EUROPEAN CHAMBER OF COMMERCE IN KOREA

ECCK White Paper 2019

Message from Chairperson

Dear Valued Members and Friends,

Following the successful launch of ECCK White Paper (White Paper) in 2015, I would like to proudly present the fifth edition of the White Paper, a compilation of key industrial issues and recommendations from the European business community in Korea, covering the year 2019.

The ECCK always strives to position itself as the major communication platform for the European business community 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.

Each year, Korea and Europe are becoming better, balanced trade and investment partners. I am particularly proud to say that the European industry continues to take up the largest source of Foreign Direct Investment (FDI) stock into Korea. 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.

Dimitris Psillakis

Dimitris Psillakis
Chairperson, European Chamber of Commerce in Korea

ECCK
EUROPEAN CHAMBER OF COMMERCE IN KOREA

ECCK White Paper 2019

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ECCK Introduction

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

Board of Directors

Dimitris Psillakis (Greece)
Chairperson of the Board
President & CEO
Mercedes-Benz Korea

Dimitris is a Greek citizen and has been holding the position of President and CEO at Mercedes-Benz Korea in Seoul since September 2015. He started his career with the Daimler Group in 1992 at Mercedes-Benz Greece and has many years of international management experience in sales and marketing. Before joining Mercedes-Benz Korea, he served as head of passenger car in Latin America.

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

Dirk 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 & Co-Branch Manager
Deutsche Bank Seoul Branch

Hyun-Nam is a Korean citizen and is Managing Director and Co-Branch Manager 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.

Board of Directors

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

Jan 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.

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

Donghwan 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 headquarters 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 has been President & CEO of AXA Korea since April 2017. Prior to his current position at AXA Korea, he served as Global CFO of AXA Global Direct (2015-2017) and CFO and corporate secretary of AXA Direct Korea (2012 to 2015). Before joining AXA, Gilles worked with Mazars in Paris and Madrid.

Julien Samson (France)
Director of the Board
VP & GM
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.

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

Elizabeth 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 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.

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

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 (yearly)
- ECCK Membership Directory (yearly)
- Business Confidence Survey (yearly)
- ECCK Connect (quarterly magazine)
- The Monthly Highlights (monthly newsletter)
- ECCK Annual Report (yearly)
- ECCK Quarterly Report (quarterly)

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.

Executive Summary

2019 Overview

Executive Summary

This ECCK's White Paper has a 5-year-history, as the first White Paper was published in 2015. 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. It further serves as an important tool of information to the European Commission, the European Parliament, the European Free Trade Associations' (EFTA) Secretariat, governments of member states of the EU and EFTA, as well as European business interest groups.

The edition of 2019 was compiled by dedicated ECCK staff with the considerable support of 166 company experts from our Committees and Working Groups nominated by the Chamber's 360 member companies. It includes 180 (123 in 2018) constructive recommendations to the Korean government raised through 20 (16 in 2018) ECCK Committees and Working Groups. In 2019, the ECCK has included new recommendations from Aerospace & Defense, Financial Services, Tourism, and Human Resources Working Groups.

In March 2019, President Moon Jae-in invited the foreign business community to a meeting at the Blue House in which he stressed the importance of foreign business to the Korean economy and the Korean society. The meeting is a commitment towards a closer communication and cooperation between the Korean government and European business.

The ECCK is grateful to have received full feedback on all 123 issues and recommendations raised in its White Paper 2018; about 40% of those were positively considered (out of 123 recommendations, 17 were accepted, 9 were partially accepted, and 23 already implemented). Despite those very positive signs, the ECCK suggests even further cooperation through strengthened communication channels between the Korean government and European business.

Compete for FDI

With a capital stock of 32%, Europe is the largest source of Foreign Direct Investment (FDI) stock in Korea. In 2018, the value of arrived European FDI amounted to USD 5.5 billion versus USD 6.9 billion in 2017. In the first half of 2019, the total FDI that arrived in Korea amounted to USD 5.8 billion versus USD 10.2 billion in the first half of 2018, thus representing a decrease of 43% or USD 4.4 billion. In this same period, FDI from Europe came up to USD 3.1 billion, therewith falling short versus the first half of 2018 by 8% or USD 0.3 billion.

Korea ranks high in the "Doing Business 2019" index by the Organisation for Economic Co-operation and Development (OECD); in the report released in 2019, Korea came up on rank five[1]. In fact, Korea is to be seen as an international role model when it comes to "Starting a Business", "Getting Electricity", "Enforcing Contracts", which are all included as elements in the index.

1. www.doingbusiness.org/content/dam/doingBusiness/country/k/korea/KOR.pdf

However, at the same time, Korea ranks 54th among 69 countries (ranked 51st out of 67 in 2017) in its FDI Restrictiveness Index organized by OECD[2]. In order to facilitate the inflow of FDI to Korea, it is important to ensure that there is a free access for European companies and its products to the Korean market. Providing a fair and open business environment is crucial to encourage and maintain FDI flows to the country.

2. www.oecd.org/investment/fdiindex.htm

Competition in today's world is not merely experienced by companies; there is also competition among countries for FDIs. Investment decision are made for a long-term period and are based on various quantitative and qualitative key parameters. An investment will be conducted in the specific country where it seems most beneficial for the company. To realize the golden opportunity to attract FDIs, it is important that the government creates the right environment for businesses to expand.

Important aspects to consider for policy making:

- consistency,
- predictability,
- reliability, and
- transparency.

Korea's future economic development can be secured by creating an environment that allows Korean and foreign enterprises and innovation to foster. In this light, ECCK will continue to serve as an efficient communication channel for the European businesses towards the Korean government and ministries.

Modernize FTAs and Embrace International Standards

In August this year, Korea marked its 20th anniversary of FTA talks across globe. Following the FTA with Chile in 1999, Korea has put 15 FTAs in place. The EFTA-Korea FTA was signed in December 2005 and entered into force September 2006 and the EU-Korea FTA was signed in October 2009 and provisionally applied as from July 2011. It can be stated without any doubt that both the EFTA-Korea FTA and the EU-Korea FTA have delivered impressive results in terms of trade development.

A positive trade development also has an impact on FDI. In 2018, 66 companies with headquarters in Europe have established new legal entities in Korea and in the first half of 2019, 41 European companies newly registered in Korea.

The ECCK has recommended to modernize both FTAs, but unfortunately there was no advancement on such. The trade relations between Korea and the EFTA, respectively the EU are of utmost importance for all parties involved. That is why it is our strong conviction that those contracts governing trade between those economic blocks and Korea should be modernized in order to get an optimal outcome. It shall be of common interest to have a thorough review of the FTAs, removal of out-dated processes, addition of state-of-the-art procedures, as well as the inclusion of new market areas respectively innovative technologies.

In this respect, the ECCK recommends to modernize the EU-Korea FTA to solve a couple specific issues, namely:

- to include truck tractors in the goods covered,
- to exempt repaired and re-entered aviation products from duties and
- to allow for indirectly shipped goods to benefit from the preferential rates.

Having raised those issues seven years ago, the ECCK and its member companies would appreciate advancements to be made, as such could be seen as a strong commitment on further future trade collaboration.

The modernization of the FTAs also could be the starting point to include more clauses on either the adoption of internationally accepted standards or an increase of equivalence agreements. In general, there are still too many rules and regulation in Korea which either diverge slightly or to a great extent from international standards, which is especially crucial for a country that relies so heavily on export. Also, following international standards will help reduce ambiguity for European companies operating in Korea in interpretation, as well as facilitate entry into new markets by Korean companies.

Enhance Truly Fair Competition

The ECCK White Paper focuses only on industry specific issues and not on company specific issues. Yet, there are unfair treatment regarding financial or other transactions have been made negatively impacting various European businesses. The ECCK has referred the companies involved to the Office of Foreign Investment Ombudsman and these are accordingly not included in the White Paper.

Fair competition can be evaluated from various directions; fair competition is also to be driven by various stakeholders. The ECCK believes that substantial efforts have been undertaken to establish a more fair and transparent business environment in Korea. Those initiatives – especially those led by the Korean central government – need to be continued.

However, despite those positive developments, the ECCK still observes business situations which rather hinder accomplishing the goal of building a fair and open competition in Korea. These include:

- the launch of reimbursement pricing policy for pharmaceutical innovative drugs with conditions which in practise can only be fulfilled by Korean companies,
- the move by shipyards to replace foreign suppliers with Korean suppliers following a localization policy, and
- accelerated activities toward certain European enterprises by governmental agencies, such as audits or other investigations with some of the financial penalties and dues to be seen as being disproportionate.

Conclusion

Korea is and remains an attractive market for European companies operating in or with Korea. European business leaders are committed to maintain and even further expand their business, which in turn will support growth of the national economy, as well as the job creations in the future. However, business needs consistent, predictable, reliable, and transparent policy making. In this respect it is crucial that Korea embraces a full adoption of international standards in rules and regulations; a full adoption is expected to facilitate the inflow of further FDI and at the same time to facilitate entering in export markets by Korean SMEs.

The ECCK acknowledges the improvement achieved in communication between the European businesses represented by the ECCK and the Korean government; considering the size and impact of European business operating in Korea that communication should happen more regularly and in a more structured fashion – especially also during the phase of policy making. This would allow European businesses to get involved in policy formulation and share their experience and insights on regulations with the Korean policy makers.

The issues listed in the White Paper are also a reminder that not everything is perfect yet; huge improvements have been made or initiated in many areas. Business issues need to be continuously identified and worked on in a steady way by Korean authorities and the ECCK. The ECCK hopes that this White Paper serves as a solid basis for further discussion with the Korean government and that feedback will be provided. The further economic development of Korea is an effort in which the European business community plays an essential part.

In 2018, the ECCK committees and working groups across 14 different sectors have raised 123 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 Committee

A total of 18 issues from the ECCK Automotive Committee were raised in the 2018 White Paper and 5 issues received responses from the Korean government, with the committee's recommendations on those issues being already implemented or partially accepted. Regarding other issues that were raised in the 2018 White Paper, ECCK readdressed the recommendations this year, reflecting the feedback from the government and the industry's opinions.

2018 Key Issues List

1. Enforcement Date of Crash Safety Standard Amendment
Government Feedback: Not Accepted
ECCK Future Action: Readdress

2. Test Standards of Traction Battery for EV/PHEV
Government Feedback: Partially Accepted
ECCK Future Action: Need to monitor

3. Recognizing Parts Self-Certification According to Vehicle Self-Certification
Government Feedback: Not Accepted
ECCK Future Action: Readdress

4. Recognizing UNECE Type-Approval According to the EU-Korea FTA
Government Feedback: On-going
ECCK Future Action: Need to monitor

5. Standard for Corporate Average Greenhouse Gas (GHG) Emissions
Government Feedback: Implemented
ECCK Future Action: Readdress

6. Recognizing Test Reports on Emission, Fuel Economy and Noise
Government Feedback: Not Accepted
ECCK Future Action: Readdress

7. Recognizing the International Standard Process Regarding EcoAs Operation
Government Feedback: Implemented
ECCK Future Action: Closed

8. Specifying the List of Emission Related Components
Government Feedback: Not Accepted
ECCK Future Action: Readdress

9. The Term of Validity of Test Report on Vehicle Energy Efficiency
Government Feedback: Not Accepted
ECCK Future Action: Readdress

10. Notification of Recall for Not Delivered Vehicles
Government Feedback: Not Accepted
ECCK Future Action: Readdress

11. Process of Reporting the Plan of Recall
Government Feedback: On-going
ECCK Future Action: Need to monitor

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

13. Vehicle Width Standards
Government Feedback: Not Accepted
ECCK Future Action: Readdress

14. Mandatory Installation of LDWS and AEBS
Government Feedback: Implemented
ECCK Future Action: Need to monitor

15. Recognizing Parts Self-Certification According to Vehicle Self-Certification
Government Feedback: Not Accepted
ECCK Future Action: Readdress

16. Green House Gas (GHS) Emission Calculation Program for Heavy Duty Vehicle
Government Feedback: Not Accepted
ECCK Future Action: Readdress

17. KC Mark Exemption Process for Tires with E-Mark
Government Feedback: Implemented
ECCK Future Action: Closed

18. Recognizing E-Mark for Tires of Foreign Origin
Government Feedback: Not Accepted
ECCK Future Action: Closed

Beer, Wine & Spirits Committee

The limits on price range of giveaways when buying liquor and their total prices have been increased in some measure by revising the notification on establishing the order of liquor transaction. In terms of the recommendation related to allowing the online marketing for liquor, it is requested to review it from the perspective of promoting relevant industries, rather than focusing on the theoretical harmful effects of the use of alcohol. Also, it is repeatedly recommended to remove the labeling requirement of bottled beers sold for discount stores and households.

2018 Key Issues List

1. Limits on Price Range and Total Amount of Liquor Promotional Items
Government Feedback: Accepted
ECCK Future Action: Closed

2. Allowing Digital Marketing for Provision of Liquor Promotional Items
Government Feedback: Not Accepted
ECCK Future Action: Readdress

3. Revision of RFID System
Government Feedback: Partially Accepted
ECCK Future Action: Closed

4. Revision of the Labeling Requirements for Alcohol Use Classification
Government Feedback: Not Accepted
ECCK Future Action: Readdress

Chemical Committee

The Chemical Committee presented 8 issues and recommendations regarding Act on Registeration, Evaluation, etc. of Chemicals (ARECs), Act on Safety Control of Household Chemical Products and Biocides (K-BPR) and the Chemicals Control Act (CCA) to the Ministry of Environment (ME) in 2018. The ME evaluated that 5 recommendations are accepted or implemented, hence the acceptance rate reached 62.5%. Still, there are redundant regulations between 'ARECs', 'K-BPR', 'CCA' and 'OSHA', and the inefficiency and inconsistency of administrative procedures are recognized as problems when complying with regulations. ECCK will continuously suggest recommendations to the ME and Ministry of Employment and Labor in order to minimize the disclosure of trade secrets and the contraction of R&D due to the excessive regulations.

2018 Key Issues List

1. Combined Volume Control
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

2. Omission of Data to be Submitted When Applying for Registration of Chemicals
Government Feedback: Accepted
ECCK Future Action: Readdress

3. Substances Subject to Intensive Management (SSIM)
Government Feedback: Not Accepted
ECCK Future Action: Readdress

4. Exemption from Registration of Chemicals
Government Feedback: Accepted
ECCK Future Action: Closed

5. Criteria of Amount in Provision of Chemical Substance Information
Government Feedback: Implemented
ECCK Future Action: Closed

6. Data Requirements for Biocidal Product Authorization
Government Feedback: Implemented
ECCK Future Action: Readdress

7. Control Practice for Imported Treated Article: Recognition for Similarity by Foreign Laws
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

8. The Problems of the Universal Chemical Tracking System
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

Cosmetics Committee

The Korean government recognized the characteristics of the cosmetics industry and excluded cosmetics from the 'Dangerous Goods Safety Management Act' in harmony with international regulations. Also, the age range of children-use cosmetics was adjusted for the equity with other laws. The ECCK is pleased that some of our recommendations were accepted. However, for the labeling and advertisement of natural/organic cosmetics, it is still necessary to discuss the claims according to the natural/organic standards certified in other countries. In addition, it is also necessary to revise the merged notice, including the reporting of cosmetic raw materials, and to review the SPF index regulations in order not to confuse consumers. The criteria for the packaging of cosmetics will be further confirmed in accordance with the waste reduction policy.

2018 Key Issues List

1. Packaging of Cosmetics
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

2. Act on The Safety Control of Dangerous Substances
Government Feedback: Accepted
ECCK Future Action: Need to Monitor

3. Labeling and Advertisement of Natural/Organic Cosmetics
Government Feedback: Accepted
ECCK Future Action: Readdress

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

5. Labeling Requirements for Children's Cosmetics
Government Feedback: Partially Accepted
ECCK Future Action: Closed

6. Designation of Human Application Test Institutes for Cosmetics
Government Feedback: Not Accepted
ECCK Future Action: Need to Monitor

7. Ingredient Reporting System of Cosmetics
Government Feedback: Not Accepted
ECCK Future Action: Need to Monitor

Fashion & Retail Committee

The ECCK was pleased to note that a sales ban will not be imposed in case of administrative labeling errors and that alternative methods are allowed in case of difficulty to individually indicate product prices. As it is possible to add labeling in bonded warehouses, the issue of inclusion of local labeling requirements has been closed.

A number of challenges raised in the White Paper 2018 have persisted and are accordingly included in the ECCK White Paper 2019.

2018 Key Issues List

1. Local Labeling Requirements After Customs Clearance and

Before Sales
Government Feedback: Not Accepted
ECCK Future Action: Closed

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

3. Price Labeling Requirement
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

4. Safety Control Act Sales Ban
Government Feedback: Partially Accepted
ECCK Future Action: Closed

5. pH Restriction Level under the Safety Quality Labeling Standard
Government Feedback: Not Accepted
ECCK Future Action: Readdress

6. Method/Requirement of Indication
Government Feedback: Partially Accepted
ECCK Future Action: Closed

7. Changes in Legislations
Government Feedback: Implemented
ECCK Future Action: Readdress

Food Committee

We will be monitoring the recommendations that are accepted or being reviewed from the 2018 White Paper made by the Food Committee. The standards of natural flavor were partially accepted, however, due to its low impact, it is asked to be reviewed again according to the international one. The process of food import clearance still remains as the barriers to market entry. Sufficient preparation time for labeling change upon regulation amendments was accepted, however, the discussion among relevant agencies was not properly made in terms of the revision of the recycling labeling for packages by the Ministry of Environment.

2018 Key Issues List

1. Expansion of Non-GMO Labeled Products
Government Feedback: Not Accepted
ECCK Future Action: Readdress

2. Improvement of EU-Korea Equivalence Arrangement on Organic Processed Food
Government Feedback: Long-Term Review
ECCK Future Action: Need to Monitor

3. Coordination Between International Standards and Specifications for Food–Definition and Specifications of 'Natural Flavor'
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

4. Coordination Between International Standards and Specifications for Food–Food Labeling Standards on 'Natural'
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

5. Improvements on Food Import Clearance Process
Government Feedback: Not Accepted
ECCK Future Action: Readdress

6. Sufficient Preparation Time Upon Regulation Amendments
Government Feedback: Implemented
ECCK Future Action: Readdress

Healthcare Committee

From the 2018 White Paper, it is worth noting that Patent Term Extension for Drugs with Different Salts has been accepted by the Supreme Court. This decision made to meet the fundamental purpose of the Patent Term Extension (PTE) system. Unique Device Identification system was already introduced and alternatives for destruction period of personal information was proposed to the operators. Also, discriminatory rules on Premium pricing for innovative drugs was revised. But the revised condition to get premium pricing for innovative drugs are too harsh to both local and multinational companies. It is not aligned to the government's goal to promote new drugs. The other recommendations which are not accepted or under long review shall be needed to keep monitoring for further development.

2018 Key Issues List

1. PE evaluation
Government Feedback: Not Accepted
ECCK Future Action: Readdress

2. Expansion of PE Exemption Criteria
Government Feedback: Not Accepted
ECCK Future Action: Readdress

3. Risk Sharing Agreement (RSA)
Government Feedback: Long-Term Review/Not Accepted
ECCK Future Action: Readdress

4. Refunding VAT Duplication (Over-burden) Issue
Government Feedback: Not Accepted
ECCK Future Action: Readdress

5. Pre-Reimbursement and Post-Evaluation
Government Feedback: Not Accepted
ECCK Future Action: Readdress

6. Price-Volume Agreement (PVA)
Government Feedback: Not Accepted
ECCK Future Action: Readdress

7. Selective Reimbursement
Government Feedback: Not Accepted
ECCK Future Action: Readdress

8. Premium Pricing for 'Innovative Drugs'
Government Feedback: Implemented
ECCK Future Action: Need to monitor

9. Unfairness of Innovative Pharmaceutical Company (IPC) Designation to foreign Pharmaceuticals
Government Feedback: Implemented
ECCK Future Action: Need to monitor

10. Patent Term Extension for Drugs with Different Salts
Government Feedback: Accepted
ECCK Future Action: Closed

11. Transparency Improvement
Government Feedback: Not Accepted
ECCK Future Action: Readdress

12. Fee Scheme for Combination Vaccine
Government Feedback: Implemented
ECCK Future Action: Need to monitor

13. Double Testing for Vaccines
Government Feedback: Not Accepted
ECCK Future Action: Readdress

14. Approval of Manufacturing Business (consignment manufacture)
Government Feedback: Not Accepted
ECCK Future Action: Need to monitor

15. Conditional Approval
Government Feedback: Implemented
ECCK Future Action: Need to monitor

16. Additional Data Requested During Investigational New Drug (IND) Review Process for Early Phase Trials
Government Feedback: Implemented
ECCK Future Action: Need to monitor

17. Slow Importing Process of Ancillary Supplies (medical device, electronic equipment, lab supplies etc) used for Clinical Trials
Government Feedback: Implemented
ECCK Future Action: Need to monitor

18. Local Labour Law Prevents Hospitals to Use Clinical Research Coordinator from Site Management Organization (SMO) to Work in Clinical Trial Sites
Government Feedback: Implemented
ECCK Future Action: Closed

19. Quarantine Process Required for the Customs Clearance of QC Testing Reagents of Animal Origin
Government Feedback: Implemented
ECCK Future Action: Need to monitor

20. Tariff Exemption of Investigational Medicinal Product (IMP)
Government Feedback: Not Accepted
ECCK Future Action: Need to monitor

21. Value of Innovative Medical Devices
Government Feedback: Implemented
ECCK Future Action: Need to monitor

22. Import Prices for Reimbursement Pricing Cut
Government Feedback: Not Accepted
ECCK Future Action: Readdress

23. Unique Device Identification (UDI)
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

24. Transaction Price Information in Distribution Reporting
Government Feedback: Partially Accepted
ECCK Future Action: Closed

25. Consent rule for digital activity
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

Insurance Committee

In ECCK White Paper 2018, total of 9 items had been addressed to Financial Services Commission (FSC), Financial Supervisory Services (FSS), Ministry of Land Infrastructure and Transport (MOLIT), Ministry of Employment and Labor (MOEL), Ministry of Justice (MOJ). Partial improvements had been made such as amendments to Regulation on Supervision of Electronic Financial Transaction and implementation of E-clean insurance system.

The ECCK Insurance committee plans to consistently raise recommendations for the benefit of insurance industry's development as well as consumer protection and anticipates Korean government's additional efforts. Especially, item regarding excluding CPI from the List of Insurance Products Subject to Forced Sale will be re-addressed in White Paper 2019 with a revised request direction due to recent submission in the National Assembly of proposal for revision of Insurance Business Act to prevent inheritance of debts.

2018 Key Issues List

1. Establishment of Standard for Oriental Medical Treatment and Cost
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

2. Usage of the Cloud Services in Korean Insurance Market
Government Feedback: Partially Accepted
ECCK Future Action: Closed (Drop)

3. Excluding CPI from the List of Insurance Products Subject to Forced Sale
Government Feedback: Not Accepted
ECCK Future Action: Readdress

4. Cross-Selling Between Life and General Insurance Products
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

5. GA's Own Liability and Exemption of Insurance Company from

GA's Own Misconduct
Government Feedback: Not Accepted
ECCK Future Action: Readdress

6. Applying the Same Standards for the Forced Sales to Insurance Products and Banking Products
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

7. Bills Regarding Special Type Workers
Government Feedback: On-going
ECCK Future Action: Need to monitor

8. Bills Regarding Statute of Limitations (SoL) Applied to Insurance Benefit Claims
Government Feedback: Not Accepted
ECCK Future Action: Readdress

9. Financial Consumer Protection Bill
Government Feedback: Not Accepted
ECCK Future Action: Readdress

Intellectual Property Rights Committee

The ECCK is pleased that its recommendations in the White Paper 2018 have been taken into consideration and that a number of the recommendations have been implemented or will be put in place in due course. A number of the points raised merit further discussion and have accordingly been included in this year's White Paper.

2018 Key Issues List

1. IP Studies
Government Feedback: Accepted
ECCK Future Action: Closed

2. Lack of Interest in IP Enforcement
Government Feedback: Implemented
ECCK Future Action: Need to monitor

3. Ineffective Sentencing of IP-Related Crimes
Government Feedback: Not Accepted
ECCK Future Action: Readdress

4. Border Seizures
Government Feedback: Accepted
ECCK Future Action: Readdress

5. Customs Recordations
Government Feedback: Implemented
ECCK Future Action: Closed

6. Seizure of IP Infringing Materials
Government Feedback: Implemented
ECCK Future Action: Closed

7. Strengthen Monitoring for Transhipments in Free Trade Zones
Government Feedback: Accepted
ECCK Future Action: Readdress

8. Open Sale of Counterfeit Products
Government Feedback: Not Accepted
ECCK Future Action: Readdress

9. Pro-Active Measures by Online Intermediaries
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

10. Provision of Evidentiary Materials to Calculate Damages
Government Feedback: Implemented
ECCK Future Action: Need to monitor

11. Damage Calculation Methods
Government Feedback: Not Accepted
ECCK Future Action: Readdress

12. Statutory Damage
Government Feedback: Long-Term Review
ECCK Future Action: Readdress

Kitchen & Home Appliances Committee

In terms of 'home appliances' for scale, it was requested for its type approval to be exempted regardless of its maximum capacity, and it was to be reviewed after collecting opinions from the interested parties within 2020. However, even as of now when the first half of 2019 has passed, no schedules related to the issue are found. When it comes to the conformity assessment for electrical appliances, the certification levels for those with relatively less harm have been lowered. As what was recommended has mostly been accepted or not accepted for valid reasons, the difficulties of the industries have been somewhat resolved.

2018 Key Issues List

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

2. Conformity Assessment for Electronic Goods
Government Feedback: Accepted
ECCK Future Action: Closed

3. Reasonable Application on Environmental Assessment of Recycling
Government Feedback: Accepted
ECCK Future Action: Closed

4. Special Act on Imported Food Safety Control, Method of Inspection of Imported Food, etc.
Government Feedback: Not Accepted
ECCK Future Action: Closed (Drop)

Logistics & Transport Committee

2018 Key Issues List

1. Unfair Market by Korean Government's 'Shipping Industry Revival Five-Year Plan'
Government Feedback: Accepted
ECCK Future Action: Closed

2. Korean Government's Leading Counteracting System Regarding Adoption of Initial Strategy for Reduction of Greenhouse Gas by IMO
Government Feedback: Accepted
ECCK Future Action: Readdress

3. Current Global Policy According to Increase in E-Commerce Transactions and Improvement of Korean Policy Direction
Government Feedback: Not Accepted
ECCK Future Action: Closed

4. Simplify the Scopes of De-Minimis Only to Range of Value
Government Feedback: Not Accepted
ECCK Future Action: Closed

Marine & Shipbuilding Committee

The challenges raised in the White Paper 2018 have persisted, despite expressed willingness by the Korea Fair Trade Commission and the Ministry of Oceans and Fisheries to improve the position of subcontractors, respectively the provision of support for smooth technical cooperation between foreign and domestic shipbuilding equipment companies.

2018 Key Issues List

1. Unfair and Impractical Purchase Terms and Conditions
Government Feedback: Not Accepted
ECCK Future Action: Readdress

2. Policy for Localization of the Shipping and Marine Plant Equipment
Government Feedback: Partially Accepted
ECCK Future Action: Readdress

3. Practice of the Lowest Price Bidding System in Domestic Shipyards
Government Feedback: On-going
ECCK Future Action: Readdress

4. 52 Hours Work Per Week
Government Feedback: On-going
ECCK Future Action: Need to monitor

Energy and Environment Working Group

The ECCK Green Working Group recommended following three issues which help practice the green growth and bring visible outcomes, and it received feedback on two issues from the Ministry of Trade, Industry and Energy (MOTIE). Still, ECCK will continue to monitor these issues' implementation and propose further recommendations toward relevant governmental bodies in order to establish adequate energy, and environmental policies and regulations, and to ensure consistency thereof, which reduces industry's turmoil and encourages sustainable development.

2018 Key Issues List

1. Green Energy Transition
Government Feedback: Implemented
ECCK Future Action: Need to monitor

2. Renewable Energy Vision
Government Feedback: Implemented
ECCK Future Action: Need to monitor

3. Creating Shared Value (CSV)
ECCK Future Action: Readdress

Taxation Working Group

In the ECCK White Paper 2018, a total of 7 items out of 11 raised have either been accepted or is undergoing review by the Korean government.

The ECCK Taxation Working group, which consists of tax experts from various industries , embraces this achievement positively and plan to further raise recommendations for the authorities' additional efforts. Especially, we plan to re-address items expected for further discussion in the White Paper 2019.

2018 Key Issues List

1. Exemption From Requirement to Submit Duplicate Transfer Pricing Documentation
Government Feedback: On-going
ECCK Future Action: Need to monitor

2. Need for Increased Resources Responsible for MAP Cases
Government Feedback: Accepted
ECCK Future Action: Closed

3. Prohibit Examination of TP Issues That are Covered in APA
Government Feedback: On-going
ECCK Future Action: Need to monitor

4. Clarification That no VAT Place of Business Where no PE for Corporate Tax Purposes
Government Feedback: On-going
ECCK Future Action: Need to monitor

5. Amendment to Allow Tax Free Merger Between Domestic Sister Companies That are Owned by the Same Foreign Parent Company
Government Feedback: On-going
ECCK Future Action: Need to monitor

6. Same Deemed Arm's-Length Interest Rate for Both Borrowing & Lending
Government Feedback: On-going
ECCK Future Action: Need to monitor

7. Need to Eliminate Requirement to Submit CbCR to Only Foreign Invested Companies That Exceed a Certain Size Threshold
Government Feedback: Not accepted
ECCK Future Action: Closed

8. Allow Deduction for Bonus Payment to Officers Provided Paid in Accordance With Employment Contract
Government Feedback: On-going
ECCK Future Action: Readdress

9. Abolish Application of Deemed Capitalisation Rule to Branches of Foreign Banks
Government Feedback: Not accepted
ECCK Future Action: Closed

10. Need to Change List of Qualified Services Eligible for Zero-Rate VAT From a Positive One to a Negative System
Government Feedback: Not accepted
ECCK Future Action: Closed

11. 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: Readdress

ECCK Committee Reports

Changhoon Rim
Head,
Automotive
Industry

Automotive

Overview of the Industry

In 2018, the market share of imported vehicles in domestic passenger vehicle market was 16.7% and the sales increased by 12% from 2017. The market share of European manufacturers among imported vehicle market was 74%. In commercial vehicle market, the market share of European manufacturers was 77.5% in tractor sector, 75% in dumper truck sector, and 33.2% in large cargo sector. The trend of increase for imported tires continued as the expansion of imported vehicle market.

In regulatory field, motor vehicle exchange/refund regulation was implemented in 2019. Also, for environmental regulation, low emission vehicle supply target regulation is under preparation in order to make car manufacturers sell low emission vehicles above certain portion of the company's total sales volume. For tires, tire noise labeling regulation will be implemented from 2020, requiring tire manufacturers to sell tires that satisfy the noise limit level. Also, the tire minimum energy efficiency grade will be elevated in line with the standard changes in the EU. The tire energy efficiency standard for tires for truck/bus is being prepared for introduction.

Key Issue & Recommendation

1. Condition and Subject of Vehicle Exchange/Refund Regulation

According to the Article 47-2 of 'Motor Vehicle Management Act', the vehicle owner can request exchange/refund for the vehicle when the cumulative number of repair days is over 30 days. However, for imported vehicles, the repair days can be extended because of parts delivery from oversea. In this case, the manufacturer can be requested of exchange/refund for the vehicle even though the defect does not exist in the vehicle.

Also, in order to ensure the regulatory predictability and prevent any unnecessary dispute between manufacturers and consumers, the used and leased vehicle should be excluded from the scope of exchange/refund.

Recommendation

It is recommended to extend the cumulative number of repair days or to exclude the time taken for the parts delivery from the calculation of cumulative number of repair days. Also, the used and leased vehicles need to be excluded from the scope of the exchange/refund.

Related Laws & Regulations:
Motor Vehicle Management Act

Government Ministry/Agency in charge:
Ministry of Land, Infrastructure and Transport (MOLIT)

2. Test Standards of Traction Battery for EV/PHEV

In Table 1-48 of 'Detailed Enforcement Regulation for the Performance and Standard for Automobile and Auto Parts', the salt-water immersion test is regulated as one of test item for traction battery. However, the salt-water immersion test in Korea is unique and there is no salt-water immersion test in GTR 20 (phase 1). It is recommended to abolish salt-water immersion test considering field data in actual vehicle operation environment.

Recommendation

It is recommended to abolish salt-water immersion test among the test items for traction battery considering the international standard.

Related Laws & Regulations:
Detailed Enforcement Regulation for the Performance and Standard for Automobile and Auto Parts

Government Ministry/Agency in charge:
Ministry of Land, Infrastructure and Transport (MOLIT)

3. Harmonization of Identification of Hand Controls, Tell-tales and Indicators

Table 2 of 'Municipal Rule for the Performance and Standard for Automobile and Auto Parts' defines the standard of tell-tales and symbols. It is deemed that the standard is adopted from UNECE R-121 standard, however the exception clauses in the footnotes are not carried over. This leads to a problem where the manufacturer needs two separate instrument clusters each for Korea and Europe.

Recommendation

It is recommended to complete the harmonization of Table 2 of 'Municipal Rule for the Performance and Standard for Automobile and Auto Parts' with UNECE R-121, Table 1 (Symbols, their illumination and colors) including footnotes.

Related Laws & Regulations:
Municipal Rule for the Performance and Standard for Automobile and Auto Parts

Government Ministry/Agency in charge:
Ministry of Land, Infrastructure and Transport (MOLIT)

4. Stipulation of Alteration Report in Law

Article 48, Paragraph 2 of 'Clean Air Conservation Act' stipulates that the automobile manufacturer has to receive 'alteration certification' when the automobile manufacturer alters important particulars that are included in the vehicle's emission certification. However, the 'alteration report' for the minor alterations that do not influence the emission is not regulated in 'Clean Air Conservation Act' directly. For this reason, the automobile manufacturer that did not report the alteration for the minor alteration is deemed to have violated the alteration certification and can be subject of criminal punishment. On the other hand, other legislations similar to 'Clean Air Conservation Act' clearly classify the 'alteration approval/permit' of important alterations and 'alteration report/registration' of minor alterations, and sanctions are differently regulated applying punishment for the violation of the former and fine imposition for the violation of latter.

Recommendation

It is recommended to regulate alteration report for minor changes separately in 'Clean Air Conservation Act' and differentiate the alteration certification and alteration report in its punishment referencing other legislation examples. When alteration certification is not proceeded, the penalty shall be given and for violation of alteration report, fines or measures other than criminal punishment shall be given.

Related Laws & Regulations:
Clean Air Conservation Act

Government Ministry/Agency in charge:
Ministry of Environment (ME)

5. Clarification of Calculation Method of Average Fuel Economy for High Fuel-Efficient Vehicles

Automobile manufacturers submit actual achievement data every year to Minister of Environment to confirm whether it has achieved the average fuel economy standard or not. Current notification stipulates the average fuel economy calculation method for electric, hydrogen fuel cell, and hybrid vehicles that can be charged outside to be proportionally applied depending on the improvement of the average greenhouse gas (GHG) emission before and after the inclusion of fuel-efficient vehicles. However, there is a difficulty calculating the average fuel economy of the fuel-efficient vehicles since the specific calculation method is not described.

Recommendation

As the sales of fuel-efficient vehicles increases, it is recommended to construct clear guideline that demonstrates the calculation method of average fuel economy of fuel-efficient vehicles for accurate achievement calculation and to manage the expected middle and long-term plan.

Related Laws & Regulations:
Notification for Motor Vehicle Average Fuel Economy Standards, Greenhouse Gases Emission Standards and Their Application and Management

Government Ministry/Agency in charge:
Ministry of Environment (ME) & Ministry of Trade, Industry and Energy (MOTIE)

6. Recognition of EU Eco-Innovation in Greenhouse Gas

According to the 'Notification for Motor Vehicle Average Fuel Economy Standards, Greenhouse Gas Emission Standards and Their Application and Management', the vehicle manufacturers

can receive the credit for GHG reducing technology if it was approved by the authority. The EU also operates similar system of recognition of GHG reducing technology, but it requires a separate approval process in Korea in order for those technology and credit value to be recognized in Korea.

This approval process creates business uncertainty, impeding the ability of European manufacturers to decide which GHG-reducing technology to include in their vehicles. To provide the certainty necessary to encourage adoption of new GHG-reducing technologies, it is necessary to recognize the EU technologies and associated credit values.

Recommendation

It is recommended to recognize the approved GHG-reducing technology and credit values of the EU.

Related Laws & Regulations:
Notification for Motor Vehicle Average Fuel Economy Standards, Greenhouse Gases Emission Standards and Their Application and Management

Government Ministry/Agency in charge:
Ministry of Environment (ME)

7. Enhancing Flexibility on Regular Inspection

According to the 'Enforcement Decree of Clean Air Conservation Act', automobile manufacturers need to proceed with the emission and noise level test based on every year's production number (customs cleared number for import manufacturers) of the same type automobiles to confirm whether the automobile under manufacture satisfies the permissible emission level. Meanwhile, automobile manufacturers regularly check through regular inspection, defect confirm test etc. to examine whether the automobile that are under operation, satisfies the permissible emission level. Also, automobiles manufactured from the EU local factory are inspected through COP(Conformity of Production) system used under UNECE.

Recommendation

As there are similar and overlapping inspections that are operating at the moment, the regular inspection shall be replaced by a similar certification from EU countries such as COP system. If necessary, it is recommended to proceed a test when conducting the facility confirmation inspection.

Related Laws & Regulations:
Enforcement Decree of Clean Air Conservation Act

Government Ministry/Agency in charge:
Ministry of Environment (ME)

8. HS Code of Semitrailer-Towing Tractors

During the EU-Korea FTA negotiations, HS Code of semitrailer-towing tractors was erroneously stated in the Annex 2-C-1 of the EU-Korea FTA, resulting in the exclusion of semitrailer-towing tractors from the subjects applied to the FTA, not recognized of its equivalence regarding vehicle safety standards. In the case of the safety standard of seat belt anchorage, in particular, it is currently not recognized to satisfy Korea's safety standard by the EU-Korea FTA equivalence rule although it is included in the item for equivalence recognition according to the EU-Korea FTA.

Recommendation

It is recommended to revise the applicable articles of the EU-Korea FTA, semitrailer-towing tractors are allowed to be applied to the EU-Korea FTA.

Related Laws & Regulations:EU-Korea FTA

Government Ministry/Agency in charge:
Ministry of Land, Infrastructure and Transport (MOLIT)

9. Vehicle Width Standard

Article 4 of the 'Municipal Rule for the Performance and Standard for Automobile and Auto Parts' states that a vehicle's width cannot exceed 2.5m. Europe's regulation on a road width is on a similar level with that of Korea, but its vehicle width is 2.55m, wider than the requirement in Korea. Considering this fact, it needs to be reviewed that the limit of a vehicle width is extended to 2.55m in Korea as well.

If it is difficult to apply the 2.55m standard to all vehicle categories, it is recommended to allow the 2.55m width standard to be limitedly applied to trucks/special motor vehicles, double-decker buses and 3 axles buses.

Recommendation

It is requested to permit 2.55m vehicle width standard for trucks/special motor vehicles, double-decker buses and 3 axles buses.

Related Laws & Regulations:
Municipal Rule for the Performance and Standard for Automobile and Auto Parts

Government Ministry/Agency in charge:
Ministry of Land, Infrastructure and Transport (MOLIT)

10. GHG Calculation Program for Heavy-Duty Vehicle

The introduction of permissible GHG emission standard for Heavy-Duty Vehicle (HDV) is currently under review, and a program named HES, to calculate GHG emission is under development.

In Europe, there is a similar GHG emission calculation program for HDV called VECTO, and there are concerns by HDV manufacturers from Europe over the discrepancies in calculation between the two programs. Due to the difference in calculation methods, a same model vehicle can render two different GHG emission results, which can lead to a trade barrier between EU and Korea. In order to secure one of the EU-Korea FTA objectives; ensuring full reciprocal market access for the both parties, relevant regulation should be made to prevent it from being a trade barrier to Korea when importing HDVs from Europe.

Recommendation

It is recommended to make the relevant regulation to ensure that the different GHG emission results from HES and VECTO, does not become a trade barrier when importing European HDVs to Korea.

Related Laws & Regulations:
Notification for Test Method for Motor Vehicle Energy Consumption Efficiency, GHG Emission and Fuel Economy

Government Ministry/Agency in charge:
Ministry of Environment (ME)

11. EU-Korea Noise Level Standard Harmonization

Harmonization of standards is recommended as the permissible noise level for a manufactured automobile described under current 'Noise and Vibration Control Act' is different from the EU. The Article 29 of the current 'Enforcement Rules of the Noise and Vibration Act' states 80dB as the permissible noise under acceleration for large heavy-duty vehicles, while the permissible level in the EU is 82dB, stated in the UNECE R-51, 03 series, Phase1.

Recommendation

It is recommended to recognize UNECE certificate as conformity of noise level standard in Korea, considering that UNECE regulation is the international standard stated in EU-Korea FTA.

Related Laws & Regulations:
Enforcement Rules of the Noise and Vibration Control Act

Government Ministry/Agency in charge:
Ministry of Environment (ME)

12. Timing of Indication of Tire Safety Certification Mark

Article 58 of the 'Operating Guide to the Electrical Appliances and Consumer Products Safety Control Act' states that the indication for the safety certification for tire should be done before customs clearance. However, for manufacturers who conduct safety mark indication in Korea, can have difficulties to conduct indication process depending on the amount of imported products during customs clearance. On the other hand, the Operating Guide regulates domestic products to indicate the safety certification mark before a product release.

Recommendation

It is recommended to revise the timing of indication of safety certification mark for imported tires from “before customs clearance” to “before product release” if the imported tire is already registered safety certification.

Related Laws & Regulations:
Operating Guide to the Electrical Appliances and Consumer Products Safety Control Act

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE)

13. Designation as Business Suitable for Livelihood for Used Vehicle Sales and Small Automobile Repair Business

It is being reviewed to designate ‘Used Vehicle Sales’ business and ‘Small Automobile Repair’ business as business suitable for livelihood. If those businesses are designated as business suitable for livelihood, it is expected that most of European imported vehicle manufacturers cannot expand their business in such business area; and it can give negative effect on customer's satisfaction and sales of new vehicles of automobile manufacturers. It is considered that the used vehicle sales business and small automobile repair business are related with safety of vehicles and support from headquarter for specialized service and continuous investment is necessary. Also, it is indicated that the restriction for such business area is not corresponding to the market access provision as stated in the EU-Korea FTA. Moreover, it is considered that the used vehicle sales business and small automobile repair business in imported vehicle are not largely engaged with small businesses; since it requires the purchase of high-priced vehicles and the substantial investment.

Recommendation

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

Related Laws & Regulations:
Special Act on the Designation of Business Suitable for Livelihood

Government Ministry/Agency in charge:
Ministry of SMEs and Startups (MSS)

Beer, Wine & Spirits

Hyokyung Suh
Director,
Beer, Wine &
Spirits
Committee

Overview of the Industry

For the last few years in Korea, research has been conducted on the pros and cons of ad valorem and specific tax systems and what effects their revision would have. Government agencies, research institutions and industries have contemplated the ways of revising the liquor tax in a reasonable way. As it is first decided that the special tax applies to Beer and Takju (raw rice wine), their taxation systems will change from next year. The notification on establishing the order of liquor transaction has been revised to define relevant requirements and by doing so, the order related to liquor transaction and distribution to be more strictly controlled by the government.

The Korea Customs Service (KCS) trade statistics showed that the import of major liquor[1] increased by 18.1% to 448 million liters in 2018 comparing to 2017. And the cost growth rate of 21.4%, was the highest in recent years. These facts implied that the liquor with relatively high price was imported more.

Beer imports increased more than 20% annually for the last decade (reaching even 50% in 2017. However, in 2018, it was only 17.1% (387 million liters in total). The beer imports from European countries stood at 33% (128 million liters in total) and it was remarkable that US imports increased significantly by 98.6% compared to the previous year. The wine imports increased by 28.6% (35 million liters in total) than the previous year.

1. Wine (red, white and sparkling), beer, whiskey, vodka, gin, rum – trade statistics

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Key Issues

1. Allowing Digital Marketing for Provision of Liquor Promotional Items

The 'Liquor Tax Act' allows the provision of liquor promotional items and sets a limit for their price range and total amount. However, the 'National Health Promotion Act' (No. 7 of the standards for advertisement specified in attached Table 1 in Article 10 of the Enforcement Decree to the Act) indicates that promotional and marketing activities for provision of liquor promotional items are prohibited. The regulation is contradictory to the fact that conducting promotional activities within certain ranges to provide benefits (including giveaways to consumers) is allowed Also, this is considered overly strict control over business activities.

Recommendation

It needs to be permitted for all consumers to be able to receive benefits without being disadvantaged due to their location or time of the day through advertisements of liquor promotion. Accordingly, we hope that the 'National Health Promotion Act' to be revised to allow the promotional and marketing activities for promotional items of alcoholic beverages.

Related Laws & Regulations:
National Health Promotion Act

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW)

2. Revision of Use Classification Labeling Requirements for Bottled Beer

The labeling requirements for alcohol use classification were revised in 2017 to remove the 'for hypermarket' and 'for household' labels for wine and canned beer. However, bottled beers are still required to have 'for hypermarket' and 'for household' labels, which makes inventory control and management difficult.

Recommendation

We request to integrate labeling requirements for bottled beer into 'for household' from 'for hypermarket' and 'for household'.

Related Laws & Regulations: Liquor Tax Act
Government Ministry/Agency in charge:

Ministry of Economy and Finance (MOEF) &
National Tax Service (NTS)

3. Allowing Liquor Sales via Mail Order and Online

According to the 'Liquor Tax Act' and its relevant subordinate laws as of now, sales of liquor through online intermediaries are in principle not allowed, while such is allowed for traditional alcohols. In the past, online sales were permitted only through the online channels ran by the Post Office, but now the online sale of any products are taking place through all kinds of intermediaries. However, as the meaning of 'traditional liquor' is not yet defined, the understanding of what could be sold online is different among the liquor sellers, which

Beer, Wine & Spirits Committee

could result in discrimination between imported and domestically produced liquor. Furthermore, prohibiting sales of liquor through online intermediaries does not seem advisable for the development and advancement of e-commerce.

Recommendation

It is recommended that the sales of all kinds of liquor, not only traditional, to be allowed online. Along with it, discussions need to be held regarding the adoption of proper regulations in order to prevent minors from purchasing liquor online and making sure only legitimate liquor consumer are able to purchase them online.

Related Laws & Regulations: Liquor Tax Act

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF) &
National Tax Service (NTS)

Chemical

Taeyang Kim
Coordinator,
Chemical
Committee

Overview of the Industry

The Korean economic development has been driven by the chemical industry which is an irreplaceable industry in the global economy. In 2017, the global chemical industry took up 7.1% of the world's GDP and the competition on the chemical market is deepening due to the chemical industry development in Asian countries (including China) to dominate global chemical sales.

The Korean chemical industry has grown to become the 5th largest in the world after China, the EU, the US and Japan, while chemical related accidents have frequently occurred. In order to protect the public safety and health as well as the environment from the accidents, 'The Act on Safety Control of Household Chemical Products and Biocides (K-BPR)' were enacted last year, and 'The Act on Registration, Evaluation, etc. of Chemicals (ARECs)' and 'The Occupational Safety and Health Act (OSHA)' were recently amended. On top of that, the lower statutes of OSHA and 'The Chemicals Control Act (CCA)' are expected to be revised too.

As the global chemical control scheme is reorganized into risk assessment and management, the EU leads the direction of international chemical regulations through the successful establishment of the REACH system, which has been enforced from 2007, and the implementation of BPR from 2013. The Korean government should establish appropriate chemical regulations and policies to enhance the competitiveness of the domestic chemical industry while at the same time securing environmental and public safety by reflecting new chemical control trends and closely cooperating with the industry, and domestic and overseas associations.

Key Issues

1. Reinforcement of Transparency on Legislation and Notification Revision

Currently, a period for public hearing for new legislation or amendments is mostly 20 days and whether a notification of a Technical Barrier to Trade is submitted to the WTO differs on a case by case basis. Even though the industry is heavily impacted by the newly designated list of hazardous chemicals (toxic chemical, etc.),

there is no proper comment period for companies whose review results differ from what has been submitted to the government. Newly designated prohibited/restricted chemicals in the 'Designation of Household Products Subject to Safety Confirmation and Safety · Labeling Standard' under the K-BPR impacts household chemical industries, however there is no specified criteria and risk assessment result shared by the government.

Recommendation

We request a proper period for public hearing, of more than 90 days, to be held and for WTO to be informed of all technical barriers to trade. Also, a proper comment period is necessary for companies that have registered the respective chemical, prior to its designation as a hazardous chemical. Finally, criteria for the prohibited and restricted chemicals must be clarified and risk assessment results should be disclosed.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (ARECs), Chemicals Control Act (CCA), Act on Safety Control of Household Chemical Products an Biocides (K-BPR), Occupational Safety and Health Act (OSHA)

Government Ministry/Agency in charge:
Ministry of Environment (ME) &
Ministry of Employment and Labor (MOEL)

2. Redundant Regulations on Chemical Substances

In spite of the confirmation and approval on safe use under 'K-BPR', household chemical products are still subject to controls under 'ARECs', 'CCA' and 'OSHA'. In the case of chemical products, similar data, like composition data, are submitted repeatedly to Ministry of Environment (ME) and Ministry of Employment and Labor (MOEL) for the 'chemical product notification under CCA' as well as 'MSDS (Material Safety Data Sheet) notification under OSHA' even if the products are same. Also, companies must comply with two different laws (submission and approval by ME and MOEL) for confidentiality protection claims.

Recommendation

We propose household chemical products to be out of scope of the 'chemical product notification under CCA', the 'intensive control substances notification under ARECs', and the 'new substance registration under OSHA' without additional administrative confirmation. Also, in case of the 'product notification under CCA' or 'MSDS submission under OSHA', and approval of confidentiality protection under 'ARECs' or 'OSHA', mutual recognition between the ME and the MOEL should take place.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (ARECs), Chemicals Control Act (CCA), K-BPR, Occupational Safety and Health Act (OSHA)

Government Ministry/Agency in charge:
Ministry of Environment (ME) &
Ministry of Employment and Labor (MOEL)

3. Timing and Requirement of Notification and Submission of Change

'CCA' and 'OSHA' regulate updates changes of the product notification as well as MSDS and composition submission, but the target scope for updating is different from each other. Furthermore, an 'immediate' update is required. This creates a big burden to the industry and will not be beneficial to the government offices.

Recommendation

We request to have the same target scope for updating obligation of the 'CCA's product notification' and the 'OSHA's MSDS and composition submission', and to allow updating once a quarter instead of requiring immediate update.

Related Laws & Regulations:
Chemicals Control Act (CCA),
Occupational Safety and Health Act (OSHA)

Government Ministry/Agency in charge:
Ministry of Environment (ME) &
Ministry of Employment and Labor (MOEL)

4. Exclusion of Chemical Substances for R&D Use From Composition Submission

Handled by experts, chemicals used in R&D have lower risk compared to others. Also, most of the R&D chemicals are used at the developmental stage and composition information tends to be confidential. It is reasonable to exempt research use chemicals from submission of composition information required by the 'CCA' and 'OSHA'.

Recommendation

We propose that chemicals for R&D use are exempted from MSDS submission and CBI application, while continuing to require MSDS preparation pursuant to the 'OSHA'. Also, the submission of chemical composition should be exempted from the product notification even though a declaration of chemical verification will continue to be required by the 'CCA'.

Related Laws & Regulations:
Chemicals Control Act (CCA),
Occupational Safety and Health Act (OSHA)

Government Ministry/Agency in charge:
Ministry of Environment (ME) &
Ministry of Employment and Labor (MOEL)

5. Exclusion of Consumer Biocidal Products from 'CCA' and Complementary Measures on the Matter in 'K-BPR'

Active substances used in consumer biocidal products have been designated as toxic substances due to environmental hazards in recent years, and the content criteria is set at 1% so that mixture products exceed the toxic substance specified contents.

In case of biocidal product categories which used to be quasi-drugs transferred from the Ministry of Food and Drug Safety (MFDS), which are currently under 'K-BPR', their exclusion from the 'CCA' is to be valid temporarily until the transition period expires. As consumer biocidal products are managed under the 'K-BPR', consumer biocidal products should be exempted from the 'CCA'. Considering the product type and direction for use of consumer biocidal products, it is unreasonable to involve 'Off-site Consequence Analyses' and to manage the handling of toxic substances, which will be exceptionally onerous to comply with due to difficulties in storage, transportation and sales management (including retailers).

Recommendation

We recommend consumer biocidal products to be excluded from the 'CCA' and complement measures in 'K-BPR' such as the implementation of additional provisions on chemical management and incident response for consumer biocidal products exceeding the toxic substance content specified. (e.g. adding first aid to the product labeling, and ensuring that the MSDS of the product is placed in storage except in retail stores.)

Related Laws & Regulations:
Chemicals Control Act (CCA), K-BPR

Government Ministry/Agency in charge:
Ministry of Environment (ME)

6. Substance Subject to Intensive Control (SSIC): Designation and Notification of Contained Products

Of the total 672 intensive control substances, 25 substances are designated because of Specific Target Organ Toxicity (STOT), and Toxic Substances, Substances Requiring Preparation for Accidents and restricted substances are 479, 17 and 41 respectively. Those substances are already required to submit composition or letter of confirmation according to the current 'CCA' and subsequent notification shall be required by the ME for each product under the Universal Chemical Tracking System according to the proposed 'CCA'.

Only 180 substances in the list for intensive control (about 27% of the total) are not regulated as hazardous substances under the 'CCA', and 35 and 78 substances thereof are required to register as the existing and new substances respectively in compliance with the 'AERECs'. Hence, only 67 substances thereof are not controlled by the 'CCA' or 'AERECs'.

Recommendation

We request to delete STOT from the criteria for designating

Intensive Control Substances. Each product controlled by Chemical Substance Identification System according to the proposed 'CCA' that is subject to notification, should be excluded from the reporting of products containing Intensive Control Substances under 'ARECs'.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (ARECs), Proposed Chemicals Control Act (CCA)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

7. Threshold of Annual Domestic Combined Volume of Imported and Manufactured Chemical Substances

It is a huge burden for the companies to register substances, due to the amount of imported or manufactured substances by others, when they are only importing or manufacturing substances in small volume. Also, there is no clear criteria to evaluate substances subject to exemption from registration when exceeding the threshold of annual domestic combined volume.

Recommendation

We recommend to exclude small volumes (less than 100kg for new substance and 1 ton for existing chemical) from calculating domestic combined annual volume or increase the threshold of domestic combined volume up to 10 tons for new substance and 100 tons for existing chemical. Also, chemicals that are more hazardous than carcinogenic, mutagenic or toxic to reproduction (CMR) substances should only be included in domestic combined annual volume.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (ARECs)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

8. Quantitative Structure – Activity Relationship (QSAR) Data Submission

Currently, QSAR data is accepted only below 10 ton registration, therefore there is no opportunity to submit it for high tonnage band registration which requires several toxicological studies (up to a maximum of 47). Due to the unavailability of international toxicological studies, 40,000 kinds of existing chemicals could not be registered within the past 10 years. So, use and acceptance of QSAR data should be encouraged, however, the evaluation period is prolonged due to frequent supplement requests when QSAR data is submitted for 10 ton registration. In practice, it is hard to say that use of QSAR is possible since the standards on supplement requests are not clear enough.

Recommendation

We encourage the use and acceptance of QSAR data by omitting the tonnage limitation (10 ton). In addition, the guidance document on evaluation and complement of QSAR data should be published so that the analysis of QSAR data on various chemical substances could be well accepted between submitter and reviewer mutually and the industries could prepare and submit required data for registration in time.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (ARECs)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

9. Simplification of Exemption Confirmation for R&D Use Chemicals

For the chemicals for R&D use, application for confirmation of exemption from registration requires the submission of documents that include explanation and planning of the use, period, logistics, quantity, disposal, etc.. Also, preparing for the documents is complicated and time-consuming, so it causes delay in research. For these reasons, concerning the exemption from registration, it is necessary to get rid of the confirmation procedures. It will be more efficient to have the company itself retain the supporting documents for the follow-up inspection.

Recommendation

We recommend that it will be allowed for companies to retain the supporting documents for the inspection of chemicals for R&D use following its own assessment of whether the relevant substance is subject to exemption from registration or alternatively the issuance of a simple report without confirmation.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (ARECs)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

10. IT System: Confidential Business Information (CBI) Protection for Exempted or/and Registered Substances by Proxy

The ME has a plan to disclose the information on the 'ARECs' IT system when proxy registered and exempted substances as being entrusted the right from registrant (importer) which was allowed under ARECs. Since there are (overseas) companies and the Only Representative (OR) would not wish to disclose CBI to importers, they might need to cancel the approved registration and exemptions and should re-submit it by OR with additional costs. For registration exceeded 10 ton per year, registrant should submit CSR (Chemical Safety Report) additionally because the CSR grace period will expire in the end of 2019. Also CBI of which the registration and exemption is withdrawn cannot be protected since it remains on 'ARECs' IT system despite the their withdrawal.

Recommendation

We request to allow that industry uses newly introduced system 'Material Information Transfer System' to transfer registration and exemption by proxy to OR without additional OR designation and re-submission of dossiers. For the withdrawn registration or exemption, chemical information should be completely deleted in order to protect CBI.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (ARECs)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

11. Commenting Period before Public Notice of Toxic Substance Designation

New chemicals and existing chemicals subject to registration may be designated as toxic substances regardless of submitted hazard data (or without additional data requests for hazard assessment).

The designation of toxic substance should be determined carefully as it is an important matter in workplaces from an environmental and safety management aspects, and it may impact compliance with other regulations, e.g. facility standard and handling business license to comply with the 'CCA'.

In addition, for new chemicals, even if they are not subject to MSDS requirements in foreign countries, it should be released on MSDS once it is designated as toxic substances in Korea, which makes it a challenge for multinational companies to promote new chemicals in Korea.

Recommendation

Under EU-REACH, various opinions are collected from registrants, NGOs, industry associations and countries outside of the EU for at least several months before determination of Substances of Very High Concern (SVHC) substances.

Likewise, we request to provide for a comment period for registrant to submit additional testing data related to classification and hazard assessment at least six months before publicly notifying the results of the hazard assessment.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (ARECs)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

12. Issue on Registration of Indirectly Imported Chemical Substance by OR

Although the quantity or number of chemicals supplied to Korea through indirect imports is not negligible, there are many limitations on verifying and managing the quantity and

importer's information as OR in relation to the CBI disclosure, so the registration and notification of change are not feasible or many restrictions are placed on performing relevant procedures. Despite these conditions, the OR is imposed with excessive responsibility that is not realistic by current 'ARECs'.

Recommendation

There is a problem with heavy responsibility for ORs in situations where the CBI prevents the sharing of information related to indirect import. Hence, we request to consider introducing a separate system for indirect importers, such as the introduction of the same definition of importer as used in EU-REACH in relation to indirect import.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (ARECs)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

13. Notification by OR of Registered Substance Under Toxic Chemicals Control Act (TCCA)

It is unreasonable that registered substances for which high cost and time is invested under the 'TCCA' cannot be notified by the OR, whereas exempted substances under the 'TCCA' are allowed to be notified by OR. Also, companies that share registration certificates by registrant companies under the 'TCCA' do not know the chemical information because such is CBI of the overseas company which is not disclosed to importers. If such were to be disclosed to the importer (customer), it could lead to a critical sales loss. In some instances, notification is not possible by the original registrant due to business closure, or the transfer of intellectual property rights to another company by a merger and acquisition. Therefore, notification by OR should be allowed as one of additional alternative notification option.

Recommendation

We propose that an OR is allowed to notify registered chemical under the 'TCCA' in light of fairness and CBI. OR or registrants can submit the list of importers and chemical information at once (If validation is needed, importers which shared the registration certificate under the 'TCCA' can submit documents on import volume, and it is considered that notification by importer is completed).

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (ARECs)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

14. 'ARECs' Guideline for Exempted Article from Registration

Under the current 'ARECs', chemicals contained in products that perform a certain function in a specific solid form and which are not released during its use are defined as articles by the industry and are accordingly exempted from registration. However, because there is no detailed explanation or example for interpreting the requirements while there are various types of products in the market, the industry is faced with issues of 'ARECs' compliance due to difficulties of self-judgement or different interpretation between concerned companies.

In addition, despite the fact that it is considered an requirement under 'ARECs', the authority sometimes asks to submit a chemical confirmation statement under the 'CCA', which causes confusion in the industry.

Recommendation

Like EU-REACH, a guideline should be issued as to the interpretation of the ARECs' requirements of articles subject to exemption to minimize uncertainty in the industry's own judgment and to narrow the gap between companies or authorities. For the implementation of current legislation and harmonization with international regulations, it is proposed to introduce interpretation based on the relevant European guidelines while preparing the guideline for 'ARECs'.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (ARECs)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

15. Registration and Notification of Change Under 'AERECs' (Update of Submitted Dossiers)

Under the current 'AERECs', if there is a change in the tonnage band and/or list of importers, a change registration and/or change notification needs to be made within one month after the change has occurred. However, in case of foreign manufacturers and/or formulators with complex supply chains, it takes a significant time to recognize the changes and to prepare additional data requirements accordingly.

Recommendation

We propose that the change notification of the list of importers is made within one month from the recognition of the change. The update of other changes such as tonnage band, use and hazard/risk information incurs additional data requirements and/or downstream use description, so it should be allowed a year period with the possibility to be extended one more year.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (AERECs)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

16. Polymer Registration

The Guidance on Polymer Registration and Exemption publication does not include enough information and standards for joint polymer registration, so it is necessary that more specific criteria are supplemented. The exceptional cases that are not included in the guidance need to be flexibly regulated on the basis of scientific proofs.

Recommendation

In case of polymer registrations, we recommend that the grouping submission has to be allowed and CSR is not automatically required to be submitted. However, the screened substances only need to submit CSR when substances are imported or/and manufactured over 1,000 ton.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (AERECs)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

17. Deletion of SSIC Requirement in Polymer Low Concern (PLC) and Polymer Notification

In case the content concentration of Intensive Control Substances is more than 0.1% w/w in residual monomer of PLC which of Mn under the 10,000, the substance is not subject to PLC and cannot be exempted from notification regardless of industrial or consumer goods use. SSIC is introduced as a similar approach to SVHC of EU- REACH to regulate consumer goods, rather than industrial products, and there is an SSIC notification requirement in 'AERECs' already. It is an excessive regulatory requirement for PLC if even the polymer for industrial use should be regulated like an SSIC for consumer goods.

Recommendation

We request that the SSIC requirement is deleted from the PLC which contains residual monomer more than 0.1% w/w, or the polymer for industrial use exempted from SSIC confirmation at least in Article 11-2 of Enforcement Decree of 'AERECs' and Article 2-4 of 'PLC Subject to Notification Notice'.

Related Laws & Regulations:
Act on Registration, Evaluation, etc. of Chemicals (AERECs)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

18. Data Exemption for Biocidal Product Registration

It is not clear whether hazard assessment is required in case of minor formula changes , such as pH adjuster, perfume, colorant, etc., which do not impact safety and efficacy of products.

It is not clear whether read-across data or non-good laboratory practice (GLP) data is acceptable or not if there is reasonable rational.

Recommendation
If the formula change does not impact the product's hazard and risk classification, we request that it is exempt from environmental and human toxicity data submission and non-GLP and read-across are accepted.

Related Laws & Regulations:
K-BPR

Government Ministry/Agency in charge:
Ministry of Environment (ME)

19. Criteria of Recognition for Imported Treated Article
For the mutual recognition of imported treated articles, it is accepted that active substances, which are used for treatment process, are approved in Korea. However, according to the foreign laws, it is interpreted that not only active substances but also biocidal products are approved in the EU as well as the product type in the EU should be identical with the one in the K-BPR. The biocidal product registration is delayed in EU-BPR, and it is very rare to have the same product type in EU-BPR versus K-BPR.

Recommendation
We request to accept approved not 'biocidal product' but 'active substance' in similar category (sterilizer group, insect repellent group, preservative group, etc.) in EU-BPR for the recognition of imported treated article.

Related Laws & Regulations:
K-BPR

Government Ministry/Agency in charge:
Ministry of Environment (ME)

20. Additional Notification for Existing Active Substance
The pre-notification period for registration of existing active substances ended at the end of June 2019. This proved too short for many companies. Thus, there might be missing substances from the suppliers, which could affect biocide products, and

treated article manufacturers and importers. Furthermore, if a supplier drops the registration after the pre-notification period, products, and treated article manufacturers and importers must stop their operation .

Recommendation
We request to have an additional pre-notification period before the end of grace period similar to the late pre-notification of 'AECs'.

Related Laws & Regulations:
K-BPR

Government Ministry/Agency in charge:
Ministry of Environment (ME)

21. Labeling Requirement for Household Chemical Products
There is no threshold to label hazardous chemicals and SSIC, so companies need to label regardless of the amount it contains (therefore even in case of very small amounts such as parts per billion (ppb) level). It is a heavy burden for companies to be required to change product labels frequently in light of the expansion of hazard chemical and SSIC lists.

Recommendation
We request to set a threshold level of 0.1% for the requirement to label hazardous chemicals and SSIC for household chemical products.

Related Laws & Regulations:
K-BPR

Government Ministry/Agency in charge:
Ministry of Environment (ME)

22. Global Harmonization of Safety Standard for Household Chemical Products
There is no coordination nor global harmonization on the threshold criteria of prohibited and restricted chemicals for each product group under the 'Designation of Household Chemical Products Subject to Safety Confirmation and Safety · Labeling Standard'. It does not consider the case to unintentionally contain

prohibited and restricted chemicals at the trace level either.

Recommendation

We request for harmonization of prohibited and restricted items on each product group, such as detergents and softner, under household chemical products standard and that at least similar standards are set in line with Korean or/and global cosmetic standards for lead, cadmium, mercury, arsenic, etc.

Related Laws & Regulations:
K-BPR

Government Ministry/Agency in charge:
Ministry of Environment (ME)

23. Duplicated Control of Hygiene Products

Hygiene products such as diapers, dish detergent, etc. are controlled by the MFDS. Hygiene products are excluded from 'ARECs' and 'K-BPR', but not from the 'CCA'.

Recommendation

We request exclusion of hygiene products from the 'CCA'.

Related Laws & Regulations:
Chemicals Control Act (CCA)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

24. Universal Chemical Tracking System (UCTN) and Duplicated Submission of Chemical Information

If the Notification of Chemical Substance Identification according to the Universal Chemical Tracking System is approved by the administrative agency, it could cause major problems when the products undergo customs clearance and delays in the issuing of the number occurs.

In addition, the ingredients, percent of each compositions, usages, and the annual manufacture/import volumes and hazard classification, which must be submitted pursuant to

the Notification of Chemical Substance Identification already have been submitted to the ME for chemical registration under 'ARECs', and such information also needs to be submitted to the MOEL when submitting the MSDS pursuant to the Proposed Enforcement Rule of OSHA. As this information was already submitted to the ME, it is considered as inefficient administrative work to re-submit the same information to another authority.

Recommendation

We request that the UCTN should be a simple notification system that is processed immediately through the chemical distribution management system without review or approval, and grace period should apply due to the huge delay in the early stage of its implementation. Also, companies that are submitting chemical information under 'ARECs' or/and 'OSHA' need to be exempted from re-submission of the same information when notifying chemical identification.

Related Laws & Regulations:
Proposed Chemicals Control Act (CCA)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

25. Notification of Chemical Substance Identification by Representative Appointed by Overseas Manufacturer

Overseas companies can appoint a Korean-based company as their representative to carry out duties, such as notification of chemical information and provision if the Identification Number pursuant to the Proposed 'CCA'. However, the appointment of representatives by overseas manufacturers is a redundant administrative process because the 'ARECs' already requires for overseas manufacturers to comply with the substances registration by appointing their representatives.

Recommendation

We recommend that the confirmation of OR appointment by the ME must be omitted in order to prevent a legal entity from being regulated repeatedly, for the duplicated appointment or dismissal, because the representative can be an OR who is

already designated by foreign manufacturer for registration or notification under the 'AERECs'.

Related Laws & Regulations:
Proposed Chemicals Control Act (CCA)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

26. Configuration of Chemical Identification Number

In case the chemical identification number is assigned to identify products by its phase, hazards and risk information, composition, usage, etc., companies' trade secrets could be compromised. Also, it would be difficult to manage if configuration of identification number is complicated.

Recommendation

We request that the chemical identification number should consist of numbers that could protect companies' trade secrets while at the same time be simple enough to be managed easily.

Related Laws & Regulations:
Proposed Chemicals Control Act (CCA)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

27. Notification of Change for Chemical Substance Identification

Under the proposed 'CCA', notification of data changes must be submitted to the respective authority within 30 days of changes in submitted data occurring.

Recommendation

We recommend to update the changes collectively by setting a period of time (e.g. quarterly basis) rather than a compliance period, since a few constituent or composition can be changed frequently due to the products properties. Also, change notifications should be applicable only in case the changes can affect the hazard classification.

Related Laws & Regulations:
Proposed Chemicals Control Act (CCA)

Government Ministry/Agency in charge:
Ministry of Environment (ME)

28. Subject to Exemption from Investigation of New Chemical's Harmfulness and Hazardousness

The management of the household chemical in OSHA is a redundant regulation because it is controlled by the K-BPR. In addition, it does not meet the purpose of OSHA to maintain and promote the safety and health of industrial workers. Therefore, the confirmation from MOEL should be removed on exemption from investigation of new chemical's harmfulness and hazardousness, which is confirmed/approved by the 'K-BPR'.

Plus, the generation of expensive data is inevitable for new substances, despite being exempted from 'AERECs', because the criteria of exemption from investigation of new chemical's harmfulness and hazardousness under 'OSHA' is different from the 'AERECs'. Therefore, the criteria of exemption under 'AERECs' should also be applied to 'OSHA' as it is desirable to unify the criteria in order to resolve the problem of redundant regulation.

Recommendation

We recommend that the household chemical product is automatically exempted from the harmfulness and hazardousness investigation by the MOEL and also the article 89-2 of the Enforcement Rule of OSHA, regarding the exemption criteria, is harmonized with the 'AERECs'; deleting tonnage limit of the export of the entire quantity, changing the polymer exemption criteria to unreacted monomer, and adding the chemicals which are produced by reaction of surface treatment.

Related Laws & Regulations:
Occupational Safety and Health Act (OSHA)

Government Ministry/Agency in charge:
Ministry of Employment and Labor (MOEL)

29. Submission of MSDS

According to the proposed Enforcement Decree of OSHA, MSDS must be submitted to the authority prior to manufacturing and importing of products. However, this is cumbersome and may delay distributing products since all substances in products are required be disclosed and identified in assistance with original suppliers of raw material, which is very difficult to achieve.

Recommendation

We recommend that the mandatory submission of MSDS should be allowed to be made within one month of manufacture or/and import of products in order to reduce damages in distributing the products in the market.

Related Laws & Regulations:
Proposed Enforcement Decree of Occupational Safety and Health Act (OSHA)

Government Ministry/Agency in charge:
Ministry of Employment and Labor (MOEL)

30. Submission of Changes in MSDS

A notification of Changed MSDS must be submitted to the authority immediately after any change in the name or contents of chemical occurs through Form 26 Classification Criteria of Harmful Factors in the Proposed Enforcement Rules of OSHA, even though there isn't any change of the GHS Classification (Section 2 in SDS) of the mixture.

Recommendation

We recommend that mandatory submission of changed MSDS should be required within a month of the change occurring, only if a change in the name or contents of the chemical affects the

Related Laws & Regulations:
Proposed Enforcement Rule of Occupational Safety and Health Act (OSHA)

Government Ministry/Agency in charge:
Ministry of Employment and Labor (MOEL)

GHS Classification (Section 2 in SDS) of the mixture.

31. Requirements for CBI Approval of MSDS

According to Form 63 of the proposed Enforcement Rule to the OSHA, in order to apply for the CBI approval of MSDS, the name of the chemical and contents of all components in the product must be submitted. However, in accordance with article 110 (1) and (2) of the OSHA, during the submission of MSDS, manufacturers and importers of the classified products must already submit the name of the chemical and contents of the “classified components”, and the information of non-classified components on the document which confirms that there are no other classified substances in the product (LoC; Letter of Confirmation). Therefore, this requirement seems unnecessary and redundant.

Recommendation

For the CBI approval on MSDS, we request that only information of trade secret subject to the approval is required to submit and review. If manufacturers and importers must submit the information of the other components, the submission of MSDS should be exempted automatically, and the information of non-classified components should be replaced by a LoC such as in article 110 (2) of the Act.

Related Laws & Regulations:
Proposed Enforcement Rule of Occupational Safety and Health Act (OSHA)

Government Ministry/Agency in charge:
Ministry of Employment and Labor (MOEL)

Cosmetics

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Overview of the Industry

The cosmetics industry is a high value-added and cultural industry that can be connected to various fields. Consumers have more interests in the environment, and they prefer to purchase more efficient and personalized products. Following this trend, the cosmetics market globally represents more attention for eco-friendly, cost-effective, and customized products.

The cosmetics industry is growing steadily with various distribution channels such as online channels, health & beauty shops and multi-shops, with the expansion of new markets.

The Korean government announced its plans to foster the bio-health industry, including cosmetics, to be made into good quality jobs as national strategic sectors. To achieve this goal, it is important to be in line with international standards.

Key Issue

1. Package Recycle Classification Regulation

Due to short "phasing-out" period and fast-moving trends in the cosmetics industry, a diverse range of products in small quantities gets produced and maintained by the cosmetics companies. For this reason, cosmetics should be exempted from the target scope of the regulation of package recycle classification. It is also very difficult to evaluate and do label package recycle classification of the cosmetics containers under the current regulations due to product composition (i.e. metal spring).

Recommendation

It is recommended for cosmetics to be taken out of the target scope of regulation of package recycle classification. If it is difficult to exempt cosmetics from the regulation scope, it is recommended to conduct an additional review of the current regulation for the cosmetic containers.

Related Laws & Regulations: Resource Recycling Act

Government Ministry/Agency in charge:
Ministry of Environment (ME)

2. Labeling & Advertisement of Cosmetics Using Natural Related Claims

Even though natural/organic cosmetics products are certified based on international standards (i.e. ISO index), if these products do not meet the Korean certification standards for the natural/organic cosmetics, the product's labeling will appear as "we cannot claim". Such regulation impedes the consumer's right to choose the product based on accurate information and is contrary to international standards.

Recommendation

It is recommended to allow labeling and advertisement of natural-related claims including international standards (e.g. ISO index, etc.), when the company can substantiate them according to the regulation on substantiation of cosmetic labelling and advertisement.

Related Laws & Regulations: Cosmetics Act

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

3. Improvement of Free Sale Certification (FSC) Submission Requirements

Free Sale Certification (FSC) is a document certifying that the product is sold in the country, which is one of the requirements for importing cosmetics. The certification is costly and time-consuming due to issuance through the agency of the country concerned. However, FSC does not provide quality or safety information for Korean consumers. FSCs are also required when exporting to overseas markets, such as China. By pre-emptively changing these unnecessary requirements, Korea can expect to reduce unnecessary administrative tasks even when exporting.

Recommendation

Replace FSC with corporation documents of importers (cosmetics marketing authorization holders registered with the MFDS).

Related Laws & Regulations:
Foreign Trade Act

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE) &
Ministry of Food and Drug Safety (MFDS)

4. Improvement of Documents for Submission of Preliminary Report for Customs Clearance

According to the public notification of integration/consolidation, the FSC and Manufacturing Certificate must be notarized to import cosmetics. The Manufacturing Certificate can be sufficiently guaranteed by the manufacturer and supplemented, if necessary, with additional documents signed by the responsible person or the registration of seal of use of the importer (registered cosmetics marketing authorization holders). Notarization procedures do not provide consumers with safety guarantees, whereas they take up additional time and costs.

Recommendation

It is recommended to remove the document notarizing requirement for importation.

Related Laws & Regulations:
Foreign Trade Act

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE) &
Ministry of Food and Drug Safety (MFDS)

5. Improvement of Entry Item of Preliminary Report for Customs Clearance

For imported cosmetics, the concentration of ingredients restricted from use must be entered in the preliminary report for customs clearance. Since the manufacturing certificate already confirms the concentration of ingredients restricted from use, it is a duplicative process to enter the information in the preliminary report for customs clearance. Also, reporting of concentration of ingredients restricted from use is not required for domestic manufactured cosmetic products, so the entry of concentration of ingredients restricted from use is a discriminative application for imported products.

Recommendation

It is recommended to remove the entry of the concentration of ingredients restricted from use in the preliminary report for customs clearance.

Related Laws & Regulations:
Foreign Trade Act

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE) &
Ministry of Food and Drug Safety (MFDS)

6. Recognition of Electronic Documents for Preliminary Report of Customs Clearance

The manufacturing certificate is a document containing prescription information strictly confidential to the company. There is a risk of loss in the process of delivering the original document during customs clearance, and it also incurs additional time and cost. Electronic documents are accepted when the relevant documents are submitted to the government for product review, etc. Therefore, it should also be allowed for preliminary report of customs clearance in electronic form, rather than through the submission of original, physical documents.

Recommendation

It is recommended to allow submission of electronic documents for import customs clearance.

Related Laws & Regulations:
Foreign Trade Act

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

7. Manufacturers Information

For imported cosmetics, a preliminary report for customs clearance through the Electronic Data Interchange (EDI) method must include information on the importer, registration number of cosmetic marketing authorization holders, origin, manufacturer, total fee, name of product, etc. for each and every import. The country name of manufacture, the name of the manufacturer, and the address shall also be indicated on the package of the cosmetics thereof.

Due to such regulations, when importing cosmetics, the manufacturer of the imported cosmetics must be declared, and the concerned cosmetics must be re-registered as new products when the manufacturer changes, even though their composition or name remained unchanged. If the company has a large number of manufacturing sources, but conducts quality control under its head office, indicating the address of the manufacturer as the representative address of the head office of the manufacturer will reduce unnecessary administrative work for both the importers and local cosmetics marketing authorization holders.

Recommendation

It is recommended to delete the name and address of the manufacturer or replace the address of the manufacturer as the representative address of the manufacturer.

Related Laws & Regulations:
Cosmetics Act

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

8. Customized Cosmetics

Only personnel that has the certificate of the customized cosmetics' preparation controller can subdivide and mix the concerned products. It means that customized cosmetics preparation controllers are required to be present at each store, and without a person in charge, concerned business cannot operate.

It is practically impossible to meet such requirements, as it is unclear for companies how many certified controllers are being produced at this early stage. As each company will run the customized cosmetics business with their guideline at their responsibility, it will not be easy to have activities which are out of the guideline. If legal responsibility of the customized cosmetics business is clearly set also to the final sellers, the possibility of the illegal activities will be extremely low.

Recommendation

It is recommended to allow personnel that have undergone proper training on and are well acquainted with the company's guideline, to subdivide and mix concerned products for customized cosmetics without the national certificate. Also, it is recommended for simple subdivisions of cosmetics with low contamination to be excluded from the scope of customized cosmetics.

Related Laws & Regulations:
Cosmetics Act

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

9. Sun Protection Factor (SPF) Indication

Regarding Sun Protection Factor (SPF) indication of sunscreens, it is the norm for manufacturers to indicate the multiples of 5 for easier consumer perception (i.e. SPF labeling guideline of Cosmetics Europe). But, according to Korean regulation (fixed number within below -20% range), there are some cases which the multiples of 5 can't be indicated (i.e. SPF 13, 14, 19). Accordingly, different SPF index on the same product can cause confusion among consumers.

Recommendation

It is recommended to revise the rules of SPF index and set the indication range wider (within the –30% range of the mean).

Related Laws & Regulations:
Regulation on Screening of Application for Functional Cosmetics

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

10. Human Application Test of Functional Cosmetics

According to the regulation on screening of application for functional cosmetics, human application test is a set of data which can prove the purported function (efficacy or effectiveness) of the product when applied to a person. It is accepted in case the result of tests was performed and evaluated under guidance and supervision of a doctor specializing in a related field or an individual with no less than five years of experience in conducting such tests in research institutes, hospitals or other similar establishments. However, an extra guideline for human application test for cosmetics (which was promoted to alleviate the symptoms of hair-loss) provides that the test should be conducted by a placebo-controlled test in principle. It does not comply with the international protocol which recognizes the test result conducted by a before and after trial.

Recommendation

It is recommended that in case of cosmetics that promote to alleviate the symptom of hair-loss, human application test results are accepted both by placebo-controlled test and by a before and after test like other functional cosmetic categories, if the efficacy and effectiveness is proven scientifically and reasonably.

Related Laws & Regulations:
Regulation on Screening of Application for Functional Cosmetics

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

11. Adding “Actors” to the Sanction List of Unfair Labeling or Advertising Forbiddance

According to the ‘Act on Fair Labeling and Advertising’ and ‘Guidelines for Advertising Review of Recommendations etc.’, only "advertiser" shall be punished if any indication of economic interest relationship is not expressed on the recommended posting. However, even if an advertiser makes an effort to enforce a contractual obligation to express to an actor, the controllable scope is limited unless an advertiser has the authority to directly manage the actual actor’s posting. In fact, given the influencer's superior status or influence, the actor should also be included in the regulatory list.

Recommendation

It is recommended to include "Actor" to the regulatory targets for unfair labeling and advertising.

Related Laws & Regulations:
Act on Fair Labeling and Advertising

Government Ministry/Agency in charge:
Korea Fair Trade Commission (KFTC)

12. Establishing the Warrant System for Corporate Investigation by the Korea Fair Trade Commission (KFTC)

Korea Fair Trade Commission (KFTC) does not submit separate search and seizure warrants during corporate investigations and requests the submission of data in the form of "arbitrary holding," which in effect constitutes a form of forced disposal. Companies may even face criminal punishment for obstructing investigations if they fail to submit data, and it is customary for investigators to refer to it from time to time.

Recommendation

Since it is a fact of the public notice that provisional holding is a de facto compulsory measure, it is recommended to ensure that corporate investigations conducted by KFTC to be subject to court control through a warrant.

Government Ministry/Agency in charge:
Korea Fair Trade Commission (KFTC)

13. Establishing the Scope and Format Limit of Data Requests from Korea Fair Trade Commission (KFTC)

KFTC does not restrict the specific criteria or scope of investigations in corporate investigations and, despite having not concerning with the purpose of the investigation, requests materials verbally that could constitute business secrets of the company without a certain format. In particular, delivering all official letters via FAX machine does not conform to the general working environment of the companies (which mainly use e-mail for communication), and allows employees who are not functionally responsible to those official documents to access

Cosmetics Committee

them. It lacks in convenience in document archiving as well as security of confidentiality.

Recommendation

For the investigation, it is recommended to inform the companies in advance on the basis of the investigation and to request only appropriate data within the scope of the purpose, not to interfere with the ordinary operations. In particular, it is recommended that all official letters will have to be delivered via e-mail, etc. on a limited basis to the staff responsible for responding to the investigation.

Government Ministry/Agency in charge:
Korea Fair Trade Commission (KFTC)

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. The domestic fashion market is expected to grow 2.6% until the end of 2019. This seems to have contributed to the success of many industry participants in the fashion and retail sector in Korea. 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 eight 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.

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 imported fashion products to Korea.

Key Issues

1. Direct Shipment Requirement

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 the EU.

Recommendation

It is recommended for the European Union and Korea to agree on

a modernization of the FTA that would allow for repackaging and redistribution in appropriate circumstances.

Related Laws & Regulations:
EU-Korea FTA

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE)

2. Price Labeling Requirement

Pursuant to Article 5-3 of the 'Enforcement Regulation on the Open Price System', the font size of the text on price labels should be over 15 points. While this might be acceptable for more common articles sold at supermarkets (such as E-Mart, Lotte Mart and Home Plus), the required font size is not suitable for all types of products, for which the corporate or brand image is part of important information to be conveyed to consumers.

This is indeed so particularly for globally marketed products for which consistency, for example with regards to the price labels, is of fundamental importance for consumer perception.

Recommendation

It is recommended that the font size of price labels is aligned with globally accepted standards. In order to do so, it is recommended that industry and industry associations are consulted.

Related Laws & Regulations:
Enforcement Regulation on the Open Price System

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE)

3. pH Restriction Level under the Safety Quality Labeling Standard

Non-industrial fabrics are required to have a pH value between 4.0~7.5 pursuant to Clause 1 of Article 4 of 'Supplement 1 of the Safety Quality Labelling Standard'. This standard is more strict than cosmetic products.

Given that these fabrics have a smaller direct contact area with the human skin than cosmetic products, the pH value standard should be broader than that for cosmetic products.

For example, in China, products have been divided into 3 categories and each category applies different pH standard. (for infant products; pH 4.0~7.5, for direct skin contact materials; pH 4.0~8.5, non-direct skin contact products; pH 4.0~9.0).

Recommendation

In light of the fact that non-industrial fabrics have a less direct contact area with the human skin than cosmetic products, we would like to request the Korean government to positively consider applying a pH value standard to non-industrial fabrics that is similar to, if not more lenient than, cosmetic products.

Related Laws & Regulations:
Safety Quality Labeling Standard

Government Ministry/Agency in charge:
Korean Agency for Technology and Standards (KATS)

4. Import 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.

The change in procedure has resulted in import procedures taking up to three times the period it took previously, a subsequent decrease in sales, as well as excessive increases in costs related to testing and storage.

As a result of such change, European companies, whose products are found to be safe in overseas safety tests and whose compliance rates are very high, are experiencing significant disruption to their operations in Korea.

Recommendation

It is recommended that for companies with high compliance rates random compliance checks of the infant textile products are conducted, rather than compliance checks of all products.

Additionally, companies with high compliance rates should further be eligible for self-verification.

Related Laws & Regulations:
Special Act on Children's Products, Customs Act

Government Ministry/Agency in charge:
Korean Agency for Technology and Standards (KATS) &
Korea Customs Service (KCS)

5. 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.

Related Laws & Regulations:
Special Act on Children's Products

Government Ministry/Agency in charge:
Korean Agency for Technology and Standards (KATS)

6. Consultations in Advance of Regulatory Amendments

European companies have broad experience in operating in countries around the world by complying with various local laws and regulations. European companies have accordingly attained empirical knowledge about legislation effective to achieve proper levels of consumer protection. They are committed to contribute to ongoing and future discussions about regulatory reforms in Korea through sharing such knowledge with governmental counterparts.

Additionally, it is practically very difficult for foreign companies to keep abreast of all regulatory changes. Legislative changes require companies to re-adjust their intricate production processes, which quite often results in high cost burdens. In addition to ensuring the introduction of changes that are least trade-restrictive, it is importance that a sufficient period of time between the publication of the regulatory change and its implementation is provided.

Changes in regulations are not effectively communicated by the government, making it necessary for companies to learn about pending changes from service providers.

Recommendation

In order to ensure that the highest effectiveness of regulations, it is recommended that industry (both domestic and overseas) is consulted from early stages of the preparation of new regulations or regulatory amendments. This will allow for relevant global experiences and practical insights to be shared beforehand and will facilitate implementation of regulations.

Related Laws & Regulations:
All

Government Ministry/Agency in charge:
Office of Foreign Investment Ombudsman

Hyokyung Suh
Director,
Food Committee

Overview of the Industry

In April 2019, the public-private taskforce for the functional labeling of general food was founded. It was the result of reflecting the necessity of adopting the system for the food having the health effects proved at a certain level in a scientific way to have the relevant labeling. The draft of revision is expected to be announced at the end of 2019.

As the 'Act on the Promotion of Saving and Recycling of Resources' was revised in December 2018, the recycling level of each product's packaging is required to be evaluated by a government institution, and the evaluation result needs to be marked on the product.

According to the 2017 statistics of the MFDS, the amount of food[1] import reached at USD 21 billion, which has increased by 7.7% comparing with last year and its weight, 17.56 million tons, which has increased by 6.4%. In terms of processed food, its amount reached at USD 6.7 billion, which has increased by 2% than the previous year and its weight, 60.09 million tons, which has increased by 3.5%. As of 2017, the amount of processed food imports from 28 members of the EU reached USD 1.2 billion, which accounts for 17.7%.

1. Agricultural products, livestock products, fishery products, processed foods

Key Issues

1. Definition and Specifications on 'Natural Flavor'

Compared to other foreign countries, Korea has set the limited range of processes and substances allowed for natural flavor. According to CODEX, EFSA and US FDA, natural flavor can be obtained by processes that may result in unavoidable, but unintentional changes in the chemical structure of the components of the flavoring. On the other hand, natural flavor can be obtained by only through physical processes that do not cause chemical change in Korea. Only water, ethanol and vegetable oil can be added for preserving quality and ethyl alcohol, hexane and isopropyl alcohol can be used as extraction solvent to be qualified as natural flavor. As a result, even the flavor that could be qualified as natural flavor in other countries, it must be labeled as a synthetic flavor or mixed blend in Korea.

Recommendation

CODEX and other foreign countries' (EFSA, US FDA) standards set a wide range of processes and substances allowed for natural flavor. It is recommended for expanding the permitted range of processes and substances allowed for natural flavor.

Related Laws & Regulations:
Food Sanitation Act

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

2. Equity is Required Between Good Overseas Manufacturer System and Good Overseas Importer System

Under the 'Special Act on Imported Food Safety Control', continuous benefits and aggressive promotion are granted to the Good Importer System by the government, whereas the Good Foreign Food Facility has benefited rather less or remained stagnant following the enactment of its first regulation. Thus, the Good Foreign Food Facility becomes less effective.

Note that the same evaluation criteria (evaluation table and on-site inspection based on local HACCP standard) and same benefits (exempt from a random inspection) of MFDS are granted, nevertheless, in the case of the Good Foreign Food Facility, all expenses for overseas on-site inspections are paid by an overseas manufacturer, and no further benefits from the government for this system are planned.

Category	Good Foreign Food Facility	Good Importer	Remarks
Applicant	Foreign Manufacturer	Importer	
Evaluation Criteria	Criteria set by MFDS	Criteria set by MFDS	Same
Inspection Cost	Covered by overseas manufacturer	Covered by government budget	Against equity
Benefits	Exempt from a random inspection	Exempt from a random inspection	Same
Further Plan	None	Adoption of a planned reporting system (Revision of administrative notification has been announced)	Against equity

Recommendation

To revitalize the Good Foreign Food Facility System, it is required to operate in the same way as the Good Importer System. It is recommended that the Good Foreign Food Facility's overseas on-site inspection cost to be covered by the government's budget and adopt a planned reporting system to the system.

Related Laws & Regulations:
Special Act on Imported Food Safety Control

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

3. Non-GMO Labeled Products from Overseas

Non-GMO labeling in Korea must meet the requirements as below:

i. Must be included in GMO approved products category (6 kinds: soybean, corn, cotton, canola, sugar beet, alfalfa) for food
ii. Containing more than 50% of the ingredients or those containing the largest quantity of the ingredients subject to labeling.
iii. No allowance for adventitious or technically unavoidable GMO genes in the final products

Within the EU and US, it is possible to mark Non-GMO both raw materials that are approved for use of GMO approved products that do not use genetically modified crops and non-approved products (e.g. peaches, apples, etc.) that do not contain genetically modified foods. Within the EU, Non-GMO labeling is not restricted to any food only if it meets the general condition. In Japan, if packages already have obtained Non-GMO labels in English when imported, the original labels can be used.

Recommendation

We hope the Non-GMO labeling to be improved as following. First, expansion of raw materials allowed for "Non-GMO" labels to the entire food as well as adjusting portion of raw materials. Finally, allowing a bit of adventitious or technically unavoidable GMO genes in the final products. Also, a discussion between the governments to keep the label for EU products could be considered.

Related Laws & Regulations:
Labeling of Genetically Modified Foods, etc.

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

4. Improvements on Food Import Clearance Process

Different requirements on document submission and notation standard for each cargo, despite importing the same products, degrades predictability. If the need for changes to these labels is detected by the MFDS at the point of import to Korea, the importers must go through extra works on attaching stickers or disposing package stocks left in the overseas factories.

i. Different information may be required upon the same product, depending on government officials in charge of importing.
ii. While it is not allowed to review documents in advance, document review and standard examination (physico-chemistry/microorganism) are executed at the same time when a product is imported. Delays in customs clearance may result in pending stocks and penalties by distributors on delays in delivery. Considering duration of marine transport, short expiration date of food, and requirements by clients, it is urgent to cut down time and cost for document review processes and maintenance works during customs clearance.

Recommendation

It is asked to submit relevant documents in a consistent way regardless of persons in charge. It is asked to review the preliminary report system which allows relevant documents including an import declaration and what are marked in Korean to be reviewed before making the import declaration as well as the plan report system which allows the annual import amounts to be reported in advance and import them.

Related Laws & Regulations:
Special Act on Imported Food Safety Control

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

Food Committee

5. Discussion Needed on the Revision of Labeling Among Government Agencies

According to the policies of the Office for Government Policy Coordination, if the laws and announcements related to the regulations of food labeling are revised by each government agency, they will start to take effect on January 1 of the even-numbered year after having more than 1 year of grace period from the revision date regardless of the date and the numbers of revision. However, when the Ministry of Environment has recently discussed the revision related to the announcement of recycling labeling, such policy was pointed out but not considered on the site. Imported food faces disadvantages as needing relatively more time to deal with revisions than domestically produced food. It needs to provide enough preparation time and interim measures if the revision is only about the changes of administrative procedures, not relevant to food safety.

Recommendation

We hope application of the revised labeling requirements by each government agency to be regularized, systemized and all led by the MFDS. Also, we hope sufficient preparation time to be granted.

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

Healthcare

Ansook Park
Director,
Healthcare
Committee

Overview of the Industry

The pharmaceutical market in Korea reached KRW 17.3 trillion in 2018, growing 6.4% CAGR over the last five years[1], while the medical devices market in 2018 reached KRW 6.8 trillion (+10.0% from the previous year) with average growth rate of 8.1%[2].

In many countries, including developed markets such as Europe and emerging markets such as China, new drug development is being promoted with various policies to strengthen the international competitiveness of each country. In 2019, the 4th Industrial Revolution Committee Under the Presidency announced the government's support plan for the development of the healthcare industry. The announced strategy included a pilot system for the production and management of big data in healthcare, new drugs development utilizing AI, establishment of smart clinical trial systems, and the development of smart convergence medical devices, and creation of innovation system in the healthcare industry. It is necessary to continue to provide policy supports to strengthen the country's international competitiveness.

1. IQVIA, market prognosis 2019-2023, March 2019.

2. Press release on 2018 Statistical Data of Medical Devices, Ministry of Food and Drug Safety (2019)

Key Issues

1. Revising the PE Guideline for New Drug Patients Access Improvement

The current Incremental Cost-Effectiveness Ratio (ICER) threshold applied up to 1 GDP/QALY and 2 GDP/QALY for cancer and rare disease drugs are not enough to reflect the burden of disease or patients' social needs. Besides, GDP criteria is outdated and needs to be revised considering its increase from USD 23,000 in 2013 to USD 31,940 in 2019. Also, the criteria about discount rate (5%) and EQ-5D tariff were outdated (no change since the first development 10 years ago) and to be updated.

Recommendation

It is recommended to apply more flexible ICER threshold considering disease severity, alternative available, life years gained rate, quality of life, value of innovation, social needs regardless disease types. Also, the update on the GDP criteria based on the latest available data is necessary as well as decrease in the discount rate by adopting the updated foreign discount rate and Korean

public-sector discount rate. Application of flexible EQ-5D tariff is recommended rather than a single HRQOL measurement.

Related Laws & Regulations:
Regulation for Evaluation Criteria and Procedure, etc.
for Reimbursement Eligibility, etc. of Drugs

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW) & Health Insurance Review & Assessment Service (HIRA)

2. Expanding the Scope of PE Exemption System to Secure New Drug Patients Access

PE exemption was introduced to improve new drug patients' access. However, its criteria are too stringent. The threshold for rare diseases (200 or less) is not in align with the 'Rare Diseases Management Act' (20,000 people or less), therefore many rare diseases with more than 200 patients are not covered. Besides, the formula of A7 prices is outdated, does not properly recognize the value of innovation.

Recommendation

It is recommended to raise threshold for rare disease in HIRA beyond 200 or uniformed orphan drug definition with MFDS and to revise the pricing rule by adopting the current pricing structure in the A7 countries and in consultation with the industry stakeholders.

Related Laws & Regulations:
Regulation for Evaluation Criteria and Procedure, etc.
for Reimbursement Eligibility, etc. of Drugs

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW) & Health Insurance Review & Assessment Service (HIRA)

3. Reforming the Formula Pathway for Fixed Dose Combination Drugs

The price of Fixed Dose Combination (FDC) has been evaluated as the highest component price of sum of 53.55% or each component reference price, which is based on the generic pricing rule. This approach is suitable to set the price of FDC combining off-patient drugs, but it is not recommended for FDCs which include the patented component. Also, it leads the unfairness for innovative FDC and also infringement of intellectual property.

Recommendation

It is recommended to revise the FDC evaluation rule for FDC including patented component and to benchmark the pricing formula for biosimilar (80% of the pre-expired original drug price for three years and then 70%).

Related Laws & Regulations:
Regulation for Criteria for Providing Reimbursed Services in the National Health Insurance

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW)

4. Revising the New Requirements Imposed Through Drug Price Agreement

National Health Insurance Service (NHIS) imposed several requirements to the pharmaceutical companies during the price negotiation since 2018 and regulated them in 2019 without any public comment period. Some requirements are overly strict with little relevance to pricing negotiation. Also, there could be a violation of the principles of EU-Korea FTA which requires the communication with industry when it comes to any changes on regulations or guidelines of general application related to the pricing and reimbursement.

Recommendation

It is recommended to consult with the industry stakeholders on any new requirements or revisions in line with the principles of the EU-Korea FTA.

Related Laws & Regulations:
Evaluation Criteria for the drug to be negotiated, such as new drug

Government Ministry/Agency in charge:
National Health Insurance Service (NHIS)

5. Making the Premium Pricing Policy for Global Innovative Drugs Realistic and Eligible

Final amendment on the premium pricing policy for global innovative drug in January 2019 without any more discriminatory condition to multinational companies. However, new drugs cannot satisfy the condition required by the new criteria, and it is unclear on what purpose the criteria are intended to serve.

Recommendation

It is recommended to revise the criteria of global innovative drugs with fair and reasonable requirements in line with the spirit of EU-Korea FTA, by granting eligibility when three out of five criteria are met.

Related Laws & Regulations:
Regulation for Evaluation Criteria and Procedure, etc. for Reimbursement Eligibility, etc. of Drugs

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW) & Health Insurance Review & Assessment Service (HIRA)

6. Expanding the Scope of Risk Sharing Agreement (RSA) for Better Patient Access

Risk Sharing Agreement (RSA)s have become popular in developed countries since 2000. RSA allows payer to negotiate a net price that is lower than the listed price, which leads to: i) a better management of healthcare cost; ii) a better access for patients with severe diseases to expensive innovative drugs that are hard to cover through conventional pricing and reimbursement system.

In Korea, RSA has been introduced in December 2013, but it is only applicable for some drugs with very narrow scope. Only 23 drugs are under RSA as of 2018. Furthermore, RSA does not apply to latecomer drugs and covers only the first drug of the class, which creates an unfortunate situation of monopoly and barrier to entry. At the end of RSA, generally a 4-year period plus a 1-year extension, a mandatory PE study must be conducted, unless the patient pool is too small and the process for coverage extension too complex.

Recommendation

It is recommended to allow latecomer drugs to offer more treatment options to patients and simplify the process for coverage expansion and revaluation at the end of RSA. Also, it is recommended to extend the RSA period, especially for refund-based RSA, upon the company request or until generic drugs are listed.

Related Laws & Regulations:
Evaluation Criteria for the drug to be negotiated, such as new drug

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW) & Health Insurance Review & Assessment Service (HIRA)

7. Eliminating the Value-Added Tax (VAT) Over-Burden (Or Double-Taxation) of RSA Refund

One type of RSA in Korea is the refund system, through which pharmaceutical companies pay back a refund to National Health Insurance Service (NHIS) based on RSA contract and quarterly notice from NHIS on the reimbursement claims. Even though pharmaceutical companies are paying value-added tax (VAT) based on the listed Maximum Reimbursement Price (MRP), the refunding amount that a company pay back to NHIS is included in the proportion of VAT again. Financial records the refund made to NHIS as the sales deduction in financial book, which is not related to VAT adjustment process under the current regulations. Therefore, there is a double taxation or over taxation from a taxpayer (company)'s point of view. Countries with refunding systems such as the UK, Australia, Italy or France do not have such issue regarding VAT.

Recommendation

It is recommended to revise the 'VAT Act' or relevant refunding process/regulation to allow pharmaceutical companies to not over-pay VAT. Collaborative discussion between Ministries is needed to find the solution align VAT rules and NHIS process.

Related Laws & Regulations:
Operation guideline for price negotiation of RSA

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW) & Ministry of Economy and Finance (MOEF)

8. Introducing an Accelerated Listing Pathway to Save Patient Lives ('Pre-Reimbursement and Post-Evaluation' System)

To improve and accelerate patient access to innovative cancer and rare disease drugs, the government introduced RSA (2013) and PE exemption (2015) pathways. However, patients' access to most innovative new drugs is still limited, and RSA scope is narrow. The PE analysis requires various kinds of evidences, however, some drugs, especially rare disease treatments, cannot develop enough evidence before launch. As a result, it is impossible to set the price of the product. The long period of non-reimbursement creates huge financial burden for patients, decreasing patients' access to treatment.

The 'Pre-Reimbursement and Post-Evaluation' system used in other countries could be a great help for patients suffering from cancer or rare diseases who are in life threatening situation, by accelerating patient access to innovative medicines with limited impact on healthcare budget. Drugs subjected to economic evaluation can select 'Pre-reimbursement' with refunding option after 'Post-Evaluation'. The first National Health Insurance master plan does not include an accelerated listing plan.

Recommendation

It is recommended to accelerate the introduction of new pathways to accelerate patient access such as 'Pre-Reimbursement and Post-Evaluation' system, especially for medicines for cancers, rare diseases or other life-threatening diseases. In particular, pilot projects scheduled in 2020 should consider including a contract-based fast reimbursement scheme when designing the project.

Related Laws & Regulations:
Regulation for Criteria for Providing Reimbursed Services in the National Health Insurance

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW)

9. The 4th National Cancer Care Plan

In Korea, the government is required to establish a National Cancer Care Plan (NCCP) every five years in accordance with the 'Cancer Management Act', with the aim of reducing personal and social burden caused by cancer and contributing to public health.

However, current NCCP focuses on general cancer and lacks policies for rare cancers, which account for 16% of all cancers. Number of rare cancer patients are increasing every year, but support for rare cancer patients is not properly provided.

Recommendation

The 4th NCCP which will take effect from 2021, needs to include the plan for management system for rare cancer, including diagnosis, treatment and support for survivors. In particular, a policy to enhance patients' accessibility to rare cancer medicines is essential, allowing patients with rare cancers to be treated in appropriate time.

Related Laws & Regulations:
Cancer Control Act

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW)

10. National Health Insurance (NHI) Coverage Expansion for Severe and Rare Disease

On April 2019, Ministry of Health and Welfare (MOHW) announced in its first National Health Insurance (NHI) master plan, that it will utilize the saved NHI budget from the re-evaluation of the listed drug price for NHI coverage expansion of severe and rare disease with high social needs.

In line with the master plan, MOHW is planning to introduce 'Severe Disease Drug Expenditure Account', but detailed plan for this initiative is not released yet. The detailed plan should be shared with the relevant industry stakeholders as soon as possible and start the discussion to share opinions and feedbacks.

Recommendation

It is recommended that MOHW to announce its policy measures which can ensure the saved NHI budget from re-evaluation of listed drug price can be utilized for NHI coverage expansion of severe and rare disease. Especially, the scope of Severe Disease Drug Expenditure Account which MOHW is planning needs more clarified details (i.e. innovative new drug for life threatening disease including next-generation genetic treatment) and the account has to be raised without further burden of pharmaceutical companies.

Related Laws & Regulations:
Regulation for Criteria for Providing Reimbursed Services in the National Health Insurance

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW)

11. Reforming the Price-Volume Agreement (PVA) system

For price and reimbursement approval, companies must submit a forecast of the prescription value in the first year and if the value exceeds >30% than the expected forecast, the price cut occurs. After the first price cut, another price cut will take place when there is a >60% value increase or >10% increase with >KRW 5 billion increase compared to the previous year.

New drugs are required to prove its cost-effectiveness or budget saving and clinical benefit etc. through HTA review and price negotiation in order to be registered. As a result, the new drugs are penalized for providing faster access to patients with its probative value.

Recommendation

For a balanced price and reimbursement system, it is recommended to limit the PVA system recognizing value with sound control of budget, PVA should not be the key to control healthcare budget. The price-volume agreement system for new drugs proved clinical benefit, cost-effectiveness, budget impact, comparison with other reference country's price should be limited to control of extreme expenditure (i.e. for drugs with > KRW 50bil sales)

Related Laws & Regulations:
Regulation for Criteria for Providing Reimbursed Services in the National Health Insurance, Operation guideline for negotiation of PVA

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW)

12. Maintaining the Current Pricing System for Loss of Exclusivity (LoE) Drugs with Less Than three Generics (Surcharge System)

MOHW announced the revision draft in July 2019 to limit the period of surcharge system to three-years (maximum up to five years) for the Loss of Exclusivity (LoE) drugs with less than three generics. The reason for such revision could be the technical difficulty in manufacturing or no business value as a result of low price. The LoE drugs already have very low price, which makes it difficult to maintain supply to the market if there is any further price cut. Also, it would directly affect the patients treatment.

Recommendation

It is recommended to maintain the current regulation and carefully assess the risks of LoE drugs' withdrawing from the market caused by low price. Also, it is recommended to extend additional period for LoE drugs with market share exceeding 60%.

Related Laws & Regulations:
Criteria determination and adjustment of the drug

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW)

13. Optimization of Planned Drug Control System E.G. Re-Evaluation, Drug Cost Control (Price Control Per Drug Class)

MOHW announced its plan for drug re-evaluation and drug class-based price control referencing other country prices for chronic or elderly disease as a plan for optimal healthcare budget expenditure, included in the first comprehensive plan for national health insurance.

Re-evaluation needs to be optimally leveraged considering the limitation of RWE and the fact that new drugs are listed with proof of various aspects such as efficacy, cost-effectiveness, budget impact, and reference country prices.

Also, new drugs are required to prove various aspects in order to be registered, making additional price cut solely by reference pricing with other countries is not consistent with the policy principle.

Recommendation

It is recommended to consider the limitation of RWD and the fact

that new drug has proved various aspects such as efficacy/cost-effectiveness for making policy decision.

Re-evaluation should focus on what RWE can prove the uncertainty from fast track reimbursement approval. Also, making additional price cut solely on reference pricing with other countries should be re-evaluated its rationality and legitimacy.

Related Laws & Regulations:
Regulation for Criteria for Providing Reimbursed Services in the National Health Insurance, Criteria determination and adjustment of the drug

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW)

14. Improving the Predictability of Health Care Policies by Enhancing Transparency in Committee Decisions

Healthcare policy decisions are comprehensive decision making, such as new drug accessibility, NHI policies and regulations, and it is important to establish a system in which various stakeholders can maintain transparent, evidence-based decisions.

Transparency has improved with recent decision on disclosure of the meeting minutes of the Drug Reimbursement Evaluation Committee (DREC), but evaluation results and meeting minutes of Severe Diseases Review Committee, PE Evaluation Subcommittee, and Risk Sharing Subcommittee are still not open to public. It is necessary to clarify the role and responsibilities of the Committee, to prevent delays in decision making.

Recommendation

It is recommended that the contents reviewed by each subcommittee under the Health Insurance Review and Assessment Service to share the meeting minutes to the pharmaceutical companies that submitted the evaluation report.

The MOHW shall legitimately consult and exercise arbitration rights in making decisions by the Commission to enhance policy predictability and to make evidence-based decisions.

Related Laws & Regulations:
Regulation for Criteria for Providing Reimbursed Services in the National Health Insurance

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW)

15. Improving Transparency on Actual Transaction Price (ATP) Based Price Decrease

When Actual Transaction Price (ATP) of medicines are below the NHIS reimbursement price, discount-based price cuts will take place every two years. (In February 2018, the prices of 3,619 products were decreased by an average 2.3% (maximum up to 10%), based on an analysis of ATP data from July 2016 to June 2017.

Considering that the 'Pharmaceutical Affairs Act' prohibits wholesalers to sell drugs with a price below than what they purchased from pharmaceutical companies, it is unreasonable to penalize pharmaceutical companies for malpractices from some wholesalers. In addition, the details for calculation method for weighted average prices are not shared, which makes it impossible for pharmaceutical companies to assess price cut decision to prevent recurrences.

Recommendation

It is recommended to share with companies the details about the calculation method of ATP before the implementation of ATP based price decrease.

Related Laws & Regulations:
Criteria for Decision and Adjustment for Drugs

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW)

16. Allowing Foreign-Invested Companies to Keep the License of Their Locally Manufactured Drugs Through a Consignment Manufacture Process

Multinational companies without local manufacturing facilities in Korea cannot hold the product license (marketing authorization) for

their locally manufactured medicines, for which they should transfer the license to a local company. Also, it is challenging for those multinational companies to get the license back even after the license contract with local manufacturer is terminated. Accordingly, those companies are again required to find another local license holder (transferee).

This policy could lead to discrimination in regard to the transfer of ownership and technology and prevents collaboration with the local industry. The scope of consignment manufacture has been expanded and multinational companies allowed to keep their product license for locally manufactured drugs by the revision of 'Regulation on the Safety and Drugs (Prime Ministerial Decree)' which was enforced on October 25, 2018. However, the scope expansion was limited to new drugs and orphan drugs.

Recommendations

It is recommended to allow multinational companies to use the consignment manufacture process for all medicines for which there is a technology transfer to Korean manufacturer, not only for new drugs and orphan drugs.

Related Laws & Regulations:
Pharmaceutical Affairs Act

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

17. Adding a New Option of Multi-Regional Clinical Trial (MRCT) Data for a New Drug Registration

Local clinical data on Korean patients are required for registration of new drugs (NCE & NBE). When local data is not sufficient as per the current bridging data requirement (ICH E5), a drug cannot be approved in Korea or a local bridging study should be performed in Korea, which could delay the approval for a few years. In the EU, the US, Japan and other ICH member countries, Multi-Regional Clinical Trial (MRCT; ICH E17) as well as Multi-National Clinical Trial (containing bridging data; ICH E5) are implemented as an option for proving clinical efficacy & safety of drugs. In China, multinational companies are now allowed to conduct global MRCT and to initiate early clinical program. Also, the registration approval in China are expected to be shortened by three to four years.

Recommendation

It is recommended to put in place MRCT as another option for new drug registration and to have scientific consultation meetings with MFDS during the planning stage of MRCTs to discuss regulatory requirements for the development plan and the acceptability of MRCT data (including required number of Korean patients thorough pooling of regions or subpopulation from MRCT data).

Related Laws & Regulations:
Regulation on marketing authorization

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

18. Creating an Expedited Process for Clinically Urgently Needed Innovative Drugs

In 2018, China has created an expedited process with a waiver on local data for a list of 48 new medicines that are clinically urgent. These products were approved in May 2019, reflecting the country's prioritization of innovation. Coupled with the reference pricing rule (China is now referencing pricing in Korea), Korea is now at a substantial competitive disadvantage compared to China.

Recommendation

It is recommended to put in place an expedited regulatory process with a waiver on local data for clinically urgent innovative drugs to ensure Korean patients could benefit faster from new and innovative options.

Related Laws & Regulations:
Regulation on marketing authorization

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

19. Simplifying the Product Registration Renewals

The product registration renewals have been implemented in Korea for three years and it is time to review its effectiveness. Product

license is effective for five years and a product registration renewals request must be filed six months before the expiration of the drug registration for every five years. If a product was in the market for 20 years, the registration renewals had to be done four times. However, most of the required documents for renewals submission are already submitted/reported to the MFDS as product lifecycle management or safety report management. Re-submission of those documents for renewals does not add value. In the EU, considering the poor effectiveness of the renewals, the regulation has been changed since 2005 and the renewals is done only once, five years after the first registration. Once renewed, the marketing authorization is valid for an unlimited period, unless the authorities decide otherwise on justified grounds (pharmacovigilance, business malpractices).

Recommendation

It is recommended to simplify the product registration renewal process, making reference to the system used in the EU. Five years after the first approval, the license should be renewed once.

Related Laws & Regulations:
Regulation on renewal of pharmaceutical approval

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

20. Creating a Mutual Recognition Agreement (MRA) with EU

There is no mutual recognition agreement between Korea and EU for Guidance on Good Manufacturing Practices (GMP) assessment and quality control testing. Local testing is required for all imported products. Similarly, since MFDS does not recognise the GMP assessment done by other countries, extensive documentation for GMP assessment is required, and it requires excessive business travels between Korea and manufacturing countries to perform on-site inspection.

In 2018, a significant progress has been made with the Mutual Recognition Agreement (MRA) for GMP assessment between Korea and Switzerland. The benefits are to: i) facilitate market access by reducing review time, ii) make it easier for regulatory authorities by reducing duplication of inspections, allowing for greater focus on sites that could have a higher risk and broadening the inspection coverage of the global supply chain and iii) facilitate trade by reducing costs for manufacturers. However, waiver on local quality control testing will be necessary in the future.

Recommendation

It is recommended that the EU and Korea work together to set up a MRA on GMP assessment and quality control testing as part of the upcoming discussion on the future EU-Korea FTA.

Related Laws & Regulations:
Enforcement regulation on the safety of drugs, etc.

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

21. Creating A More Favourable Conditional Approval for Innovative Medicines

A fast track review system has been implemented since 2010 to grant conditional approval to drugs for life-threatened disease such as anticancer drugs based on Phase II study, with Phase III and other required data submitted post-launch. However, the Korean process is much more stringent than the European Medicines Agency (EMA) Conditional Marketing Authorization or the US Food and Drug Administration (FDA) Accelerated Approval Program. The MFDS accepts surrogate endpoints from Phase II study such as objective response rates (ORR), but only for very rare diseases. The requirement to conduct confirmatory Phase III study in the same patient group than the Phase II is not aligned with the common practice in the EU or the US, where confirmatory study is conducted in patients with less refractory or an earlier stage of disease, for obvious reasons such ascetical challenge to introduce a control arm with less effective treatments, no availability of the drug or low prevalence of the late stage, etc.

Recommendation

To accelerate access to new drugs for patients with high unmet needs, it is recommended to improve the conditional approval by conducting confirmatory study in patients with less refractory or an earlier stage of disease and granting full approval based either

on alternative data (i.e. overall survival) from patients' follow-up or surrogate endpoints (i.e. ORR) in case of very rare diseases.

Related Laws & Regulations:
Regulation on marketing authorization, Article 58

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

22. Reducing the Tendency to Request Additional Data During the Investigational New Drug (IND) Review Process for Early Phase Trials

Pharmaceutical multinational companies are focusing their R&D in oncology and immunology, where various combination treatments could greatly benefit different population groups. There are many innovative studies that are being conducted simultaneously during a very early stage, in phase I or IIa.

In Korea, multinational companies still face difficulties in getting CTA approval for early phase trials on time, since MFDS expects more efficacy/safety data than the EU, the US or Japan and requests frequent amendments of protocol which are only relevant to Korea (i.e. eligible patient failed all available treatment options in Korea). It takes longer period to get CTA approvals due to negotiation with MFDS/central research team or to amend the study design. Accordingly, it prevents multinational companies from conducting early phase trials in Korea, despite the fact that these early phase trials have more scientific value for the medical community.

Recommendation

It is recommended to simplify the Investigational New Drug review by reducing the additional data requested by MFDS to attract more early phase trials.

Related Laws & Regulations:
Regulation on approval for investigational new drug application of drugs

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

23. Reforming the Post-Marketing Surveillance (PMS)

Korean law requires a Post-Marketing Surveillance (PMS) period of six years following the approval of a new drug or new combination, to monitor adverse drug reactions not detected during clinical trials and confirm efficacy. The added value of the PMS is very limited in practice. The current system does not bring additional value on top of the data collected in clinical trials. It could be seen as a duplication of the pharmacovigilance system. It does not leverage the state-of-the-art, real-world evidence based on the use of electronic medical records (eMR), which could provide better insights. Many countries either focus their PMS requirements to specific products presenting a special benefit-risk profile like in the EU, or are leveraging eMR and real-world evidence like in Japan.

Recommendation

It is recommended to replace the PMS system with a modern and effective approach based on real-world evidence.

Related Laws & Regulations:
Enforcement regulation on the safety of drugs, etc.

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

24. Revisiting the Repacking Requirements

When there is a regulatory change, packages of the product are updated without a grace period. However, for imported drugs, at least a period six months is needed after the label change to arrive the product with a new label. There are two options for multinational importers: (i) If product release is delayed due to repackaging operations, product supply may be disrupted with risk of out of stock. Thus, importers need to prepare sufficient amount of stock before the newly labelled products arrive in Korea. (ii) Importers need to repackage all the imported products in stock before the newly labelled products arrive. Repackaging, preparation of stocks will save a lot of time, cost and resources and ultimately affect the patients access to the drugs. Also, MFDS has accepted repackaging by importers, but there is a no clear legal grounds for repackaging work and standards for quality management left to the companies' discretion.

Recommendation
It is recommended to create the grace period to 6 to 12 months and to introduce e-labeling to make it easier without compromising the safety. Also, it is needed to clarify the regulation on repacking.

Related Laws & Regulations:
Regulation on labels of drug, etc.

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

25. Innovative Pharmaceutical Company Designation Criteria to Be Fair to Foreign-Invested Companies

Under the 'Pharmaceutical Industry Promotion and Support Act' of 2012, MOHW can designate companies that have contributed to the R&D environment in Korea as Innovative Pharmaceutical Company (IPC) and provide benefits such as tax credit, R&D investment, and drug pricing. As of January 2019, only four multinational companies have been recognized as IPCs out of total 47 IPCs.

The main barrier for multinational companies to be recognized as IPCs is that the designation criteria does not capture activities properly that foreign-invested companies contribute. For example, export status, technical transfer/collaboration with foreign companies are the only designation criteria for multinational companies, while R&D investment paid by the companies' headquarters and run by contracted research organization is not recognized as part of R&D contribution.

Recommendation
In order to facilitate foreign companies' contribution to R&D environment in Korea, which is a critical element to achieve objective of R&D promotion, it is recommended to modify current IPC designation criteria for foreign companies to accurately capture the activities of foreign-invested companies such as open innovation etc.

Related Laws & Regulations:
Regulation on designation for Innovative Pharmaceutical Company

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW)

26. Simplification of Importing & Post-Usage Reporting Process of Ancillary Supplies (Medical Device, Electronic Equipment, Lab Supplies Etc.) Used for Clinical Trials

The ancillary medical device for Clinical Trial of Medicine can be imported under the import confirmation letter issued by MFDS, who confirms the approval status of supplies by foreign RA. This process has been revised in 2017, but it still requires a lot of efforts and times for the preparation of the documents and explaining further details with regional office. For the supplies that are not approved in Korea (but approved in other countries), local guidance requires further explanation from the sponsor in addition to the submission of the accepted evidence approval (i.e. EU CE Certification). In addition, regional office does not accept the manufacture certification in third countries except for the countries where the supplies are manufactured. Also, medical device for research uses can only be exempted from import confirmation letter or not without clear guideline. The MFDS requires protocol for ancillary medical device in addition to clinical trial approval letter of medicine, invoice, catalogue and certificate. After the study completes, post-usage report at the study is also required to be submitted to MFDS.

Recommendation
It is recommended to simplify the review process of foreign approval status for the supplies not approved in Korea, but commercially available in other countries and to make clear guideline on the exemption of supplies for research use only. Also, it is recommended to require the protocol for ancillary supplies and post-usage report after study close, instead requesting the sponsor to maintain such a record internally. Or, allow all importing process of ancillary devices to be replaced with the notification to MFDS with minimum number at the submission of CTA dossier.

Related Laws & Regulations:
Enforcement regulations of Medical Device, Regulations on exemption of import requirements of Medical Device

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

27. Simplifying the Quarantine Process Required for the Customs Clearance of QC Testing Reagents of Animal Origin

Animal origin QC testing reagents should be taken the local release testing and custom clearance in the import quarantine procedure. For quarantine, duplicated certification statement documents are required from both the shipping country and the manufacturing country.

Recommendation

According to EU-Korea FTA regarding consideration of acceptance of conformity assessment of either party, it is recommended that the customs to accept the certification documents from the EU shipping country as is and allow the custom clearance with no further requirement of the duplicated certification from the manufacturing country.

Related Laws & Regulations:
Quarantine Methods and Standards of Designated Products

Government Ministry/Agency in charge:
Animal and Plant Quarantine Agency

28. Removing the BSE Free Statement for Every Batch and Shipment with COS Number

Even though mad cow disease crisis is over for many years in the EU, Korea still requires EU manufacturers to submit to Korea Pharmaceutical Traders Association (KPTA) a notarized Bovine Spongiform Encephalopathy (BSE) free statement document with a Certificate of Suitability (COS) number for every shipment (every batch) before the customs. The COS document is already certified by European Directorate for the Quality of Medicines and the manufacturer produces the product according to the European directives. Also, BSE statement and COS number does not change for every batch. Accordingly, the current regulation is creating additional burden, due to the documentation and notarization process in the manufacturing site and creates a non-tariff barrier for EU medicines, resulting in costs and delays in supply.

Recommendation

It is recommended to submit BSE document only for the first import batch or when there is a change in COS number, to make it easier and secure supply for patients.

Related Laws & Regulations:
Pharmaceutical Affairs Act, Foreign Trade Act

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE)

29. Implementing the Tariff Exemption for Investigational Medicinal Products (IMP)

The IMP custom tariff exemption has been lifted in 2016 with the signing of the EU-Korea and US-Korea FTAs. However, many pharmaceutical multinational companies operating in Korea are not getting the benefits of the FTA as most of the Investigational Medicinal Products (IMP) are not directly imported from the US or the EU, but from the rest of the world. Meanwhile, the custom tariff/VAT has been significantly increased, recorded KRW 11.5 billion in 2016 and KRW14 billion in 2017 among 28 pharmaceutical multinational companies.

Recommendation

In order to promote clinical trials and pharmaceutical industry in Korea, it is recommended to implement the tariff exemption of IMP regardless of the EU and US FTA.

Related Laws & Regulations:
Enforcement regulations of Customs Tax

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF)

30. Improving the Vaccination Fee Scheme to Support Vaccination

Combo vaccines developed to protect multiple vaccine-preventable diseases are prevalent in the EU and the US since the 1990s. They can reduce the stress suffered by kids by reducing the number of vaccination shots and can improve vaccination rate with simpler injection schedules. But there are some constraints that makes it difficult to generalize combo vaccine in Korea, and one of the key reasons is the vaccination fee scheme for combo vaccines. Current fee scheme for combo vaccines reduce the income of hospital/clinic when they use the combo vaccines instead of monovalent vaccines. Similarly, the vaccination fee is not based on the vaccination course but on each vaccine injection, which creates a wrong incentive to increase the number of shots.

Recommendation

In order to reduce injection frequency for infants and to improve vaccination rate, it is recommended to revise the vaccination fee scheme as follow: (i) for combination vaccines, the fee should be based on the number of components or provide an incentive to hospitals contributing to the increase in vaccination rate; (ii) for all vaccines, the fee should be for each course, and not for each shot.

Related Laws & Regulations:
Regulations on consignment of vaccination

Government Ministry/Agency in charge:
Korea Centers for Disease Control and Prevention

31. Eliminating the Double Testing (Local QA Testing) for Vaccines and Medicines

MFDS requests double testing of imported pharmaceutical products: one at the manufacturing before importation and an additional one at the importer local laboratory once the imported product is delivered in Korea. Local manufacturers are only required to perform single release testing at their manufacturing site in Korea. Korea is one of the rare exceptions in the world to perform such a double standard approach, which leads to long delay for product release and higher costs including technical transfer, training and creates a discrimination between local companies and multinational companies.

Recommendation

It is recommended to consider a few pilots with drugs that requires prompt supply and the test method requires high technical methods, (i.e. biologics, DTP-containing vaccines (Tdap, combination vaccines)), and exempt local testing by mutual recognition of both Korea and EU standard. In line with the spirit of EU-Korea FTA, global and local vaccines manufacturers should follow the same inspection periods and the process should be simplified further.

Related Laws & Regulations:
Enforcement regulation on the safety of drugs, etc.

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

32. Cancelling the New Regulation Imposing the Full Testing for Vaccines

In addition to the quality control testing done by manufacturers, MFDS performs a National Lot Release (NLR) testing for biological products and vaccines. But until recently, some testing items were not required by MFDS to make it easier for global manufacturers importing vaccines to Korea since the products were already going through a quality testing. In July 2018, MFDS announced their new interpretation of local testing requirements and asked importers of biological products to perform a full release testing by 2022 regardless of the NLR testing explaining that the NLR is recognized as a quality verification process by the authority which should be separated from importer quality control testing. This creates additional testing requirement for Vaccines with no real added value in terms of quality.

Recommendation

According to the EU-Korea FTA and the clause regarding consideration of acceptance of conformity assessment of either party, it is recommended that MFDS accept the manufacturing site test results and not to require a duplicated importer local testing for imported products.

Related Laws & Regulations:
Regulations on the Designation, Approval Procedure, and Method of Biological Products, Subject to National Lot Release

Government Ministry/Agency in charge:
Ministry of Food and Drug Safety (MFDS)

33. KC Certification for the Service/Maintenance Components of Medical Devices

When the components (spare parts) of medical devices are imported for servicing and/or maintenance purpose, they cannot clear Korea Customs due to the lack of KC certification even the medical device itself was registered in Korea, but the specific component is not clearly stated in the license.

Recommendation

If the imported component is a part of medical device which was already registered in Korea, even the specific component is not exactly stated in the license, it is recommended to provide the alternative option to waive the KC certification such as manufacturer's statement letter or expansion of Korea-EU MRA[3].

3. In the case of KC requirement for radio wave, Korea EU agreed on phase 1 MRA which means KC certification can be issued based on EU test report, but if it expands to phase 2 MRA, the CE certification itself will allow to enter Korea market.

Related Laws & Regulations:
Radio Wave Act, Electrical Appliances and Consumer Products Safety Control Act

Government Ministry/Agency in charge:
Ministry of Science and ICT (MSIT) & Ministry of Trade, Industry and Energy (MOTIE)

34. Import Prices for Reimbursement Pricing Cut

Korean government has used import prices for cutting the reimbursement prices, which lacks procedural transparency.

Recommendation

It is recommended to use actual transaction price system instead of import price. Also, percent margin needs to be investigated properly during the distribution process.

Related Laws & Regulations:
Regulation for Criteria for Providing Reimbursed Services in the National Health Insurance

Government Ministry/Agency in charge:
Ministry of Health and Welfare (MOHW)

Siyoon Kim
Coordinator,
Insurance
Committee

Insurance

Overview of the Industry

The Insurance Committee of the ECCK represents the common voice of the European 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 burden 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 Financial Services Commission and Financial Supervisory Service, in order to advance efficiency of supervision and monitoring
- Ensuring that all market participants compete on the same field under the fair competition environment
- Flexible rules with exceptions rather than 'one-fits-all' rule to support product innovation

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Key Issues

1. Cancellation of Protections to Drivers Driving Under the Influence of Alcohol

In Korea, an average of 40,000 casualties occur as a result of drivers driving under the influence of alcohol. In case of a death of a victim, drunk drivers can avoid responsibility or be reduced by paying a penal settlement of KRW 30 million, while in other countries killing a third party while driving under the influence of alcohol would be considered murder.

Recommendation

It is recommended to revise the current legislations such as 'Criminal Act' and 'Act on Special Cases Concerning the Settlement of Traffic Accidents', while insurance companies should still pay the liability to the victims or their beneficiaries (so the victims and beneficiaries are not affected), such payment should be recovered from the driver at 100% by revising terms and conditions of motor insurance. Moreover, penalties for driving under the influence should be more stringent, up to levels observed at international levels, like in the other OECD countries. In Korea, a death caused by DUI results in a maximum of 1 year imprisonment and penalty of KRW 30 million. Meanwhile, in other countries penalties are as follows: France, maximum 7 years imprisonment, KRW 120 million; UK, maximum 14 years imprisonment, 2 years of driving disqualification (no upper limit on fine); Japan, 1 to 20 years imprisonment (up to 30 years imprisonment depending on the cases); US, different per states (New York, maximum 25 years imprisonment, Washington, maximum death sentence or life imprisonment).

Related Laws & Regulations:
Criminal Act, Act on special cases concerning the settlement of traffic accidents

Government Ministry/Agency in charge:
Ministry of Justice (MOJ)

2. Prior Notice and Disclosure of Increase in Automobile Parts Price

The Ministry of Land, Infrastructure and Transport (MOLIT) releases the standardized repair cost and hours for auto insurance claims based on the results from research projects. However, when it comes to automobile parts price, details like when and how much it will increase are not disclosed to public, infringing consumers' rights to know and choose.

Motor insurance premiums are heavily impacted by spare part

costs. In 2018 the average parts price increase was 15%, and such increase is being transferred to the loss ratio of the insurance companies, which will eventually be transferred to the premium that customers pay (also impacting the Consumer Price Index).

Recommendation

It is recommended to revise 'Regulations on Self Certification for Automobiles and Vehicles Parts' and require part manufacturers to report and register their price increase to MOLIT in order to make the data public and available to insurance companies and the general public. Also, increase in spare parts costs as disclosed by Korea Insurance Development Institute (KIDI) should be automatically reflected, once a year, in the TPPD and OCD cover, to reflect the higher repair cost.

Related Laws & Regulations:
Enforcement Decree of Automobile Management Act

Government Ministry/Agency in charge:
Ministry of Land, Infrastructure and Transport (MOLIT)

3. Simplification of Identity Verifying Process in Quotation of Premiums

Insurance customers are mandatorily required to verify their identity by using digital certificate, mobile phone, or credit card every time they get a quote on a digital platform upon 'Enforcement Decree of the Insurance Business Act' article 43 and KIDI 'Guidelines on Insurance Information Network Management' article 15. Customers are required to go through this identity verification process even for a simple quotation procedure and encounter the same situation again even if they have already completed the identity verification through digital certificate before. It is burdensome to customers to verify identification repeatedly.

Recommendation

If the insurance companies can apply their own verification methods to confirm the customer identity with reminders, the verification process can be further simplified for customer convenience (i.e. the customers can pass the verification process if they already logged in or quote the premiums through the digital platform, by verifying their identify with digital certificate, by accessing with the same device from the same IP or Mac address, etc. and they are informed of their consent history).

Related Laws & Regulations:
Enforcement Decree of Insurance Business Act

Government Ministry/Agency in charge:
Financial Services Commission (FSC)

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

The MOLIT releases the standardized repair cost and hours of domestic cars. Yet, there are no such criteria for imported cars, which often leads to disputes between repair shops and insurers. There are more than two million imported cars registered in Korea, which represents 10% of the total registered vehicles in the country.

Recommendation

It is recommended to establish and disclose standardized repair cost and hours of imported vehicles through research projects.

Government Ministry/Agency in charge:
Ministry of Land, Infrastructure and Transport (MOLIT)

5. Requesting a Supportive Review on the Proposal for Revision of Insurance Law for the Purpose of Prevention of Inheritance of Debts

'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 product.

Credit insurance is an insurance policy in which the insurer reimburses the debt to the lender for the borrower if the borrower dies or otherwise rendered incapable of repaying the debts thus prohibiting the inheritance of debts. Credit insurance (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 (v) provides innovative growth engine in insurance company. With these benefits, credit insurance is used as a social safety net that

Insurance Committee

promotes welfare of the society.

Recommendation

It is recommended to positively review the proposal for revision of 'Insurance Business Act' for the purpose of prevention of inheritance of debts. On July 30, 2018, a proposal for revision of Insurance Business Act to prevent inheritance of debts was submitted by Congresswoman Park, newly adding Paragraph 2 under Article 100 of 'Insurance Business Act' and excluding credit insurance product from the applicability of prohibition provision of forced sale.

Related Laws & Regulations:
Insurance Business Act, Supervisory Regulation of Insurance Business Act

Government Ministry/Agency in charge:
Financial Services Commission (FSC) &
Financial Supervisory Service (FSS)

Intellectual Property Rights

Sven-Erik Batenburg
Director,
Intellectual Property Rights Committee

1. WEF (2018), Global Competitiveness Report 2018.
2. Korea Institute of Intellectual Property (2018) Study on IP-intensive Industries' Contribution to the Korean Economy.

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).

The global perception of IP protection in Korea has gradually increased, with Korea ranking 47th out of 140 countries in terms of IP protection. While reflecting an increase compared to 2018, Korea does rank behind various European countries, as well as Asian countries such as Singapore (3rd), Japan (11th), and Taiwan (29th)[1].

The ECCK is pleased to recognize a number of recent actions to provide a more supportive environment for IP in Korea (and which align with its recommendations in the White Paper 2018). These include the publication of a study on the economic contributions of IP-intensive industries, the organization of a Roundtable on Online IP Protection and Enforcement and the easing of the requirements for customs recordation of industrial designs, patents and plant varieties.

A number of common challenges that could benefit from amendments in legislation or practice are listed below.

Key Issues

1. Studies about Economic Impact of Counterfeit Industry

At the end of 2018, the Korea Institute of Intellectual Property (KIIP), published a study[2] which quantified the economic contributions of IP-intensive industries. These industries accounted for 43% of Korea's GDP, employ 6 million Koreans and on average pay 50% higher wages than other industries. These figures exemplify the importance of IP-intensive industries and will be a helpful resource in the creation of new legislation.

The quantification of the economic contributions of IP-intensive industries has been used by the European Union Intellectual Property Office (EUIPO) and OECD in conducting further research, such as into the economic impact of IP infringements.

The KIIP study can equally serve as an excellent basis of further research. In particular studies into the damage inflicted by the counterfeit industry in Korea would be helpful as research conducted by ECCK has found that counterfeit products remain of appeal[3].

Recommendation

Following on the economic benefits provided by IP-intensive industries, it is recommended that further research is being conducted into the economic impact of IP infringements. In particular, research into the impact of the counterfeit industry, which is estimated to have amounted to 3.3% of global trade in 2016[4], would be helpful.

Government Ministry/Agency in charge:
Korea Institute of Intellectual Property (KIIP)

3. 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.

4. OECD/EUIPO (2019), Trends in Trade in Counterfeit and Pirated Goods.

5. OECD (2018), Governance Frameworks to Counter Illicit Trade.

2. 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 OECD has pointed to the importance of "strengthening co-operation and expanding the scope of international frameworks".[5] It is recommended 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 at all agencies mandated to enforce IPR would be welcomed.

Related Laws & Regulations:
Various

Government Ministry/Agency in charge:
All

3. Ineffective Sentencing of IP-Related Crimes

Article 61 of the 'Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)' 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 Copyright Act', 'Trademark Act', 'Design Protection Act' and 'Patent Act' allow for up to five years of imprisonment and a financial penalty up to KRW 50 million, respectively seven years of imprisonment or a financial penalty up to KRW 100 million in case of infringement.

Unfortunately, however, the actual sentences handed down in IP infringement cases remain low compared to other nations. The level of sentencing in Korea was also indicated as a 'systemic deficiency' and "considered insufficient to ensure adequate deterrence"[6].

6. European Commission (2018) Commission Staff Working Document - Report on the protection and enforcement of intellectual property rights in third countries.

Recommendation

It is recommended that awareness of the importance of IP (as quantified by the Korean Institute of IP) is raised amongst all enforcement officials and judicial authorities, in order to assure their understanding of the implications of IP infringements. This will drive in-depth investigations, motivate vigorous prosecution and result in deterring sentencing.

Related Laws & Regulations:
Various

Government Ministry/Agency in charge:
Supreme Court Sentencing Advisory Council

4. Border Seizures

The ECCK is pleased to note the willingness of the Korea Customs Service (KCS) to align its annual report on seizures of counterfeit products with international standards.

It is further noteworthy that as of November 2018, the KCS has amended article 8-2 of the 'Regulation of Customs Clearance of International Mail Items'. Following such sensible change, officials can seize and store counterfeit products, rather than return these illicit products to their sender.

The quantity of Korean imports and exports has increased by 11% from 2017 to 2018 and is further expected to grow throughout 2019[7]. Such growth combined with the forecast increase of global trade in counterfeit products[8] means that customs officials may be faced with a higher number of counterfeit products.

Recommendation

It is important that an adequate shipment examination rate is maintained, as long as it does not unduly impede on trade activity, and that a sufficient number of officials are dedicated to the examination of shipments.

It is recommended that officials' skills to conduct investigations in a swift, yet thorough manner are developed through a sufficient number of capacity building seminars.

Related Laws & Regulations:
Customs Act

Government Ministry/Agency in charge:
Korea Customs Service (KCS)

7. KCS Statistics.

8. Frontier Economics (2017), The Economic Impacts of Counterfeiting and Piracy.

5. Parallel Importation

Parallel imported products are genuine products which are imported from a different market and sold without the consent of the IP owner. Parallel imports are a matter of concern for IP owners as they complicate supply chain integrity.

Korea subscribes to the international exhaustion doctrine, under which the sale of products by, or with the consent of, the IP owner in any markets leads to the global exhaustion of the IP rights of commercial exploitation over such products. Accordingly, IP owners cannot restrict the sale of legitimately sold products after their first sale, making parallel importation generally permissible. An exception applies where there is a material difference between the parallel imported products and the regular products, however such is not easily found to be the case.

The counterfeit industry has taken advantage of the tolerance towards parallel imports by importing a mixture of parallel imported products and counterfeit products.

Recommendation

It is recommended that all imported products are properly scrutinized in order to avoid continuation of the abuse of the tolerant approach to parallel imported products.

Related Laws & Regulations:
Customs Act

Government Ministry/Agency in charge:
Korea Customs Service (KCS)

6. Investigations at Free Trade Zones

As of the end of 2018, Korea counts 13 'free trade zones' (FTZs) in which a total of 1,132 companies operate. These are designated areas where regular administrative hurdles are alleviated, and bureaucratic necessities are minimized in order to facilitate trade, foreign investment and regional development.

While FTZs provide certain economic benefits, research has shown that free trade zones can be "significant enablers for the activities of counterfeiters",[9] "are a particularly useful tool for counterfeiters,

9. Europol and OHIM (2015), 2015 Situation Report on Counterfeiting in the European Union.

who tend to exploit them regularly in their operations"[10], and "continue to be associated with a number of IPR crimes, and harmonized enforcement standards are still required in certain geographical areas"[11].

While transshipped containers take up the majority of the containers handled at the Busan Port, transshipments are rarely subject to inspection. Additionally, the fact that FTZs are operated by various government entities, elevates the risk of abuse.

Recommendation

In light of the potential for abuse of FTZs, a number of improvements were suggested by the OECD[12]. In line with these, ECCK would like to recommend that: (i) supervision of activities in FTZs is improved; (ii) competent enforcement authorities are allowed to conduct ex officio investigations in FTZs; (iii) cooperation with stakeholders is enhanced and codes of conduct are developed; (iv) specific IPR enforcement policies for FTZ are adopted.

Related Laws & Regulations:
Customs Act, Act on Designation and Operation of Free Trade Area

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE) &
Korea Customs Service (KCS)

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, frustrate detection. This makes it practically impossible for a single agency to completely end the sale of counterfeit products. It is noteworthy that limited structural support from other enforcement agencies (both on a local level, as well as on a national level) has been provided to Seoul's local government officials.

Recommendation

It is recommended that local government officials of other large cities in Korea request the Prosecution Service to be assigned special judicial authority to investigate counterfeiting activities and seize illicit products.

In addition to employing support from local government, it is important that the burden of counterfeit enforcement activities is shared amongst all capable authorities in order to make a lasting impact.

Related Laws & Regulations:
Trademark Act, Unfair Competition Prevention and Trade Secrets Act

Government Ministry/Agency in charge:
Various

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

10. OECD/EUIPO (2018), Trade in Counterfeit Goods and Free Trade Zones: Evidence from Recent Trends.

11. Europol and EUIPO (2017), 2017 Situation Report on Counterfeiting and Piracy in the European Union.

12. OECD (2018), Governance Frameworks to Counter Illicit Trade.

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.

Related Laws & Regulations:
Trademark Act

Government Ministry/Agency in charge:
Various

9. Pro-Active Measures by Online Intermediaries

Over the past decade the number of transactions made through online sources has increased globally. The counterfeit industry has keenly followed such trend and has also expanded to the online space in order to distribute its illegitimate products to (unsuspecting) consumers. In light of such global challenge, the European Commission has published an overview of the most problematic online and physical markets situated outside the EU that are reported to engage in or facilitate IPR infringements.[13]

While the Act on the Consumer Protection in Electronic Commerce, etc. has been amended in 2017 an effort to better reflect the increasing role of online marketplaces, these amendments stop short of making changes that will ensure that no counterfeit products are sold online, and consumers are properly protected. The European Commission also indicated that enhanced attention should be placed on online IP infringements by authorities.[14]

Additionally, while some online intermediaries are committed to protecting their platforms against abuses of their services for the sale of counterfeit products, the adopted practices differ substantially.

Recommendation

In order to protect consumers and enhance the reliability of the e-commerce environment in Korea, it is recommended that new legislation is proposed which takes proper account of the role online intermediaries play.

13. European Commission (2018) COMMISSION STAFF WORKING DOCUMENT - Counterfeit and Piracy Watch List.

14. European Commission (2018) COMMISSION STAFF WORKING DOCUMENT - Report on the protection and enforcement of intellectual property rights in third countries.

Adoption of the following three measures by online intermediaries is further recommended: (i) adoption of keyword filtering systems; (ii) implementation of efficient and expeditious take-down procedures; (iii) deletion of ID and account(s) of sellers caught offering counterfeit products for sale.

Related Laws & Regulations:
Trademark Act

Government Ministry/Agency in charge:
Korean Intellectual Property Office (KIPO)

10. Stakeholder Cooperation on Online Enforcement

Over the past decade the number of transactions made through online sources has increased globally. The counterfeit industry has keenly followed such trend and has also expanded to the online space in order to distribute 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[15] between pertinent stakeholders.

Taking account of such developments, a Roundtable on Online IP Protection and Enforcement was organized in Korea in March 2019. ECCK fully supports such initiative and was pleased to participate together with online intermediaries, rights owners and Korean and EU officials.

Recommendation

As the online sale of counterfeit products is a global phenomenon, ECCK encourages 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).

15. Memorandum of Understanding on the Sale of Counterfeit Goods via the Internet.

Related Laws & Regulations:
Trademark Act

Government Ministry/Agency in charge:
Korean Intellectual Property Office (KIPO)

11. Copyright and Royalties

Korea has signed various international treaties[16], 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 of amongst others their public performance rights.

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 quality for such exemption. Moreover, the applicable fees provided for are exceptionally low and cannot be considered a fair reflection of the value of the music.

Recommendation

In order to establish an environment 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 and that parties are allowed to reach an agreement on the applicable compensation through negotiation.

Related Laws & Regulations:
Copyright Act

Government Ministry/Agency in charge:
Ministry of Culture, Sports and Tourism (MCST)

16. Including the WIPO Performances and Phonogram Treaty, the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") and the Berne Convention.

12. Standard Essential Patents

Global standards are fundamental to today's ubiquitous connectivity. Historically, there was no uniformity between the telecommunication technologies adopted by different regions. With the support of industry, it has been possible to create globally standardized communication technologies that ensure end-to-end system performance and worldwide interoperability.

Over the next decade, 5G will serve 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 defence.

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 recommended 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 contribution of cutting-edge technology to open standards in exchange for the right to license their intellectual property on fair, reasonable and non-discriminatory (FRAND) terms.

Related Laws & Regulations:
Patent Act

Government Ministry/Agency in charge:
Korean Intellectual Property Office (KIPO) &
Korea Fair Trade Commission (KFTC)

13. 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 particular, the ambiguity on the interpretation of (i) 'National Core Technology' defined in the Act on Prevention of Divulgence and Protection of Industrial Technology, and (ii) 'Strategic Technology/Material' defined in the Foreign Trade Act restricts the possibilities for international collaboration for the innovation on a wide array of technologies.

Recommendation

It is recommended that clear guidance is provided on the scope and meaning of 'National Core Technology' and 'Strategic Technology/Material', including explanations and practical examples.

Related Laws & Regulations:
Act on Prevention of Divulgence and Protection of Industrial Technology, Foreign Trade Act

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE)

14. 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.[17]

17. 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.

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.

Related Laws & Regulations:
Trademark Act

Government Ministry/Agency in charge:
Office of Court Administration

15. Statutory Damages

Article 111 of the 'Trademark Act' allows for statutory damage claims, provided these do not exceed KRW 50 million. Given the absence of a minimum amount and the relatively low maximum amount, the current provision is not actively used and accordingly does not have deterrent effect on infringements.

Recommendation

It is recommended that a minimum amount of compensation would be introduced and that the current maximum amount is increased. In order to appropriately alter the aforementioned amounts of compensation, it is further recommended that all relevant stakeholders are consulted.

Related Laws & Regulations:
Trademark Act

Government Ministry/Agency in charge:
Korean Intellectual Property Office (KIPO)

16. Consultations in Advance of Regulatory Amendments

European companies have broad experience in operating in countries around the world by complying with various local laws and regulations. European companies have accordingly attained

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empirical knowledge about legislation effective to achieve proper levels of consumer protection. They are committed to contribute to ongoing and future discussions about regulatory reforms in Korea through sharing such knowledge with governmental counterparts.

Additionally, it is practically very difficult for foreign companies to keep abreast of all regulatory changes. Legislative changes require companies to re-adjust their intricate production processes, which quite often results in high cost burdens. In addition to ensuring the introduction of changes that are least trade-restrictive, it is importance that a sufficient period of time between the publication of the regulatory change and its implementation is provided.

Changes in regulations are not effectively communicated by the government, making it necessary for companies to learn about pending changes from service providers.

Recommendation

In order to ensure that the highest effectiveness of regulations, it is recommended that industry (both domestic and overseas) is consulted from early stages of the preparation of new regulations or regulatory amendments. This will allow for relevant global experiences and practical insights to be shared beforehand and will facilitate implementation of regulations.

Related Laws & Regulations:
Various

Government Ministry/Agency in charge:
Various

Kitchen & Home Appliances

Hyokung Suh
Director,
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 EMC Registration/Certification and Electrical Appliances Safety Certification to be imported.

The processes of certification and import clearance are running systematically, however, delayed updates of Korea's Technical Regulation Standard or the safety standards only apply in Korea often make it difficult to proceed with the certification process of foreign products.

Key Issues

1. Easing Test Standards for Household Scales

The import requirements for scales with measuring capacity of 1kg or less are simpler than that are over 1kg, which needs a formal approval. The procedure to obtain a formal approval is extremely strict. Particularly, digital reading scales require too much information related to key technologies such as source programs. Under these circumstances, foreign suppliers who are unwilling to expose their technical information are giving up exporting to Korea. Due to such strict regulatory hurdles and

requests, household scales available in the domestic market are limited in type and sold at relatively high prices, while detail precision is not even needed for household use. In this regard, the regulation is considered to hamper the purpose of the FTA between the EU and Korea, which has been aimed at giving Korean consumers an opportunity to have access to more various products at reasonable prices.

Recommendation

We recommend 'for commercial use' scales to be clearly distinguished as the ones for formal approval and 'for household use' to be exempted from formal approval regardless of their maximum capacity.

Related Laws & Regulations:
Measures Act

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE) & Korean Agency for Technology and Standards (KATS)

2. Latest Version Needs to be Adopted for the Technical Regulations

The technical regulations for electrical products and components – safety requirements for portable sealed secondary cell, and for batteries made from them, for use in portable application (KC 62133) – adopted International standard IEC62133 (2013.12) and there was no update version acquired since 2012. Therefore, the most recent version (2017) of international standard testing report cannot be recognized in Korea.

The testing reports for newly launched products are mostly updated version so that exporting countries cannot provide 2012 version for only Korean market, which means all the new products need to get tested again in Korea. In this case, importers need to submit 21 battery pack for testing, while only 3 products are needed for tested products in overseas. If the company receive the battery packs via air freight, importers cannot receive more than 4 unit at once because of the maximum limit of the air freight regulation.

Recommendation

We hope the certification process to be carried out efficiently by adopting the latest version of the technical regulation standard.

Related Laws & Regulations:
Electrical Appliances and Consumer Products Safety Control Act

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE) & Korean Agency for Technology and Standards (KATS)

3. Internationalization of the Korean Technical Regulations

According to the revision of secondary cells and batteries containing alkaline or other non-acid electrolyte – safety requirements for portable sealed secondary cell, and for batteries made from them, for use in portable application (KC 62133) of 'Technical Regulations for Electrical and Telecommunication Products and Components' (in July, 2015), the portable cell for handheld devices became subject to the safety verification.

The portable cell was defined as the cell used for portable devices or equipment and its shape was not specified. The cell, in most cases, is covered with its protection circuit along with its end cell in the form of a pack, but small handy devices have such structure that the protection circuit and the end cell are combined on the device's PCB. The ones with the form of a component, the tests (related to vibration, shock, etc.) are conducted with the internal circuits exposed. However, the component that is not a final product needs to be reprocessed into the appropriate form for the test to be carried out. As this is the special case found only in Korea and no such international requirement exists, it is difficult for importers to make exporters understand the situation.

Recommendation

The unification of the safety standards related to certification for electrical appliances is intended to reduce the time and cost of certification of products for importing as well as exporting companies. If the standards concerned are the only way to confirm the safety of portable electrical appliances, it is recommended to propose the Korea's technical standard to the international standards.

Kitchen & Home Appliances Committee

Related Laws & Regulations:
Electrical Appliances and Consumer Products Safety Control Act

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE) & Korean Agency for Technology and Standards (KATS)

Logistics & Transport

Christoph Heider
President, Logistics & Transport Committee

Overview of the Industry

The logistic industry in Korea is and remains an important contributor to economic growth. The competitiveness of the Korean logistic industry is manifested in the Logistics Performance Index published by the World Bank. Korea was ranked 25th in the edition of 2018. In line with the decrease in ex- and import, in- and outbound shipment overall decreased in value and in quantity. Although it needs to be said that companies changed from air cargo to sea freight for their shipments to soften additional cost impacts. Industry watchers indicated also that transhipment at Busan port which remained below previous year in July 2019 might decrease further due to the trade friction between the US and China. The growth perspectives for the express delivery market in Korea was and remains positive as more and more consumers are moving to online purchases. Business challenges in respect to safe-guard sustainable companies' existence remain to a certain degree labor policy, or more specifically wage development and inflexibility of working hours, and in the near future certain transition periods and/or fiscal incentives for an implementation of greener business processes. Lastly, although efficiency at Korea Custom Service can be considered high, certain amendments in the EU-Korea FTA might help to speed custom clearance procedures and therewith indirectly benefiting Korean consumers.

Key Issues

1. Tonnage Tax Regime (TTR)

In order to promote Korean flag and Korean based shipping industry, supported by the Ministry of Oceans and Fisheries (MOF) and Korea Shipowners' Association (KSA), the Ministry of Economy and Finance (MOEF) initiated a Tonnage Tax Regime (TTR) in 2005. The regime has been extended twice, with the current regime to end this year. On July 26, the MOEF announced its 2019 Tax Reform Plan which included a 5 years extension of TTR. The State Council will make their decision on August 27, submitting it to National Assembly on September 3 and with voting expected in December 2019.

Recommendation

It is recommended that the TTR will be extended by a further 5 years as from 2020.

Related Laws & Regulations:
2019 Tax Reform Plan

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF)

2. Coastal Cabotage Exemption

A cabotage rule applies to car-carrying ships not flagged in Korea, to protect domestic shipping industry from foreign competition. As the domestic operators do not have sufficient capacity to cover historic growth in the coastal transport need, the MOF has given temporary exemptions to the rule. The latest starting July 2016, for 3 years. In June 2019, the MOF announced that it will extend the temporary exemption for another 3 years.

Recommendation

It is recommended to grant a new 3-year exemption following June 2019. Also, it is recommended to change the temporary exemption policy to a constant exemption in order to remove uncertainties for involved businesses.

Related Laws & Regulations:
Ship Act, Article 6 (Amended by Act No. 11690, Mar. 23, 2013)

Government Ministry/Agency in charge:
Ministry of Oceans and Fisheries (MOF)

3. Sustainability & Environmental Legislation & Challenges (1)

The International Maritime Organization (IMO) introduced new greenhouse gas (GHG) targets as of 2030 and 2050, but currently no engine technology (with subsequent fuel/energy choice) that can meet 2050 targets is foreseen.

Multinational corporations' ambition is to offer a zero-emission supply chain by 2050. Specifically, multinational corporations would be looking to Korean ship builders to develop engine and energy technology to meet this ambition. It is however necessary for governmental partners with history and capacity within the ship building industry, such as Korea, to cooperate and see both social and economic opportunities in this area. Significant opinion making is needed for Korean ministries and politicians to adopt an understanding of environmental challenges and disruption that lies ahead, and the opportunities that exist for Korean business in being a part of developing solutions to meet these challenges.

Recommendation

It is recommended that the initiatives laid out by the IMO shall be incorporated in the activity plan by the National Council on Climate and Air Quality. Furthermore, Korea should define marine engine and engine technology as a future growth key area.

Related Laws & Regulations:
International Maritime Organization (IMO)

Government Ministry/Agency in charge:
Ministry of Oceans and Fisheries (MOF)

4. Sustainability & Environmental Legislation & Challenges (2)

Scrapping of outdated ships has significant negative environmental and social impact, which is known as beaching, is still the most common method. Multinational corporations have since the last 20 years exercised responsible ship recycling, at significant cost, but available recycling operations globally are becoming scarce.

Some selected multinational corporations have founded the SRTI in March 2018 with the ambition to ensure a responsible ship recycling, establishing a new norm focusing on social, environmental and economic factors. In order to succeed, this initiative needs to be extended. In this respect governmental partners with history and capacity within the ship building industry, such as Korea, are needed to cooperate and to see both social and economic opportunities in this area.

Recommendation

The establishment of strong communication lines with Korean ministries and politicians is recommended in order to adopt understanding of environmental challenges and disruption that lies ahead, but also to get Korean shipbuilders involved. The latter point shall ensure that opportunities that exist for Korean business are explored in being a part of developing solutions to meet these challenges.

Related Laws & Regulations:
International Maritime Organization (IMO)

Government Ministry/Agency in charge:
Ministry of Oceans and Fisheries (MOF)

5. Sustainability & Environmental Legislation & Challenges (3)

IMO has ruled that from January 2020 ships will have to use fuel with a maximum of 0.5% sulfur content, down from the current 3.5%.

Recommendation

In order to meet the IMO targets in a short-term, shipowners will start using low-sulfur fuel, which is more costly than the fuel currently in use. It is recommended to lower the tax rate for low-sulfur fuel to ensure a quick adoption and to ensure competitiveness respectively.

Related Laws & Regulations:
International Maritime Organization (IMO)

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF)

6. 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.

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.

Related Laws & Regulations:
EU-Korea Free Trade Agreement, Article 13

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE)

7. 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 then reloaded by an Logistics & Transport service provider to a vessel to be shipped to the final destination 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 on the determination of direct or indirect shipment. The ECCK recommends that KCS drafts an internal communication to its employees to ensure that a common procedure is established.

Related Laws & Regulations:
EU-Korea Free Trade Agreement, Article 13

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE)

Marine & Shipbuilding

Sven-Erik Batenburg
Director,
Marine & Shipbuilding Committee

Overview of Industry

The global new shipbuilding order volume rose in 2018 by 1.7 percent on-year to 28.6 million Compensated Gross Tonnage (CGT). For the first time since 2012, Korean shipbuilders took up the largest share of CGT orders. Key to the Korean shipbuilders performance has been the receipt of 44% of the global orders for carriers of containers and Liquefied Natural Gas (LNG).

Orders for new shipbuilding in the first half of 2019 however fell 42.3% year-on-year to 10.26 million CGT, with Korea taking up a 30.8% share due to a slump in the tankers and container ships markets.

Korean shipbuilders are still trying to recover from management difficulties in 2016 caused by oversupply and a sharp decrease in orders. With restructuring efforts through downsizing and wage freeze are taking place across the industry, Hyundai Heavy Industries Co. and Daewoo Shipbuilding & Marine Engineering Co. are seeking approval to merge.

The Korean government has continued a localization strategy under which it promotes the use of domestically produced products and parts. This is a hurdle to non-domestic companies that would like to sell their quality products.

Key Issues

1. Policy for Localization of Shipping and Marine Plant Equipment

The Korean government has continued its policy to promote the localization of marine and shipbuilding products. While this policy is rooted in a wish to decrease expenses and the Korean government has indicated that the purpose of such localization policy does not lie in replacing imported goods, it has brought about severe challenges for foreign supplies.

In order to appease the Korean government, local shipyards simply exclude foreign suppliers. Additionally, rather than paying foreign suppliers for products which incorporate their proprietary technology, products infringing upon such technology are produced locally.

The localization policy forces foreign producers to downsize their operations (including cutting down on investments and decreasing their headcount). It further discourages innovation (resulting in a decrease of quality jobs at domestic companies) accordingly making Korean companies less competitive on a global level.

Recommendation

The Korean government should set out to promote technological cooperation between foreign equipment companies (which hold original technologies) and domestic equipment manufacturers.

Products infringing intellectual property (IP) are not acceptable in any industry and proper protection of IP should be ensured. The importance of IP needs to be promoted and IP infringements in the marine and shipbuilding industry actively investigated.

Government Ministry/Agency in charge:
Ministry of Oceans and Fisheries (MOF)

2. Harmonization of Standards

The use of standards leads to enhanced product quality and safety, innovation of business processes, decrease in production costs and increased competition. Importantly, it also facilitates the penetrating of new markets , which is why 'Article 2.4 of the Agreement on Technical Barriers to Trade' (to which Korea is a member by virtue of its membership of the World Trade Organization (WTO)) promotes the use of standards.

In order to enter the Korean market, overseas companies are often required to obtain Korean approvals for their products, even though their products have been certified overseas.

A lack of standardization serves as a barrier to successful trade, making it difficult for foreign companies to enter the Korean market while simultaneously frustrating Korean companies from entering new markets.

Recommendations

It is recommended that the standards used in Korea are aligned with international standards. For the instances where such is

already the case, it is recommended that overseas certifications are also accepted, avoiding time-consuming double testing.

Related Laws & Regulations: Various

Government Ministry/Agency in charge:
Ministry of Oceans and Fisheries (MOF) & Ministry of science and ICT (MSIT)

3. Unfair and Impractical Purchase Terms and Conditions

In 2018 the Korea Fair Trade Commission announced amendments to the 'Act on the Fair Trade of Standard Subcontracts', in an effort to enhance the position subcontractors compared to original business operators. It further provides information on standard subcontracting contracts so that the terms of transactions can be balanced to protect the rights of subcontractors.

Unfair business practices by local shipyards against suppliers remain prevalent. These practices include the requirement to deliver products prior to the finalization of a written contract, undue demands for changes to layouts, unilateral decreases in unit prices and requirements to sign additional unduly burdensome contracts in order to avoid legal liability.

In particular, the requirement to accept unduly one-sided general terms and conditions in online purchasing systems are of concern.

Recommendations

It is recommended that more efforts are undertaken to enhance the actual use of standard purchasing agreement in order to assure transparency and avoid any subcontractors being forced to accept unreasonable conditions in order to be selected.

Additionally, announcing the results of investigations into compliance with the revised subcontract-law is recommended.

Related Laws & Regulations:
Act on the Fair Trade of Standard Subcontracts

Government Ministry/Agency in charge:
Fair Trade Commission (FTC)

4. 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 promotes due consideration for safety, technology, quality and business experience, rather than merely price, in bidding processes.

Government Ministry/Agency in charge:
Fair Trade Commission (Subcontract Division)

Aerospace & Defense

Key Issues

1. Facility Security Clearance (FSC) for Korean Small and Medium - sized Enterprises

The transfer of classified information from European to Korean companies for the performing of subcontracts (including offset) requires that a Korean authority to guarantee (G2G) that the companies are approved to handle classified information by requesting for a facility security clearance assurance. The approval process has been defined for the large defense companies within Korea but is not clear for small and medium - sized enterprises (SMEs).

A total of 89 defense companies are registered as a defense company, according to the 'Defense Program Acquisition Act Article 35 (Designation of Defense Contractor)'. The companies must follow the 'Defense Security Regulation' guided by the Ministry of National Defense (MND). But some SMEs, which produce defense materials, don't have to follow the security regulation mandated by the MND. More than 50% of the defense companies are considered as an SME and a total of 1,427 defense material (441 finished products and 986 parts) listed in Korea.

Recommendation

It is recommended to update and clarify the process for obtaining facility security clearance for SMEs and the G2G process to issue facility security clearance assurance.

Related Laws & Regulations:
Defense Program Acquisition Act Article 35

Government Ministry/Agency in charge:
Defense Acquisition Program Administration (DAPA)

2. Offset Project Process

The submission of an offset project is made through a proposal prepared by a foreign company and sent to the offset team at the Defense Acquisition Program Administration (DAPA). The offset project is then reviewed and analyzed by different teams from DAPA, Agency for Defense Development (ADD), Defense Agency for Technology and Quality (DTaQ), etc. After a few potential iterations to answer questions, the foreign company is then notified if the offset project has been accepted or rejected, without further details or having the chance to plead for the project to make sure the project and its benefits for all parties have been well communicated and understood. The lack of transparency in the decision-making process and feedback represents challenges for the foreign companies for future projects.

Recommendation

It is recommended to update the offset submission process for the foreign companies and its Korean partners. An official presentation (face-to-face) of the proposed offset project to all parties involved in the decision-making (DAPA, ADD, DTaQ, etc.). This would allow the proposed offset project itself and all parties (including end-users, Korean industries, etc.) to communicate better.

Also, an official debriefing session (face-to-face) by the parties involved in the rejection decision is recommended. This would allow to give a chance to clear out any misunderstanding and better understand how to improve next offset project proposal for better chance of success.

Government Ministry/Agency in charge:
Defense Acquisition Program Administration (DAPA)

3. White List for Compliance of Korean Industries

The Korean offset regulations applied on big defense projects impose the foreign companies to cooperate and partner with Korean companies to provide some valuable local content. In particular, the Korean government encourages the collaboration with Korean SMEs for export projects. The European Aerospace and Defense companies are very aware and careful of all international compliance regulations. While they are happy to collaborate with Korean companies, the foreign companies have difficulties to identify the right local partners approved by the Korean Government (i.e. DAPA) for defense projects amongst a multitude of Korean SMEs.

Recommendation

It is recommended to provide foreign companies with an access to a white list of Korean companies or to an official organization that can confirm in a responsive manner if a Korean company is eligible and authorized to work on Korean defense-related projects with a foreign company. Also, it is recommended to provide a timestamped proof of eligibility to the foreign company.

Government Ministry/Agency in charge:
Defense Acquisition Program Administration (DAPA)

4. Inconsistent Application of Evidence / Documentation Required to Prove Eligibility to Attend Explanatory Sessions

When announcing the release of a tender for defense articles, different Integrated Program Teams (IPTs) within the DAPA apply the relevant attendance regulations differently. Specifically, there are differences in the evidence / documentation required to prove eligibility to attend explanatory sessions. When original documents are required to be provided by a bidder, signed personally by the global CEO, it is incredibly difficult to achieve this in the standard 10 calendar days between announcement and explanatory session.

Recommendation

It is recommended to update and reissue DAPA guidelines for IPTs clearly stating that non-original signed documents are permitted.

Government Ministry/Agency in charge:
Defense Acquisition Program Administration (DAPA)

5. Requirement of CEO Signature

The DAPA's requirement for CEO signature on various documents is opposed to the more general international application of power of attorney (POA) documents.

Also, a refusal to acknowledge the business registration documents from home country which clearly state the authorities of the company directors, which permit them already to sign proposal documents, without a specific POA. In practice, this means the companies must get their CEOs' signatures for multiple proposal documents, and it defeats the purpose of POA and the business registration.

The DAPA's 'Regulation No. 415 (General Instruction to Bidder)' requires the signatures of the bidder's representative, president and CEO on each of the different forms. As a result, some officer requests only CEO's signature meanwhile other officers request representative's signature who has a POA.

Recommendation

It is recommended to issue specific guidance to all IPTs to clarify meaning and acceptance of POA documents

Government Ministry/Agency in charge:
Defense Acquisition Program Administration (DAPA)

Energy & Environment

Overview of Industry

The Sustainable Development Goals (SDGs) are global mandates that all developed and developing countries are responsible for achieving by 2030. Korea raised its status in the international community as ranking 18th according to the '2019 SDG Index & Dashboard Report' published by the Sustainable Development Solution Network.

Korea, the 9th largest country in terms of CO2 emissions in the world in 2017, however needs to accelerate its green growth actions, especially in the fields of climate change, energy and air quality. While the International Energy Agency insists that the enhancement of energy efficiency and renewable energy are the most effective policies to impact on the Green House Gas (GHG) emission reduction by 40% and 35% respectively, Korea unfortunately ranks at the bottom of 35 OECD member states in the level of energy efficiency and its rate of renewable energy takes up only 4.4% of total electricity generation in 2018 (according to the Enerdata statistics).

The Korean government should adopt policies and regulations on energy and environment to decrease the pollution, as well as to reach the 2040 objective of 3rd National Energy Plan and Paris Agreement.

Key Issues

1. Electric Vehicle Charging System Standard

Currently, the Korean electric vehicle (EV) charging system adopts IEC 61851-1 Edition 2.0 (issued in November 2012) and IEC-61851-22 Edition 1.0 (issued in January 2011) standards. In 2017, the IEC 61851 updated to Edition 3.0 , which applies to EV supply equipment for charging system and includes significant technical changes, and the latest edition recommends stronger safety requirements. However, the Korean government still applies the old standards. These old standards may cause safety issues to EV car users and operation issue to EV infrastructure operators.

Recommendation

It is recommended to apply updated IEC 61851-1 Edition 3.0 standards for Electrical Vehicle charging system. Especially, for earth leakage protection devices, IEC 61851-1 Edition 3.0 is required to use SI Type or B type Earth Leakage Protection devices with having better anti-noise specification to secure better safety of customers.

Related Laws & Regulations:
Technical Regulations for Electrical and Telecommunication Products and Components (KS R IEC 61851-1)

Government Ministry/Agency in charge:
Korean Agency for Technology and Standards (KATS)

2. Consistency of Renewable Energy (RNE) and Recycling Policies: Biofuel Mandates in Liquid Fuel

Incorporation of biofuel in liquid fuel is an approach to reduce carbon intensity of energy product sales and meet the Paris Agreement targets (incorporation rate in the EU: 10% by 2020). In Europe, biofuel is identified as a main method to reduce CO2 emission for transport, and as a compatible resource with mitigation of organic waste disposal. However, Korea currently limits not only the mandate for biofuel incorporation such as 3% on diesel and 0% on gasoline, but also the production capacity for biofuel.

Recommendation

It is recommended to increase the mandate for biofuel incorporation in diesel and gasoline, including Hydrotreated Vegetable Oil (HVO), and implement a favorable import tariff to biomass for HVO production in Korea. Furthermore, it is recommended to give incentives to HVO production for the local market and create opportunities to develop export markets, and finally to promote and give incentives on R&D for non-mature technologies such as 2G and 3G (woods and microalgae).

Related Laws & Regulations:
Act on the Promotion of the Development, Use and Diffusion of New and Renewable Energy

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE) & Korea New and Renewable Energy Center

3. Favor Gas Power Plant Development

Considering GHG and fine dust emission compared to coal, gas only can back up intermittency of renewable energy, supposed to rapidly increase according to the energy basic plan (targeting 30-35% of renewable energy generation by 2040). A substantial portion of renewable energy in the power generation mix as planned will give a huge burden to the power grid. Gas generation would be the most realistic solution, completed by biomass power plants, compared to coal and nuclear which cannot control their power output flexibly.

However, policies towards LNG are less favorable: (i) the revised tax scheme in LNG for import tariff is 3.8 and custom tariff is 7.2, while nothing is imposed to Coal (ii) dispatchability of gas power plant lags behind coal, because it does not reflect all environmental cost, while coal consumption has increased by 2.4% in 2018 (iii) while the legal framework to access gas logistics (terminal + pipeline) is in place, but the infrastructure is undersized to allow more development.

Recommendation

It is recommended to exempt customs or/and import tariff on LNG, which are not levied on coal in consistency with environmental benefit, include environmental costs of CO2 emission in Merit Order Dispatch, and ensure spare capacity of infrastructure by promoting construction of more gas infrastructure. We also suggest, in complement, to consider replacing coal by biomass in existing coal-fired power plants, and adjust REC allocation accordingly.

Related Laws & Regulations:
Customs Act, Petroleum and Alternative Fuel Business Act, Electricity Market Rule

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF) & Ministry of Trade, Industry and Energy (MOTIE) & Korea Power Exchange

4. Financial Support for RNE: Limit of Current REC (Renewable Energy Certificate)

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 PPA (power purchase agreement) for small and medium generation capacity (typically between 0.3 to 2.0 MW). The implementation of the REC policies doesn't look 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 and to extend applications to smaller capacity and more divers renewable and new energy technologies (i.e. fuel cell, heat pump, etc.).

Related Laws & Regulations:
Act on the Promotion of the Development, Use and Diffusion of New and Renewable Energy

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE) & Korea New and Renewable Energy Center

5. Energy Efficiency in Building: G-SEED Certification for Green Buildings

Korea has established a green building design standard (G-SEED) focusing on building design, but no particular mechanism for operation of buildings, and especially as regard actual energy efficiency or environmental impact during operation. Some other internationally recognized standards like Leadership Energy and Environmental Design (LEED) by US Green Building Council or Building Research Establishment Environmental Assessment Method (BREEAM) by the UK Building Research Establishment address actual performances during operation and throughout the lifecycle of the building, and extend impact assessment to the neighborhood.

Recommendation

It is recommended to extend G-SEED throughout the overall lifecycle of the buildings, especially addressing actual energy performance during commercial operation (including monitoring & verification reports).

Related Laws & Regulations:
Rules for Green Architecture Certification

Government Ministry/Agency in charge:
Ministry of Land, Infrastructure and Transport (MOLIT)

6. Third Party Access to Domestic Electricity Market

In the electricity market, it is difficult to implement low-carbon solutions for energy efficiency especially in buildings, because of restrictions on third party access to electricity sales.

The public monopolistic actor, KEPCO, is entering the Korean market of energy management services through its division KEPCO Energy Solutions, and is bidding against European companies on overseas markets including Europe.

Recommendation

It is recommended to allow private players to develop energy services to clients, including low carbon solutions and on-site electricity sale. Also, we suggest to foster fair competition between all participants in the energy management services industry, in order to reach 2030 targets.

Related Laws & Regulations: Electric Utility Law

Government Ministry/Agency in charge:
Ministry of Trade, Industry and Energy (MOTIE)

7. Third Party Access to Domestic Water Market

The water market is facing a similar situation like electricity market where K-WATER is de facto benefiting from a monopolistic market position for the management of water / wastewater treatment plant and networks in Korea, where it is also entering the industrial and commercial private sectors.

Recommendation

It is recommended to allow private players to develop services for the management of water and waste-water networks in practice, especially aimed at improving the water quality and the none revenues water (NRW) ratio. Furthermore, we suggest to ensure that bidding conditions are consistent between European and domestic companies, especially as regard references.

Government Ministry/Agency in charge:
Ministry of Environment (ME)

8. Accelerating Smart, Sustainable Cities Around the World Together

The Korean government is well poised to accelerate smart city exports to key global markets in the Middle East, Africa, and Asia. However, Korea does not possess all the smart city technologies that are needed to be competitive: (i) Korea can win smart city projects around the world more effectively by working together with the leading EU smart city solution providers; (ii) Korea's winning bids should incorporate a holistic smart city solution that integrates "best in class" smart city partners (some from the EU); (iii) Korea's global competitiveness can be better demonstrated in Korean smart city projects with the world's best in class partners and more competitive holistic smart city solutions.

Energy and Environment Working Group

Recommendation

It is recommended to foster collaboration with leading smart city solutions from the EU, such as sustainable design toward carbon neutral cities, living lab, digital twin, into Korea's smart city projects, and also cooperation with EU technologies for large developments to build the smart/green technologies and community to accelerate Korea's smart city exports. Regular workshops with the EU will support capacity building and global best practices for smart cities.

Government Ministry/Agency in charge:
Ministry of Land, Infrastructure and Transport (MOLIT)

Financial Services

Financial Services Working Group

Key Issues

1. Frequent and short-term noticeShort-Term Notice of Regulatory Changes

New regulations are expected to be implemented within three months or less (sometimes immediately) even for situations which requires time for changing IT system specifications. In addition to frequent changes in regulations, regulators often request certain data and information that are not readily available from entities on short notice.

Recommendation

It is recommended to allow more lead time for implementation of new regulatory requirements and preparation of data/information for entities.

Related Laws & Regulations:
Special Credit Finance Business Act, Money Lending Business Act, Anti-Money Laundering Act, Personal Information Protection Act, Electronic Financial Transaction Act, Credit Use and Protection Act, or other finance laws

Government Ministry/Agency in charge:
Financial Services Commission (FSC) & Financial Supervisory Service (FSS)

2. Influence of Regulators on Business Model and Pricing Decision

Despite the fact that there is no special act that limits the pricing of financial products, regulators take actions in prescribing entities on pricing topics such as delinquent interest rate, early termination penalty, cash conversion ratio of credit card mileage, etc. on the pretext of consumer protection.

Recommendation

It is recommended to allow financial companies to determine the pricing and business model with the requirements of full disclosures to customers. The market should regulate the pricing through the supply and demand principles.

Related Laws & Regulations:
Special Credit Finance Business Act, Money Lending Business Act

Government Ministry/Agency in charge:
Financial Services Commission (FSC) & Financial Supervisory Service (FSS)

3. Retrospective applicationApplication of New Regulations

In the past, the interpretation of new laws requested implementations retrospectively. (i.e. new terms and conditions, interest rate cap, etc.)

Recommendation

It is recommended to stop the retrospective application of new laws and regulations.

Related Laws & Regulations:
Special Credit Finance Business Act, Money Lending Business Act

Government Ministry/Agency in charge:
Financial Services Commission (FSC) & Financial Supervisory Service (FSS)

4. Limited Flexibility of Regulators And Unwillingness to Discuss Options to Implement Regulatory Requirements

The financial entities are commonly faced with slow response rate from regulators on receiving approvals for requests (i.e. new terms and conditions, outsourcing decisions, etc.). Also, there is a high level of inflexibility and evasive response by the regulators when discussing options to meet new regulations, which are for the benefits of the customers. Yet, financial companies are reluctant to pursue discussions on such issues with regulators due to fear of risking regulatory sanctions.

Recommendation

It is recommended to exercise the discretion in the spirit and intent of new laws and regulations and encourage constructive dialogue with financial companies.

Related Laws & Regulations:
Special Credit Finance Business Act, Money Lending Business Act

Government Ministry/Agency in charge:
Financial Services Commission (FSC) & Financial Supervisory Service (FSS)

5. Cap on Growth Rate of Private Loan

To overcome a stagnant business and diversify an existing portfolio, some auto financial companies have started used-car financing business a few years ago and maintained the business to small scale. However, some companies are suffering from the guideline of cap on growth rate of private loan since the newly started business is keep growing in small scale, and it is difficult to meet the guideline.

Recommendation

It is recommended to consider the size of the business when applying the guideline of cap on growth rate of private loan and self-employed loan.

Related Laws & Regulations:
Guidelines

Government Ministry/Agency in charge:
Financial Services Commission (FSC) & Financial Supervisory Service (FSS)

6. Insurance Agency Business

According to 'Enforcement Degree of Insurance Business Act', capital companies are not allowed to be an insurance agency whereas commercial banks and credit card companies are allowed. However, there is a market demand that it is more efficient and beneficial to customer to provide auto financing and insurance services.

Recommendation

It is recommended to revise 'Enforcement Degree of Insurance Business Act' and allow capital companies to act as an insurance

agency for the benefit of the customers.

Related Laws & Regulations:
Insurance Business Act

Government Ministry/Agency in charge:
Financial Services Commission (FSC) & Financial Supervisory Service (FSS)

Human Resources

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

In order to comply with the spirit behind the provision of leave days and avoid abuse, it is recommended that in case of resignations the total leave day entitlement is calculated on a pro-rata basis.

Related Laws & Regulations:
Labor Standards Act

Government Ministry/Agency in charge:
Ministry of Employment and Labor (MOEL)

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.

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.

Related Laws & Regulations:
Various

Government Ministry/Agency in charge:
Ministry of SMEs and Startups (MSS)

3. 52-Hour Working Week

As of July 2018 the Ministry of Employment and Labor (MOEL) has reduced the maximum 68 working hours per week to a maximum of 52 hours per week, in an effort to boost consumption and economic growth.

While the reasoning behind the move is understandable, the stringent application of the requirements has made it very difficult for companies which are faced with high fluctuations in the amount of work, which have to report to headquarters in a different time zone, or whose employees engage in overseas business trips, to comply with the legislation.

Recommendation
It is recommended to increase the number of categories of professions for which a flexible application of the maximum 52-hour requirement can be applied throughout the year.

Related Laws & Regulations:
Labor Standards Act

Government Ministry/Agency in charge:
Ministry of Employment and Labor (MOEL)

4. Workplace Harassment

Following an amendment of the 'Labor Standards Act', a ban on workplace harassment has gone into effect on July 16, 2019.

Article 76-2 defines workplace harassment as "an act of an employer or employee inflicting physical or mental suffering on other employees or worsening the working environment by taking advantage of his/her superiority in status or relationship in workplace beyond the appropriate scope of work". Article 76-3 indicates the measures that should be taken by employers in case of workplace harassment.

While the idea behind the amendment is understandable, the new articles contain terminology that is open to interpretation. This has made it a challenge for companies to understand the articles' scope and take appropriate actions.

Recommendation
It is recommended that more clarification and practical examples as to the interpretation of various parts of articles 76-2 and 76-3 of the 'Labor Standards Act' is provided. In particular, it would be helpful if the MOEL were to inform ECCK of planned information sessions.

Related Laws & Regulations:
Labor Standards Act

Government Ministry/Agency in charge:
Ministry of Employment and Labor (MOEL)

5. Comprehensive Wage System

It is of great importance to both employees and employers to have a clear and predictable salary in place. In order to meet such wishes a comprehensive wage system has been developed, through which various allowances are included in a fixed salary.

There is currently insufficient clarity as to the acceptability of such comprehensive wage system, or the conditions under which it is acceptable.

Recommendation
It is recommended that official guidance is published as to the acceptability and the scope of a comprehensive wage system.

6. Public Holidays for Private Companies

Following amendments to the 'Labor Standards Act', the number of annual paid holidays for employees in retail stores will increase by 200%.

While companies fully support the proper provision of holidays to employees, the inherent nature of retail store activities is different from that of office activities.

The upcoming changes are likely to impact retail store operators in a number of ways that are not foreseen when the amendments were proposed.

Recommendation

It is recommended that institutional or education support is provided in order to assist retail store operators in preparing measures for the additionally required workforce.

Related Laws & Regulations:
Labor Standards Act

Government Ministry/Agency in charge:
Ministry of Employment and Labor (MOEL)

7. Flexibilization of Labor Legislation

Korean labor law stems from the 1960's and focused on creating an effective manufacturing industry. Since such time, the importance of the service economy has increased, increasing the importance of individual intellectual contributions. In 2015, 64% of global GDP was generated by the service sector and 58% of Korea's GDP.

The enhanced importance of individual contributions has made it important for companies to assure that individuals are able to intellectually fulfill their job requirements. In order to take account of such, labor legislation in various countries has been amended to allow for greater flexibility.

The current 'Labor Standards Act' has not been adapted in line with the requirements of the service economy and is particularly rigid in the field of unilateral termination.

Recommendation

It is recommended that the 'Labor Standards Act' is amended to take proper account of the requirements of the service economy, in particular enhancing the opportunities for employers to part ways with employees that do not perform their responsibilities.

Related Laws & Regulations:
Labor Standards Act

Government Ministry/Agency in charge:
Ministry of Employment and Labor (MOEL)

Key Issues

1. APA Completion Process

APA is an important tool for multinational corporations to reduce tax risks and uncertainties in the context of transfer pricing. However, in the case of the bilateral APA the average time taken from the commencement date to the completion date is almost 3 years according to APA annual report. At the same time, the dedicated personnel to the case changes every year so that it causes a lot of cost and time consumption of taxpayers. And the chance of Competent Authority meeting is not enough compared to the preparation procedure of taxpayers.

Recommendation

In order to ensure smooth communication between National Tax Service (NTS) and the taxpayers, it is recommended to limit the fluctuation of the APA team members.

Related Laws & Regulations:
Law for the coordination of International Tax Adjustment

Government Ministry/Agency in charge:
National Tax Service (NTS)

2. 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. It should be based on the audited statutory FS and the FS audit report should be issued by the annual shareholder's meeting (generally middle ~ end of 3rd month after the year-end). Accordingly, by considering issuance date of the audit report, it's difficult to review and file the tax return within a short time frame. Also, it is quite earlier by considering other countries' filing deadline (*China 5/31, US and French 4/15, Australia 6/1, etc.).

*Assuming that the year-end is December 31.

Recommendation

In order to review carefully and file tax return precisely, it is recommended to extend the deadline of the tax filing.

Related Laws & Regulations:
Corporate Income Tax Act

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF)

3. Request for Clarification of the Reporting Criteria of Simplified Payment Statement

Under the 'Individual Income Tax Law', simplified payment statement should be reported for residents' salary income and business income subject to withholding tax, whereas it should also be reported for income attributable to foreign companies according to the relevant reporting template.

Recommendation

The purpose of reporting is relevant to the labor encouragement subsidies application. Accordingly, in order to remove uncertainties, we'd like to ask to exclude income attributable to foreign companies from the reporting criteria of simplified payment statement in the reporting template.

Related Laws & Regulations:
Income Tax Law

Government Ministry/Agency in charge:
National Tax Service (NTS)

4. 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'.

Related Laws & Regulations:
Income Tax Law

Government Ministry/Agency in charge:
National Tax Service (NTS)

5. Application of Transfer Pricing Regulations Under the Law for the Coordination of International Tax Adjustment to Domestic Related Party Transactions

The 'Article 52 (Regulations for rejection of unfair act and calculation) of Corporate Income Tax Act' is applied to transactions made by domestic related parties.

It is required to prepare a basis for applying the transfer pricing regulations in analyzing the arms' length price of a multiple types of complex transactions made by domestic related parties.

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.

Related Laws & Regulations:
Corporate Income Tax Act

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF)

6. 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 Country-by-Country (CbC) notification form. The taxpayers often get 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.

Related Laws & Regulations:
Law for the coordination of International Tax Adjustment

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF)

7. Guidelines for Preparation of Local Files for Financial Companies

The current guideline for preparation of local file is for general companies (e.g. manufacturers, distributors, etc.) so the guideline is not fully suitable for the financial companies. Therefore, there are several items that are difficult for the financial companies to fill in.

Recommendation

It is requested to offer a separate guideline of preparation of the local files for financial companies.

Related Laws & Regulations:
Law for the coordination of International Tax Adjustment

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF)

8. Inclusion of Expenses Occurred Overseas as Global Income Tax Filing Deductible

Individuals who reside five years or more are requested to file their global tax return in May to the NTS. In this respect, income from overseas sources needs to be reported and is taxed additionally to the income from Korean sources. Instead 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.

Related Laws & Regulations:
Income Tax Law

Government Ministry/Agency in charge:
National Tax Service (NTS)

9. 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.

Related Laws & Regulations:
Income Tax Law

Government Ministry/Agency in charge:
National Tax Service (NTS)

10. 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 (e.g. 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 arears refers to national tax only (not local tax).

Related Laws & Regulations:
Law for the coordination of International Tax Adjustment

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF)

11. 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.

Related Laws & Regulations:
Corporate Income Tax Act

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF)

12. Amendment of Tax Laws to Allow Companies to Participate Efficiently in Group Cash Pooling Arrangements

A company in both a lending and borrowing position during the same fiscal year cannot deduct its interest expense of the borrowing according to the non-business asset tax regulations. These rules make it very difficult for Korean subsidiaries of multinational groups to participate in global cash pooling arrangements of the group.

Recommendation

Where a Korean company is a party to a global cash pooling arrangement, exclude surplus cash positions from the definition of non-business assets when applying the non-business asset interest limitation formula (similar to the position if a Korean company has a surplus balance in its bank account with a 3rd party bank).

Related Laws & Regulations:
Corporate Income Tax Act

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF)

13. Allow Deduction for Bonus Payment to Officers Provided Paid in Accordance With Employment Contract

According to 'Article 43-2 of the Presidential Decree of the CITL', bonus payments to officers of a company are deductible only when such

bonus payments are determined in the Articles of Incorporation, shareholders' meeting or board of directors (BOD) meeting. However, most foreign invested companies determine
the bonus in each employment contract under internal rules and policies of the parent company. In particular, for a Korean branch office of a foreign company, it is practically very difficult to change the Articles of Incorporation or hold a shareholders' meeting or BOD meeting just to comply with Korean tax law.

Recommendation

Considering the general practice of foreign invested companies, it is recommended that the CITL is amended to allow the deduction of bonus payments to officers of a company provided such bonus payment is paid in accordance with an employment contract.

Related Laws & Regulations:
Corporate Income Tax Act

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF)

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

As a result of the recent change in 'Article 24 of the VAT Law', zero rate VAT is applied on reciprocal basis for professional services and business support services provided to a foreign recipient. Therefore, Korean taxpayers must check whether the foreign country where the foreign recipient of such service is established provide VAT exemption or zero rate VAT to apply zero rate VAT.

Recommendation

In practice, it is very difficult for taxpayers to check each country's VAT law and VAT treatment of professional service and business support services provided to foreign entities. Therefore, it is strongly recommended that the Korean tax authorities to deliver a list of countries that provide the same VAT treatment (VAT exemption or zero rate VAT) as Korea on professional services and business support services provided to foreign entities so that taxpayers can make reference to such list and determine the correct VAT treatment.

Related Laws & Regulations:
VAT Law

Government Ministry/Agency in charge:
Ministry of Economy and Finance (MOEF)

Tourism

Key Issues

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

Corporation in Korea (a branch of foreign company) and the representative of the corporation has been jointly punished for the violation happened by professional negligence in a third country, owing to the application of 'Immigration Act', Article 99-3 (Joint Penalty Provisions). This article should not apply where such corporation in Korea (a branch of foreign company) or the representative of the corporation has a great difficulty to give due attention and supervision on the violation happened in a third county.

Recommendation

It is recommended to exclude corporation in Korea (a branch of foreign company) or the representative of the corporation from the application of 'Immigration Act', Article 99-3 (Joint Penalty Provisions) for the violation happened in a third county.

Related Laws & Regulations:
Immigration Act, Article 99-3

Government Ministry/Agency in charge:
Ministry of Justice (MOJ)

Appendix

Abbreviation

Abbreviated	Expanded
AEBS	Advanced Emergency Braking System
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
CBI	Confidential Business Information
CCA	Chemicals Control Act
CGT	Compensated Gross Tonnage
CMR	Carcinogenic, Mutagenic and Reprotoxic
CODEX	Codex Alimentarius collection of food standards
CPI	Creditor Protection Insurance
CSV	Creating Shared Value
DUI	Driving Under the Influence
EcoAs	Eco-Assurance System of Electrical and Electronic Equipment and Vehicles
EDI	Electronic Data Interchange
EMC	Electro Magnetic Compatibility
EU	European Union
EV	Electric Vehicle
FDC	Fixed Dose Combination
FRAND	Fair, Reasonable And Non-Discriminatory
FSC	Facility Security Clearance
FTA	Fair Trade Agreement
FTZs	Free Trade Zones
G-SEED	Green Standard for Energy and Environmental Design
GDP	Gross Domestic Product
GHG	Greenhouse Gas
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GLP	Good laboratory practice
GMO	Genetically modified organism

Abbreviated	Expanded
GMP	Good Manufacturing Practices
HACCAP	Hazard Analysis Critical Control Point System
HDV	Heavy-Duty Vehicle
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
KORUS FTA	United States-Korea Free Trade Agreement
KRW	South Korean Won
LDWS	Lane Departure Warning System
LEED	Leadership Energy and Environmental Design
LNG	Liquefied Natural Gas
LoC	Letter of Confirmation
LoE	Loss of Exclusivity
MNC	Multinational corporation
MRA	Mutual Recognition Agreement
MRCT	Multi-Regional Clinical Trial
MRP	Maximum Reimbursement Price
MSDS	Material Safety Data Sheet
NCCP	National Cancer Care Plan
NHI	National Health Insurance
NLR	National Lot Release
NRW	None Revenues Water
OR	Only Representative
ORR	Objective Response Rates
OSHA	Occupational Safety and Health Act
PE	Pharmaco-Economics
PHEV	Plug-in Hybrid Electric Vehicle
PLC	Polymer Low Concern
PMS	Post-Marketing Surveillance
POA	Power of Attorney
PPA	Power Purchase Agreement
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
RFID	Radio-frequency identification
RSA	Risk Sharing Agreement
SDGs	Sustainable Development Goals
SME	Small and Medium-sized Enterprise
SMO	Site Management Organization
SoL	Statute of Limitations
SPF	Sun Protection Factor
SRTI	Ship Recycling Transparency Initiative
SSIC	Substance Subject to Intensive Control
SSIM	Substances Subject to Intensive Management
STOT	Specific Target Organ Toxicity
SVHC	Substances of Very High Concern
TBT	Technical Barriers to Trade
TCCA	Toxic Chemicals Control Act
TPPD	Third party property damage
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TTR	Tonnage Tax Regime
UCTN	Universal Chemical Tracking System

Abbreviated	Expanded
UDI	Unique Device Identification
USD	United States Dollar
VAT	Value-Added Tax

Organizations

Abbreviated	Expanded
ADD	Agency for Defense Development
DAPA	Defense Acquisition Program Administration
DREC	Drug Reimbursement Evaluation Committee
DTaQ	Defense Agency for Technology and Quality
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
IMO	International Maritime Organization
KATS	Korean Agency for Technology and Standards
KCS	Korea Customs Service
KEA	Korean Energy Agency
KECO	Korea Environment Corporation
KEPCO	Korea Electric Power Corporation
KFTC	Korea Fair Trade Commission
KIDI	Korea Insurance Development Institute
KIIP	Korea Institute of Intellectual Property
KIPO	Korean Intellectual Property Office
KPTA	Korea Pharmaceutical Traders Association
KSA	Korea Shipowners' Association
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
MOJ	Ministry of Justice

Organization

Abbreviated	Expanded
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
NTS	National Tax Service
OECD	Organisation for Economic Co-operation and Development
RRA	National Radio Research Agency
UNECE	United Nations Economic Commission for Europe
US FDA	US Food and Drug Administration
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.

- Prominent Platform for Information Exchange: ECCK publishes a variety of periodicals – magazine, newsletter, annual white paper, membership directory, and survey reports – to inform members of current market issues and business trends.

- Networking Opportunities ECCK functions as the first point of contact for European executives or officials visiting Korea and regularly hosts various formal and informal gatherings.

To join us or for more information, please visit our website www.ecck.eu or email us at ecck@ecck.eu.