ministry of Trade, industry and Energy (MOTIE) / Korea Energy Agency (KEA)

Recommendation Status Updated

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12. Energy Efficiency in Building: G-SEED Certification for Green Buildings
Korea has established a green building design standard (G-SEED), but there is no particular mechanism for building management and operation in consideration of energy efficiency and environmental impact.

Leadership Energy and Environmental Design (LEED) in the US and Green Building Council or Building Research Establishment Environmental Assessment Method (BREEAM) in the UK regulates the performance of buildings during its operation or life-cycle as well as the assessment of the impact on the neighborhood.

Recommendation
In addition to current evaluation during the design and construction phases, it is recommended to extend G-SEED throughout the overall lifecycle of the buildings, especially addressing actual energy performance during actual commercial operation (including monitoring & verification reports).

In Europe, there is Energy Performance of Buildings Directive 2010/31/EU (EPBD) and the Energy Efficiency Directive 2012/27/EU. Both Directives were amended in 2018 and 2019 respectively as part of the Clean energy for all Europeans package.

The "Renovation Wave", part of the European Green New Deal, started in 2019 and is planning to renovate the existing building with the goal of "Carbon Neutral by 2050".

Relevant Act/Regulation Green Buildings Construction Support Act/Standards on Green Construction Certification

Responsible Authority & Division Green Architecture Division / Ministry of Land, Infrastructure and Transport (MOLIT)

Recommendation Status Updated

Human Resources

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Human Resources
Working Group

Overview of the Industry

The outbreak of COVID-19 has created risks for financial stability. The various fiscal policies by the Korean government are helping companies to stay afloat. The current circumstances have placed a higher importance on resolving structural challenges in the labour market.

As indicated by the OECD in its recent report on Korea: "Reducing labour market rigidities and strengthening social protection is necessary to reduce labour market duality and improve job matching. A focus on protecting workers, through the expansion of the social safety net and active labour market policies, rather than protecting jobs, would contribute to raising well-being, employment and labour productivity, which is only about half of that in the top half of OECD countries. Greater use of foreign workers could alleviate labour shortages and related pressure to work long hours in small and medium enterprises (SMEs)."

It is clear that there is much to gain from enhancing flexibility in the Korean labour market and ECCK remains ready to contribute to any dialogues in this regard in cooperation with its members.

The ECCK is pleased to note the various plans to alleviate pertinent challenges in the labour market through incorporation of (part of) the recommendations contained in its White Paper 2019. These include the planned publication of a casebook on standards for Workplace Harassment, preparation of guidelines on comprehensive wage system, consultations with relevant ministries to establish support programs for private enterprises on applying public holidays, as well as the legislative debate on the establishment of a system of a flexible working hours period of up to six months. ECCK is looking forward to seeing the above plans materialize in concrete results.

Nonetheless, ECCK would like to raise awareness on a number of outstanding challenges which would merit improvement.

Human Resources Working Group

Key Issues

1. Annual Leave Entitlement

In order to guarantee a basis number of official holidays to employees, the 'Labor Standards Act' provides employees with a total of 11 days of annual leave for their first year of employment. Upon completion of their first year, employees are entitled to 15 additional annual leave days for each following year.

While the idea behind the provision of a basic number of leave days to employees is fully accepted, this particular arrangement has resulted in employees resigning exactly when they have become entitled to 15 new annual leave days, in order to receive full compensation for all leave days.

Recommendation

ECCK is pleased to note MOEL's initiative to conduct a study into the activation of annual paid leave and improvement of the system.

In order to comply with the spirit behind the provision of leave days and avoid abuse, it is recommended that amendments of the 'Labour Standard Act' are put in place as per which all unused leave entitlement of the first year of employment are forfeited upon passing of the first year of employment.

Relevant Act/Regulation Labor Standards Act

Responsible Authority & Division Wages and Working Hours Division/Ministry of Employment and Labor (MOEL)

Recommendation Status Updated

2. Exclusion from Benefits to Small and Medium-Sized Enterprises

Small and Medium Sized Enterprises (SMEs) make up the vast majority of companies in Korea and employ close to 90% of the Korean working population. In order to help SMEs stimulate the economy, a number of economic benefits are available to SMEs.

While satisfying the conditions to be considered an SME in Korea (for example in terms of total number of employees or by total revenue), local offices of foreign companies are often not entitled

to the benefits provided to domestics SMEs.

These companies are faced with the same issues as local SMEs and therefore any differentiated treatment of entities which comply with local legislation, duly pay corporate taxes and create job opportunities is hard to justify.

In fact, local offices of foreign companies in Korea are able to offer quality jobs that allow for development of their staff. This is of particular relevance to the employment of young professionals, which category has seen an increase in their unemployment rate of 1.7%p over the past seven months.

Equal access to various benefits as Korean SMEs would greatly enhance these companies' contribution to the economy.

Recommendation

It is recommended that any determination as to the eligibility of companies for specific benefits is determined based solely on the characteristics of the operation in Korea, rather than the size of its operation overseas.

In particular, it is recommended that foreign companies that fit the criteria for being an SME (absent their operation overseas) are eligible to receive an income tax reduction benefits for young people as well as participate in the welfare fund programs initiated by the Ministry of Employment and Labor.

Relevant Act/Regulation Various

Responsible Authority & Division Ministry of SMEs and Startups (MSS)

Recommendation Status Retained

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3. Employment of Personnel with a Disability

As per article 28 of the Act on the Employment Promotion and Vocational Rehabilitation of Persons with Disabilities, employers who employ at least fifty employees "shall employ persons with disabilities to fill at least a ratio [...] set by Presidential Decree". Article 33

of the same Act provides that employers that employ more than 100 employers and who do not meet the prescribed ratio of employed persons with disabilities are required to pay a 'contributory charge'.

Companies are fully committed to provide adequate employment opportunities to persons with disabilities. Under the current system however, there are a number of challenges that frustrate such.

In particular, it is difficult to find a person with a disability who has the right capacity for available jobs. As per the data published by the Korea Employment Agency for Persons with Disabilities (KEAD), the demand for 'office workers' and for 'professionals' exceeds the supply by 80%, respectively 60%.

Additionally, the hiring of persons with disabilities is not centralized and can be done through a number of agencies.

Recommendation

In order to enhance the actual employment of persons with a disability, it is recommended that the various agencies involved in preparing persons with disabilities align their job training with industry demand. Industry remains available to share its insights with these agencies to enhance the employment opportunities for persons with a disability.

Moreover, it is recommended that a single contact point is established for industry to contact in order to facilitate their search for suitable candidates.

Relevant Act/Regulation Article 28 & 33/Act on the Employment Promotion and Vocational Rehabilitation of Persons with Disabilities

Responsible Authority & Division Korea Employment Agency for Persons with Disabilities / Ministry of Employment and Labour (MOEL)

Recommendation Status New

Overview of the Industry

Information & Communication Technology (ICT) is a key industry segment and is expected to remain a key-driver for the Korean economy. Korea is the host of the global #2 and #4 producers of semiconductors, namely Samsung Electronics and SK Hynix and has been since long focusing on an excellent ICT infrastructure visible in high speed internet and an early adoption of 5G technology. The market for online platforms is dominated by Korean players such as Naver, Kakao, or Coupang and not as in other markets by the internationally known global market leaders.

Production in ICT in 2019 amounted to a bit more than KRW 500 trillion growing versus previous year by almost 2% primarily due to investments in 5G, GIGA Internet and Digital Contents. Semiconductors and ICT equipment primarily are produced for export and thus have been hit hard in 2020 by lock-down of overseas markets and economies. The market environment for commercial software remains challenging despite growth foreseen in software for mobile game and security. The outlook nevertheless remains cautiously optimistic, due to expected growth in e-learning, e-government, e-logistics.

Key Issues

1. Cloud Security Assurance Program (CSAP)

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

Other public institutions/agencies may use private cloud systems but the 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 that 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 utilizing their global service partnership to operate or manage the 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 residing abroad are qualified in the field and apply the latest business processes.

Recommendation

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

Relevant Act/Regulation Cloud Computing Development and User Protection Act; Article 23 Paragraph 2

Responsible Authority & Division Ministry of Science and ICT (MSIT)

Recommendation Status New

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2. e-Government Standard Framework Preferred Application

The Ministry of the Interior and Safety (MOIS)'s 'Guidelines for the Establishment and Operation of Information Systems of Administrative and Public Institutions' stipulate that when developing information system of the public sector, the application of the eGovernment Standard Framework should be considered as a primary factor, but it is a common practice for administrative agencies to interpret and apply it as a de facto compulsory provision.

The e-government standard framework is a framework that can only be applied to JAVA-based web systems. Thus, in reality, the framework restricts the participation of the packaged software that aren't JAVA-based in the public sector information technology projects.

Recommendation

The prerequisites for the application of the e-government standard framework are currently stipulated in the 'Standard Framework Application Guide for Information System Construction Orders' of the

National Information Society Agency. It is recommended to elevate the conditions of application to the guidelines administered by Ministry of the Interior and Safety, which is a higher-level agency.

In addition, it is recommended to exclude the restriction of other software development languages than JAVA in consideration of rapid application of new technologies and diversification of programming languages.

Relevant Act/Regulation Guidelines for Establishing and Operating Information Systems for Administrative and Public Institutions & Notification number 2019-69 of the Ministry of the Interior and safety) & Standard Framework Application Guide for Information System Implementation vendors; Version 2.9, March 2020.

Responsible Authority & Division Ministry of the Interior and Safety (MoIS)

Recommendation Status New

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3. Application of Foreign Vendor Standard Contract By The Public Agencies

When public institutions sign contracts to purchase goods, regardless of the type of the product, it is mandatory to use the general conditions of the purchase (manufacturing) contract and the special conditions of the purchase (manufacturing) contract. The contract is signed through an electronic agreement through the 'Korea ON-Line E-Procurement System'.

H/W and S/W license vendors in the ICT field are unable to use their own standard contracts, making it impossible to sign contracts directly with the public institutions.

If administrative agencies accept standard contracts from vendors or negotiate and adjust contracts between the client and vendor, it is believed that the cost of introduction and administration costs will be reduced.

Recommendation

It is recommended to apply a more flexible approach to mandatory application of the general conditions of the purchase (manufacturing) contract and the special conditions of the purchase (manufacturing) contract. In addition, it is recommended to establish an institutional arrangement that allows the ordering administrative agency to flexibly sign contracts by creating an exception clause that accepts contracts using standard contracts from vendors.

Relevant Act/Regulation Contract Rules Number 491

Responsible Authority & Division Ministry of Economy and Finance (MoEF)

Recommendation Status New

Siyoon Kim
Manager,
Taxation
Working Group

Key Issues

1. Request for a Deadline Extension of Corporate Tax Return Filing

Under the corporate income tax law, the corporate tax return should be filed by the 3rd month after the year-end.

Due to the recent amendment of 'Act on External Audit of Stock Companies', the scope of company subject to audit was broadened. Also, audit report release tends to be more delayed than before due to institution of standard audit hours. Therefore, many companies subject to external audit may have difficulties with meeting the deadline of CIT filing due to delaying of audit report release. Especially, most of European based foreign companies subject to external audit are unlisted in the Korean stock market so they may not be a priority for external auditor. Therefore, audit report release for European companies is much delayed which cause delaying of corporate tax filing.

For reference, due date of CIT filing of other countries are as following: the UK (December 31), Ireland (September 30), Italy (June 30), Spain (June 25), Hungary, Netherlands, Portugal, China (May 31), Hong Kong, Singapore (November 30), Malaysia (July 31), Australia (June 1), the US (April 15, however, can be extended for 6 months upon extension request)

Recommendation

In order to review carefully and file tax return precisely, we would like to ask to extend the deadline of the tax filing.

Relevant Act/Regulation Article 60 of the CITL

Responsible Authority & Division Ministry of Economy and Finance (MOEF) /Tax Policy Division

Recommendation Status Updated

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2 Request to Ease Tax Requirements of Salary Income for Foreigner with Regards to COVID-19

In general, salary income of foreigners is subject to payroll tax if the foreigner stays in Korea for more than 183 days in total during taxable year (or fiscal year) regardless of the purpose of their stay.

Taxation
Working Group

Due to COVID-19, there exists some cases where salary income of foreigner is subject to payroll tax since they cannot return to their own country (due to lockdown or flight suspension, etc.) although they stay in Korea not for business purpose.

Recommendation

We would like to request to ease tax requisition of salary income for foreigner by excluding lockdown period of its own country or flight suspension period from staying period determination, if staying in Korea is inevitable due to COVID-19. In case of India, a lockdown period is not to be counted for determining residency status of NRI (Non-Resident Indian).

Relevant Act/Regulation Individual Income Tax Law Article 1-2 Definition

Responsible Authority & Division Ministry of Economy and Finance (MOEF) /Tax Policy Division

Recommendation Status New

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3. Improving the Convenience and Administrative Efficiency of Individual Income Tax Return Filing & Tax Payment Procedures for Non-resident Partners for Foreign Law Firms

Following changes to the definition of foreign corporation under Article 2 of the Korean Corporate Income Tax Law (CITL) and Article 2(2) of the Presidential Decree of the CITL effective from January 1, 2020, certain overseas partnerships may no longer be regarded as a foreign corporation for Korean tax purposes.

There is also a considerable administrative burden for the Korean tax office to ensure such tax returns are properly filed and in administering/processing the returns including the process of registering each of the partners and processing the changes in the partners every year.

Other countries take a pragmatic approach to ease the administrative burden placed on taxpayers and tax authorities in these circumstances such as allowing a single composite income tax return to be filed on behalf of all partners. Such approaches are allowed in the UK.

Recommendation

It is recommended that the Ministry of Economy and Finance (MOEF) allows for easement of the tax compliance requirements requiring all non-resident partners to file individual income tax returns in these circumstances and instead allows for one single composite return to be submitted by the representative resident partner on behalf of all non-resident partners (provided that such non-resident partner's Korean source income is only business income from the law firm operating in Korea).

Relevant Act/Regulation Individual Income Tax Law

Responsible Authority & Division Ministry of Economy and Finance (MOEF) / Tax Policy Division

Recommendation Status New

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4. Creation of a Permanent Establishment (PE) due to the Temporary Displacement of Employees due to COVID-19 Travel Restrictions

The domestic tax law definition of fixed place of business Permanent Establishment (PE) under Article 94 of the Corporate Income Tax Law states that a PE can be created where a foreign enterprise provides services in Korea if the services last for more than six months in a consecutive 12-month period.

In addition, a PE may also be created in cases where the business activities of a foreign enterprise are performed in Korea through an agent having the authority to conclude contracts and habitually exercises such rights.

Due to travel restrictions imposed by national governments or quarantine requirements, there are business concerns that employees may be present in Korea long enough to trigger PE under these tax laws.

Recommendation

In these exceptional and temporary circumstances, it is recommended to provide guidance making it clear that the presence of company employees within Korea due to travel restrictions arising from COVID-19 would not create a Permanent Establishment (PE) in Korea. Such guidance would be consistent with the recommendations

made by the OECD Secretariat* on April 3, 2020 that tax administrations are encouraged to provide guidance on the application of the domestic law threshold requirements, domestic filing and other guidance to minimize or eliminate unduly burdensome compliance requirements for taxpayers in the context of the COVID-19 crisis. Other countries including Australia and Ireland have issued such guidance.

*https://read.oecd-ilibrary.org/view/?ref=127_127237-vsdagpp2t3&title=OECD-Secretariat-analysis-of-tax-treaties-and-the-impact-of-the-COVID-19-Crisis

Relevant Act/Regulation Corporate Income Tax Law

Responsible Authority & Division Ministry of Economy and Finance (MOEF) / Tax Policy Division

Recommendation Status New

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5. Unclear Audit Period for Documentary Audit

The period for a customs audit given in Article 139-2 (1) of the EDCL and Article 12 (1) of the Customs Directives is 90 days (or 120 days in some cases). There are two types of customs audit:

- On-site audit and follow-up desk audit, or
- Documentary audit (without on-site audit)

For an on-site audit, it is clear under Article 12 (4) of the Customs Directives that the audit commences on the first day of the on-site audit and the audit period will be counted from the first day. There is therefore no uncertainty regarding the audit period and when the audit will end.

However, the first day of a documentary audit is not clearly stipulated in the customs laws. According to Article 12 (5) of the Customs Directives, the audit will commence from the next day of the submission date when the submission of documents requested by the customs authority is completed. However, there are often different views between the customs authority and taxpayers in determining when the submission of documents is completed (i.e. submission date) and thus taxpayers may experience uncertainty regarding the audit period and when the audit will end.

Recommendation

To make the tax law clearer and provide more certainty to taxpayers, it is recommended to be more specific in the customs law regarding the start date of a documentary audit. For instance, a documentary audit should be commenced on the date of receipt of notification of customs audit or the customs authority should clearly specify the first day of a documentary audit in such notification.

Relevant Act/Regulation Enforcement Decree of the Customs Law (EDCL) / Customs Directives on Operation of Customs Audit (Customs Directives)

Responsible Authority & Division Ministry of Economy and Finance (MOEF) / Korea Customs Service (KCS)

Recommendation Status New

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6. Tariff Assessment on the Transfer Pricing Adjustment

It is typical practice for companies engaged in cross border intercompany transactions to make periodic transfer pricing adjustments post-importation to achieve a specific arm's length margin for corporate tax purposes in applying their transfer pricing policies in accordance with the OECD guidelines.

In certain circumstances under the Customs Law, a post-import downward revision of the transaction value based on the arm's length price for corporate tax purposes may be accepted for customs purposes through the filing of provisional/final value declarations only where certain prescribed conditions are met, i.e. submission of documentation on planned post importation adjustments prior to the importation of goods etc. (Article 16(1) of the Presidential Decree of the Customs Law).

Consistent with these regulations, a post-import upward transfer pricing adjustment does not necessarily mean that an adjustment to the import value for customs purposes is required. In practice however it is often observed that assessments are made by the Korea Customs Service (KCS) for upward transfer pricing adjustments.

Recommendation

To achieve a consistent application of the rules, it is recommended to make it clearer that a post-import upward transfer pricing adjustment does not necessarily mean that an adjustment to the import value for customs purposes is required on the same basis that a downward transfer pricing adjustment is not always reflected in the import price for customs purposes.

Relevant Act/Regulation Article 30 Paragraph 1 of the Customs Law

Responsible Authority & Division Ministry of Economy and Finance (MOEF) / Tax Policy Division

Recommendation Status New

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7. The Criteria of Income Classification for Use of Software

There are some categories of income from software usage that are regulated by law, but there are limitations in classifying in practice. Also, due to the rapid growth of the technology industry, many software products have become more common compared to the past, making it difficult to make accurate classification when making payments to foreign corporations.

Recommendation

It is recommended to provide examples or criteria for software classification to help to make practical decisions on the classification of commercial or general-purpose software.

Relevant Act/Regulation Article 93 of the Corporate Tax Act

Responsible Authority & Division Ministry of Economy and Finance (MOEF) / Tax Policy Division

Recommendation Status New

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8. Deductions/Credits for Housing Related Expenses

Eligible individuals may claim the following deductions and credits related to housing costs to reduce their income tax liability. However, these deductions and credits are only available to Korean nationals since only Korean nationals can be the head of a household

under the Korea Resident Registration Law. Therefore, foreign national residing in Korea are not eligible for such credits/deductions:

- Income deduction for housing fund (Individual Income Tax Law Article 52) - i.e. long-term mortgage interest payment etc.
- Income deduction for savings account for housing purchase (STTCL Article 87)
- Tax credit for monthly rent (STTCL Article 95-2)

Recommendation

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

Relevant Act/Regulation Individual Income Tax Law / Special Tax Treatment Control Law (STTCL)

Responsible Authority & Division Ministry of Economy and Finance (MOEF) / Tax Policy Division

Recommendation Status New

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9. Deductions for Overseas Education Fees

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 New

10. Inclusion of Expenses Occurred Overseas as Global Income Tax Filing Deductible

A foreign national individual that is resident in Korea is in principle liable to Korean income tax on their worldwide income. However, by exception, foreign residents who have stayed in Korea for five years or less during the last ten-year period are taxed on Korea-source income, and foreign-source income is reportable only in the case where foreign-source income is paid by a Korean entity or transferred to Korea. Foreign individuals who have stayed in Korea for longer than five years during the last ten-year period are taxed on their worldwide income and are requested to file their global tax return in May to the National Tax Service. In this respect, income from overseas sources needs to be reported and is taxed additionally to the income from Korean sources. However, overseas expenses such as contribution to foreign pension or donations cannot be deducted.

Recommendation

In order to create a fair global tax settlement not only income but also expenses which are tax deductible for expenses occurred overseas should be considered to be tax deductible in the process of global income tax filing.

Relevant Act/Regulation Income Tax Law

Responsible Authority & Division Ministry of Economy and Finance (MOEF) / Tax Policy Division

Recommendation Status Updated

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11. Exclusion of Over par Purchase Bond Cost From Global Income Tax Calculation

Interest income from bonds held at overseas financial service providers are taxed in the process of global income tax return. In case a bond purchased over par, the taxpayer pays a higher price for a bond but receives higher interest payments. The taxpayer pays accordingly its taxes on the higher interest coupon but is not able to set this off with tax loss derived from the higher bond purchase price.

Recommendation

Investment in bonds should have a fair taxation base; thus over par

purchase costs should be able to be deducted from the global income tax calculation.

Relevant Act/Regulation Income Tax Law

Responsible Authority & Division Ministry of Economy and Finance (MOEF) /Tax Policy Division

Recommendation Status Retained

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12. WHT Issue When the Down Payment Paid to a Foreign Corporation is Substituted With Penalty/Compensation

Under Article 127, Paragraph 1, Item 6 of the Income Tax Law, in the case where the down payment paid to non-resident is substituted with penalty or compensation, it shall not be subject to withholding tax. However, the Corporate Income Tax Law (CITL) does not have similar provision and it may be treated as other income under the CITL. There is an issue that the withholding tax on the same income may differ depending on whether the recipient is a corporation (foreign corporation) or an individual (non-resident) due to the inconsistency of withholding regulation of the Income Tax Law and CITL. The withholding agent has to exercise the right to reimbursement on withholding tax amount as the withholding obligation rises after paying the down payment to a foreign corporation due to change in income classification from business income or capital gains to other income, but it is practically very difficult. The foreign corporation may raise a question why the withholding tax amount should be returned due to the change in income classification while withholding was not made at the time of payment.

Recommendation

When the down payment paid to a foreign corporation is substituted with penalty or compensation, withholding tax on already paid amount is impossible, and ex post exercise of right to reimbursement does not correspond with the purpose of the withholding system. As such penalty and compensation can be regarded as damages from the termination of the contract not subject to withholding tax under the existing CITL, and there may be a dispute with foreign corporation, it is appropriate to exclude them from other income subject to withholding tax as regulated by the Income Tax Law.

Relevant Act/Regulation Income Tax Law

Responsible Authority & Division Ministry of Economy and Finance (MOEF) /Tax Policy Division

Recommendation Status Retained

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13. Application of Transfer Pricing Regulations Under the Law for the Coordination of International Tax Adjustment to Domestic Related Party Transactions

Article 52 (Denial of Unfair Transactions) of the Corporate Income Tax Law (CITL) applies to transactions made by domestic related parties. However, since domestic related party transactions have become much more complicated, and since they now cover a much wider variety of different situations than previously, it is difficult for every domestic related party transaction to fall within the scope so as to be regulated by Article 52. The Denial of Unfair Transactions rule contained within Article 52, which only applies to transactions by domestic related parties, is not reasonable in comparison with the general transfer pricing rule which applies to transactions between international related parties. For example, Article 52 does not allow corresponding adjustments. It would be desirable for the arm's length principle, applicable to international transactions, also to be applicable to domestic related party transactions.

Recommendation

Similar to tax laws in the US, a revision to tax law for applying the transfer pricing regulations in calculating the arm's length price of domestic related party transactions is recommended.

Relevant Act/Regulation Corporate Income Tax Act

Responsible Authority & Division Ministry of Economy and Finance (MOEF) /Tax Policy Division

Recommendation Status Updated

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14. Deadline for Country-by-Country Reporting Notification Form

Unlike the deadline for submitting the master file and local file, there have been cases in which the taxpayers such as foreign invested companies have missed the deadline for submitting the CbC notification form. The taxpayers often confused with the deadline for submitting the CbC notification form since it is 6-months from the last day of taxpayer's fiscal year.

Recommendation

It is recommended to revise the deadline for submitting the CbC notification form from 6 months to 12-months after the last day of taxpayer's fiscal year.

Relevant Act/Regulation Law for the Coordination of International Tax Adjustment

Responsible Authority & Division Ministry of Economy and Finance (MOEF) / Tax Policy Division

Recommendation Status Retained

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15. Clarification of Conditions for Deferment of Collection

According to item 1 of Article 40 (4) of the Presidential Decree of Law for the Coordination of International Tax Adjustment, deferment of collection is not approved when the applicant has been in arrears with their tax. However, it does not further clarify when, how much, how long, and why such tax has been in arrears and it can be enforced at the discretion of tax authorities against the purport of the law.

Recommendation

It should be further clarified as to when (i.e. for the past 5 years or 10 years), how much and how long (to avoid a situation where deferment of collection in the amount of billions of tax is denied due to a few thousands of tax in arrears for only a few days) such tax has been in arrears.

For reference, under the government tax law change proposal for 2019 (Article 91-2 of Presidential decree of VAT Law), it is proposed to allow deferred payment of import VAT when a taxpayer had been in arrears for his/her tax if such overdue tax was paid within 15 days

from the payment due date.

Also, it should be further clarified that the tax in arrears refers to national tax only (not local tax).

Relevant Act/Regulation Law for the Coordination of International Tax Adjustment

Responsible Authority & Division Ministry of Economy and Finance (MOEF) / Tax Policy Division

Recommendation Status Retained

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16. Public Notice of a List of Foreign Corporations by Category

According to Article 2 (3) of Presidential decree of Corporate Income Tax Act, the Commissioner of the National Tax Service may publicly notify a list of foreign corporations by category. However, such a list has not been publicly notified and triggers uncertainties and disputes as to a certain foreign entity qualifies as foreign corporation or not.

Recommendation

Public notice of a list of foreign corporations by category should be released.

Relevant Act/Regulation Corporate Income Tax Act

Responsible Authority & Division Ministry of Economy and Finance (MOEF) / Tax Policy Division

Recommendation Status Retained

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17. (Special Case) Beneficial Ownership Test for Foreign Entities other than Overseas Investment Vehicles (OIVs)

Upon the introduction of Article 93-2 of the Corporate Income Tax Act (CITA) (special beneficial ownership test for OIVs), the test that must be met in order for an OIV* to be considered the beneficial owner of Korean source income has been clarified. Specifically, the test requires that an OIV: (i) is liable to pay tax in its country of residence; and (ii) was not established for the purpose of avoiding tax.

However, Article 93-2 of the CITA only provides a beneficial ownership test for OIVs. Similarly, Articles 98-4 and 98-6 of the CITA prescribe the rules for filing applications for Non-Taxation and Exemption, or for Reduced Tax Rate, respectively. Again though, these provisions only apply to OIVs. Accordingly, Korean tax law has not offered a clear test to determine the beneficial ownership of foreign investment entities which do not satisfy the definition of an OIV, such as holding companies and intermediate subsidiaries. In addition, uncertainty and confusion exists over whether foreign entities that are not OIVs (i.e. a foreign intermediate subsidiary which is a conduit) may file applications for Non-Taxation and Exemption, or for Reduced Tax Rate, as if they were an OIV.

* OIV: a vehicle established outside Korea which conducts the investment activities of acquiring, disposing of, or otherwise operating assets, using funds raised from outside investors, and with the intention of distributing returns to the investors.

Recommendation

We recommend that new provisions to be included into the CITA, in order to clarify that foreign entities that do not fully satisfy the definition of an OIV, but yet meet the two abovementioned conditions under the Article 93-2 test, should be recognized as beneficial owners of Korean source income; and also clarifying that such foreign entities that are conduits are eligible to file applications under Articles 98-4 and 98-6 of the CITA, as if they were an OIV.

Relevant Act/Regulation Articles 93-2, 98-4 and 98-6 of the Corporate Income Tax Act (CITA)

Responsible Authority & Division Ministry of Economy and Finance (MOEF) / Tax Policy Division

Recommendation Status New

Tourism

Bo Sun Kim
Vice President

Overview of the Industry

As airlines run fewer routes and outbound demand converges to 'zero', airlines as well as travel agencies are fastening their belts with paid and unpaid leave. Since March, airlines and travel agencies have been striving to secure funds by implementing a high intensity leave system.

In the second quarter, the contrast between national FSC and national LCC was mixed. In the case of national FSC, operating profit and net profit were achieved due to an increase in air freight due to a sharp decline in passenger operations. Sales also decreased by only half compared to the same period last year. On the other hand, for national LCCs, as international flights were blocked, they tried to reduce the deficit through domestic flights, but most of them showed a decrease of close to 90%.

Looking at the overall performance of the first half, listed airlines recorded a total of KRW 7.6 trillion in sales, but a 40% decrease from the same period last year of KRW 11.7 billion. Meanwhile, a total of 840 employees of listed travel agencies and airlines have left the company by the end of June compared to last December.

The airlines are gradually restarting international routes. However, it is still difficult to expect fast growth in demand, so it will take some time for airlines to get out of the deficit operation. Currently, LCCs are focused on domestic routes. Domestic flights do not account for a high proportion of total revenue, so the unpaid leave program for employees is likely to continue.

Travel agencies are also facing many difficulties. Since May, many travel agencies had to implement paid/unpaid leave for employees in order to reduce labor costs. The travel industry is currently designated as a special employment support industry and can receive up to 90% of paid leave and leave allowance for up to six months. In the case of unpaid leave, up to KRW 1.98 million is supported within 50% of wages for a maximum of 180 days. As some airline routes are resumed from next month, there is an expectation that the industry will be able to take a leap again, but barriers to overcome, such as a two-week quarantine measure for foreign visitors, appear to be high.

In the second quarter, the sales of stock-listed travel companies were only KRW 11.7 billion. This is a 95% decrease from the same period last year of KRW 336.4 billion. Sales in the first half of the year also reached KRW 218 billion, down 70% from in the same period last year.

According to the Financial Supervisory Service, most travel agencies showed a 95-99% reduction in sales in the second quarter due to the outbreak of COVID-19. For listed travel companies, if their quarterly sales do not exceed KRW 500 million, the stock trading gets suspended, and the company has to go through a substantive examination of eligibility for resumption.

Key Issues

1. Improper application of Immigration Act, Article 99-3 (Joint Penalty Provisions)

Due to the expanded application of Article 99-3 of the 'Immigration Act (Joint Penalty Provisions)', double fines are imposed not only on the corporation in Korea (branch office of foreign corporation) but also on the representative for violations caused by business negligence in a third country. However, it does not meet the original purpose of the Joint Penalty Provisions.

It is unfair to impose a fine on the representative of the Korean branch in lieu of the violator for the reason that the violator is in a foreign country or it is difficult to identify the person (including errors in the unmanned ticket machine such as kiosk). This is contrary to the purpose of the Joint Penalty Provisions, and if the individual violator cannot be specified, it is reasonable to impose it on the corporation other than the representative of the branch office on behalf of the violator.

The fact that there is a person who committed a crime, that is, the violator, and that another person is punished for the individual is contrary to the current legal system. In accordance with the original purpose of the Joint Penalty Provisions, a fine may be imposed on a corporation by asking for management responsibility for the person who committed the crime. Therefore, if the violator cannot be specified, it is judged that it is appropriate to impose both a fine for the violator and a fine for the management responsibility of the violator on the corporation.

It is not the purpose of the Joint Penalty Provisions to impose a fine on a corporation other than the violator, and simply impose a fine on the representative of the branch office on behalf of the violator simply because the individual violator cannot be specified. It is not a Joint Penalty Provisions that punishes both 'person' and 'corporation' at the same time whoever the violator is.

Recommendation

Instead of simply imposing a fine on the representative of the branch office for the fact that the violator cannot be specified, it is recommended to impose fine for the violator and the fine for the management responsibility of the violator on the corporation.

Relevant Act/Regulation Immigration Act/Article 99-3 (Joint Penalty Provisions)

Responsible Authority & Division Investigation and Enforcement Division/Ministry of Justice (MOJ)

Recommendation Status Updated

Abbreviation

Abbreviated	Expanded
AI	Artificial Intelligence
ARECs	Act on Registration, Evaluation, etc. of Chemicals
ATP	Actual Transaction Price
BREEAM	Building Research Establishment Environmental Assessment Method
BSE	Bovine Spongiform Encephalopathy
CAGR	Compound Annual Growth Rate
CAPEX	Capital Expenditure
CbC	Country-by-Country
CBI	Confidential Business Information
CCA	Chemicals Control Act
CGT	Cell and Gene Therapy
CGT	Compensated Gross Tonnage
CHP	Combined Heat and Power
CIT	Corporate Income Tax
CODEX	Codex Alimentarius collection of food standards
COVID-19	Coronavirus Disease 2019
CSAP	Cloud Security Assurance Program
CSV	Creating Shared Value
CTD	Common Technical Document
DUI	Driving Under the Influence
EcoAs	Eco-Assurance System of Electrical and Electronic Equipment and Vehicles
EMC	Electro Magnetic Compatibility
EMS	Express Mail Service
EPBD	Energy Performance of Buildings Directive
EPR	Extended Producer Responsibility
EU	European Union
EV	Electric vehicle
FDC	Fixed Dose Combination
FRAND	Fair, Reasonable And Non-Discriminatory
FSC	Free Sale Certification
FSC	Facility Security Clearance
FTA	Fair Trade Agreement

Abbreviation

Abbreviated	Expanded
FTZs	Free Trade Zones
GDP	Gross Domestic Product
GHG	Greenhouse Gas
GMO	Genetically modified organism
GMP	Good Manufacturing Practice
G-SEED	Green Standard for Energy and Environmental Design
GW	Gigawatt
HRQoL	Health Related Quality of Life
HTA	Health Technology Assessment
HVO	Hydrotreated Vegetable Oil
ICER	Incremental Cost-Effectiveness Ratio
ID	Identification
IMP	Investigational Medicinal Products
IND	Investigational New Drug
IoT	Internet of Things
IP	Intellectual property
IPC	Innovative Pharmaceutical Company
IPR	Intellectual property rights
IPT	Integrated Program Team
K-BPR	Act on Safety Control of Household Chemical Products and Biocides
KENCIS	Korea Emission & Noise Certification Information System
KORUS FTA	United States-Korea Free Trade Agreement
KP	Korean Pharmacopoeia
KRW	South Korean Won
LCOE	Levelized Cost of Electricity
LEED	Leadership Energy and Environmental Design
LNG	Liquefied Natural Gas
LoE	Loss of Exclusivity
MRA	Mutual Recognition Agreement
MRCT	Multi-Regional Clinical Trial
MRP	Maximum Reimbursement Price

Abbreviated	Expanded
MSDS	Material Safety Data Sheet
NCCP	National Cancer Care Plan
NEDC	New European Driving Cycle
NG	Natural Gas
NHI	National Health Insurance
NIER	Notification of the National Institute of Environmental Research
NLR	National Lot Release
NRW	None Revenues Water
OEM	Original Equipment Manufacturing
OIV	Overseas Investment Vehicle
OPEX	Operation Expenditure
OR	Only Representative
ORR	Objective Response Rates
OSHA	Occupational Safety and Health Act
PE	Polyethylene
PE	Pharmaco-Economics
PE	Permanent Establishment
PEN	Polyethylene Naphthalate
PET	Polyethylene Terephthalate
PHEV	Plug-in Hybrid Electric Vehicle
PLC	Polymer Low Concern
PMS	Post-Marketing Surveillance
PP	Polypropylene
PPA	Power Purchase Agreement
PPE	Personal Protective Equipment
PSR	Process Safety Report
PVA	Price-Volume Agreement
QA	Quality assurance
QC	Quality control
QSAR	Quantitative Structure–Activity Relationship
R&D	Research & Development
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
REC	Renewable Energy Certificate

Abbreviated	Expanded
RFID	Radio-frequency identification
RSA	Risk Sharing Agreement
RWD	Real World Data
RWE	Real World Evidence
SDGs	Sustainable Development Goals
SME	Small and Medium-sized Enterprise
SMO	Site Management Organization
SMP	System Marginal Price
SOx	Sulfur oxide
SPF	Sun Protection Factor
SRI	Supervisor Radiography Isotope
SSIC	Substance Subject to Intensive Control
TBT	Technical Barriers to Trade
TCCA	Toxic Chemicals Control Act
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TTR	Tonnage Tax Regime
UDI	Unique Device Identification
USD	United States Dollar
VAT	Value-Added Tax
VLCC	Very Large Crude Oil Carriers
WLTP	Worldwide Harmonized Light Vehicle Test Procedure
WTG	Wind Turbine Generator

Organizations

Organization	Abbreviated	Expanded
	ADD	Agency for Defense Development
	DAPA	Defense Acquisition Program Administration
	DREC	Drug Reimbursement Evaluation Committee
	DTaQ	Defense Agency for Technology and Quality
	ECHA	European Chemical Agency
	EFSA	European Food Safety Authority
	EMA	European Medicines Agency
	EUIPO	European Union Intellectual Property Office
	FSC	Financial Services Commission
	FSS	Financial Supervisory Service
	HIRA	Health Insurance Review & Assessment Service
	ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
	IMO	International Maritime Organization
	KATS	Korean Agency for Technology and Standards
	KCS	Korea Customs Service
	KDIA	Korea Defense Industry Association
	KEA	Korean Energy Agency
	KEAD	Korea Employment Agency for Persons with Disabilities
	KECO	Korea Environment Corporation
	KEEI	Korea Energy Economics 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
	KOGAS	Korea Gas Corporation
	KPBMA	Korea Pharmaceutical and Biopharma Manufacturers Association
	KPTA	Korea Pharmaceutical Traders Association
	KSA	Korea Shipowners' Association
	KTC	Korea Testing Certification
	KTL	Korea Testing Laboratory
	KTR	Korea Testing & Research Institute
	MAFRA	Ministry of Agriculture, Food and Rural Affairs
	MCST	Ministry of Culture, Sports and Tourism
	ME	Ministry of Environment
	MFDS	Ministry of Food and Drug Safety
	MND	Ministry of National Defense
	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
	MOJ	Ministry of Justice
	MOLIT	Ministry of Land, Infrastructure and Transport
	MOTIE	Ministry of Trade, Industry and Energy
	MSIT	Ministry of Science, ICT
	MSS	Ministry of SMEs and Startups
	NHIS	National Health Insurance Service
	NIFDS	National Institute of Food and Drug Safety Evaluation
	NTS	National Tax Service
	OECD	Organisation for Economic Co-operation and Development
	PCIP	Presidential Council on Intellectual Property
	RRA	National Radio Research Agency
	SIEF	Substance Information Exchange Forum
	UNECE	United Nations Economic Commission for Europe
	US FDA	US Food and Drug Administration
	WHO	World Health Organization
	WTO	World Trade Organization

European Chamber of Commerce in Korea

The European Chamber of Commerce in Korea (ECCK) is a distinguished association of European companies operating in Korea. The ECCK's primary objective is to promote an optimal business environment and provide its members with information, communication, and access pertaining to doing business in Korea. ECCK is a non-profit and non-political organization.

- Prime Communication Channel to the Korean government, the European Union Delegation in Seoul, European embassies, influential private organizations and business associations, as well as the media.

- Committees and Forums Organized by industry, these platforms they are tasked to closely follow market trends and changes in the regulatory environment relevant to the interests of our members.

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