2018

ECCK White Paper

EUROPEAN CHAMBER OF COMMERCE IN KOREA

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ECCK White Paper 2018

Message from Chairman

Dear Valued Members and Friends,

Following the successful launch of ECCK White Paper (White Paper) in 2015, I would like to proudly present the fourth edition of the White Paper, a compilation of key industrial issues and recommendations from the European business community in Korea, covering the year 2018.

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 trade and investment partners. I am particularly proud to say that over the first half of 2018, the European industry took up the largest share of the total pledged FDI into Korea, being responsible for USD 4.6 billion. 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
Chairman, European Chamber of Commerce in Korea

EUROPEAN CHAMBER OF COMMERCE IN KOREA

ECCK White Paper 2018

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ECCK Introduction

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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)
Chairman 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.

André Schmidtgall (Germany)
Vice Chairman of the Board
Country Retail Manager & Managing Director
IKEA Korea

André is a German citizen and has been holding the position of Country Retail Manager/Managing Director at IKEA Korea Ltd. since 2013. He started his career as Shopkeeper Living Room at IKEA Hamburg in 1993 and had held various positions at IKEA since then - including Store Manager and Deputy Retail Manager. Prior to the current position, he was Retail Manager/Managing Director at IKEA Finland from 2009 to 2013.

Jan Benggaard (Denmark)
Vice Chairman 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.

Board of Directors

Mauricio Coarasa (Mexico)
Vice Chairman of the Board
CFO & Corporate Secretariat
AXA Korea

Mauricio is a Mexican citizen and has been Chief Financial Officer and Corporate Secretariat of AXA Korea since 2015. Before moving to Korea, he was in AXA Mexico (Strategy and Investments). In his pre-insurance life, Mauricio was a financial regulator for the Mexican government, a consultant at McKinsey & Company and a real estate developer at his own firm. Mauricio joined the ECCK Insurance Committee upon arrival to Korea, and since last year he was appointed Chairman of such Committee.

Dirk Lukat (Germany)
Director 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.

Philippe Hubert (France)
Director of the Board
CFO
Veolia Korea

Philippe is a French citizen and is CFO of Veolia Korea since March 2016. He worked for Veolia for the last 15 years in various positions at the Head-Office and as CFO of Water France activities. Before joining Veolia, Philippe worked for Total Upstream in several countries.

Hyun-Nam Park (Korea)
Director 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, also the Head of Global Markets, Korea. Hyun-Nam 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.

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
Sven-Erik Batenburg
Director, Legal & International Affairs
Hwonnarae Ha
Senior Manager, Marine & Shipbuilding/
Logistics Committees
Ansook Park
Director, Cosmetics/
Healthcare Committees
Changhoon Rim
Head, Automotive Committees
Hyokyung Suh
Director, Food/Beer, Wine & Spirits/
Kitchen & Home Appliances Committees
Jeong Hyun Kim
Manager, PR & Communications
So Hyeun Cho
Assistant Manager, PR & Communications
Hyewon Shim
Assistant Manager, Event Management
Hyeeun Cho
Assistant Manager, Membership Management
Hyun Sung Rhee
Manager, Finance Control & HR

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

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

Executive Summary

The annual White Paper is the most important publication by the Chamber since it was first published in 2015. It aims to capture the essence of major industrial issues raised by the European businesses operating in Korea and propose constructive recommendations to facilitate open and effective dialogue with the Korean government and relevant ministries. The White Paper also serves to provide updates of the Korean business environment to the policy makers in the European Commission, 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 white paper includes 123 constructive recommendations to the Korean government and its ministries, worked out by the ECCK Committees and Working Groups. In this respect, the ECCK relied on the input from its 350-member companies, but especially on 110 company experts being a member of the ECCK Committees or Working Groups.

This publication is a compendium of issues and recommendations identified in 2018. Many issues and recommendations included in this publication have been delivered to the Korean government on a steady basis by sending position letters or by participating in governmental meetings. Through continuous efforts by the ECCK and the Korean government, the ECCK was able to build up good relations with various Korean ministries. Yet, naturally, there is still room for improvement to create a more efficient communication channel between the government and the European business community.

The European businesses contributed considerably to the economic development of Korea in many ways. On that note, we strongly believe that the strengthening of communication between the Korean government and European businesses is crucial to support the mutual benefit of both parties. In an all connected world, it is even more important to exchange views and opinions to ensure that the rules and regulations and business approaches are in line with global standards and best practices.

With the rising trade protectionism around the world, the trade

conflict between the G2 heightened as well as the implementation of additional duties on steel and aluminum by the US in 2018. Especially at times like these, Korea should lead conviction and promise as an exemplary role model embracing free trade and free market access. Korea's GDP ranks 11th in the world and ranks 6th in the world's export ranking. These economic indicators clearly show that Korea is in a position to take a more prominent role in the international trade policy arena.

Ensure Additional Inflow of Foreign Direct Investment (FDI) and its Full Utilization

With a capital stock of 32%, the EU is the largest source of Foreign Direct Investment (FDI) stock in Korea, followed by Japan (26%) and the US (19%). In 2017, the FDI made by the EU businesses amounted to USD 6.5 billion, an increase of 68% versus 2016 when the FDI stood at USD 3.8 billion. However, at the same time, Korea ranks 51st among 67 countries in its FDI Restrictiveness Index organized by Organisation for Economic Co-operation and Development (OECD).

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.

When multinational companies, including members of the ECCK, make decisions relating to investments in a particular country, one of the key criteria for consideration is the overall business environment in that country, and the companies usually perform multilateral assessments as a basis for reaching their decisions.

In Korea, there are still many cases where rules and regulations that affect foreign businesses, as well as domestic businesses, change too quickly without adequate input from stakeholders. Sometimes, in some instances, without adequate evaluation on whether the new policies will have the desired effect without unintended consequences. 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.

We believe if a stable and predictable corporate business environment is reached, confidence to Korea would grow, thus drawing further foreign investments and supporting real economy growth. Korea's future economic development can only occur by creating an environment that allows enterprise and innovation to foster.

In this light, ECCK will continue to serve as an efficient communication channel for the European businesses as well as the Korean government and ministries. The ECCK operates various committees and working groups where potential new laws or proposed law amendments are reviewed by industry experts and provide qualified feedbacks to the authorities. Thus, a more structured and enhanced approach would not only benefit European companies but also support the business growth in Korea therewith FDI inflow into the country.

Modernize the Korea-EU FTA and the Korea-EFTA FTA

ECCK would like to encourage all governments involved to work on the modernization of FTAs; the Korea-EU FTA and the Korea-EFTA FTA. The Korea-EU FTA was signed in October 2009 and provisionally applied as from July 2011. While the Korea-EFTA FTA was signed in December 2005 and entered into force September 2006.

Since the conclusion of the final text of the FTA, there have been various developments (technological as well as economical) that have had a certain impact on the way trade is being conducted and with the commencement of the fourth industrial revolution many further developments are to be expected. This means that while the text of the FTA was indeed 'state-of-the-art' at the time it was agreed upon, this is not necessarily the case anymore. In fact, certain aspects of the FTA are presenting hurdles to trade, contrary to the purpose of the FTA.

The aforementioned obsolesce of certain parts of the FTA, combined with the expansion of free trade by both Europe and Korea means that in order to safeguard Korea-EU and Korea-EFTA trade, there is a need for modernization of the FTAs. While it would be a fundamental benefit for modernizations to be discussed and implemented on a continuous basis, the current situation has placed a certain urgency on such modernization.

Thus, it is of utmost importance to modernize certain aspects of the FTA among others, so that:

- Truck tractors are included and covered by the Korea-EU FTA,
- Aviation products repaired and re-entering the Korean market are exempted from duties,
- Goods where indirect shipment is applied do benefit from the Korea-EU FTA, and
- Rules and regulations related to equivalence procedures are understood and applied in the same way by both contract partners.

Further Enhance Fair Competition

The ECCK White Paper focuses only on industry specific issues and not on company specific issues. This nevertheless does not mean that those issues do not exist. The ECCK has observed various situations where – from our point of view – unfair treatment regarding financial or other transactions have been made negatively impacting the European businesses. The ECCK delivered such cases to the Office of Foreign Investment Ombudsman.

Fair competition can be evaluated from various directions; fair competition is also to driven by various stakeholders. The ECCK believes that substantial efforts have been undertaken to establish a more fair and transparent market place in Korea. Those initiatives and support – 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 hinders accomplishing the goal of building a fair and open competition in Korea.

- The Korean government launched a pricing policy for innovative drugs in 2016. This policy primarily was launched to honor innovative developments of pharmaceutical drugs. However, the policy is beneficial primarily for Korean pharmaceutical companies while European and other multinational companies only could fulfil those requirements theoretically as defined in the act. Thus, the revision of the act or the introduction of different method to honor innovative drugs of European healthcare companies would lead to an even playing field for Korean and European companies.

- European companies participating in bidding processes in the Marine & Shipbuilding industry are faced with the problem that certain specific conditions are to be met which can be in fact only be satisfied by the local companies. The introduction of a standard purchase agreement in which clauses can be reasonably accepted by both sellers and buyers would lead to a more fair and transparent business environment.

- The Korean government has launched in April 2018 the "Shipping Industry Revival Five-Year Plan" to support the country's ailing shipbuilding industry. It needs to be ensured that benefits of this plan does not solely benefit the Korean companies as then it would rather be a pure governmental subsidy program; instead it is recommended to seek alternative ways to help domestic and global shipping companies to grow through cooperation and coexistence.

Fair competition is also an issue in respect to certain governmental agencies. The ECCK was able to observe accelerated activities toward certain European enterprises by the governmental agencies such as in audits or other investigations. In some cases, it is perceived by companies even as concerted activities when audits or investigations are carried out by different agencies either at the same time or within a short time frame. The ECCK also considers some of the financial penalties and dues as being disproportionate. This perception – also fuelled by the respective media coverage – had a negative impact on the business sentiment. Overall, the ECCK would like to encourage the Korean government and its respective agencies to review the procedures in respect to delivering a fairer and even playing field for both

Korean and multinational companies.

Conclusion

Europe is and will remain a reliable and important economic partner for Korea. European business leaders are committed to maintain and even further expand its business which will support the growth of national economy as well as the job creations in the future.

However, business need a consistent, predictable, reliable, and transparent policy making. We believe this can be achieved by the establishing a stronger communication channel between the European businesses represented by the ECCK and the Korean government. This would allow European businesses to get involved in policy formulation and share their experience and insights about international rules and 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 nevertheless 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 feedbacks are received. The further economic development of Korea is a joint effort in which the European business community is an essential part of.

ECCK Committee Reports

Automotive

Changhoon Rim
Head,
Automotive
Committees

Overview of the Industry

Imported automobiles accounted for about 13% in the domestic passenger vehicle market in 2017. European automakers have a share of more than 70% in the total imported car market, continuously taking up a high ratio in Korea's imported automobile market. In terms of the commercial vehicles market, European commercial vehicle manufacturers have remained strong as their dump trucks and tractors earned a market share of 71% and 75% respectively in the domestic market in 2017. While midsize and large-size cargo trucks recorded a market share of 8.2% and 26.4% respectively, they showed a rapid growth compared to that of the last year (midsize: 4.1% and large-size: 22.5%.) Meanwhile, it was analyzed that the reason behind the fact that the total sales volume of dump trucks in Korea decreased by 36% compared to the previous year was the slump in the domestic construction business. In the tire market, domestic tire makers still account for a high sales ratio but imported ones including European ones are armed with high performance and distinction. They are often installed in premium vehicles and they are continuously expanding the domestic tire market's variety.

Since January 10, 2018 eight (8) more part items were added to the self-certification of the parts. The applicable parts have to meet the Korean safety standards and then, should be sold with KC mark attached. In addition, in order to prevent the accidents of heavy commercial vehicles, the vehicle categories which should install safety device such as LDWS (Lane Departure Warning System) and AEBS (Advanced Emergency Braking System) were expanded to all bus category vehicles and trucks of more than 3.5 tons except forlight duty van and few vehicle categories.

In regard to automobile environment related fields, as a lot more attention is being paid to clean air, various environment related policies have been planned and implemented. The national roadmap to reduce greenhouse gas emissions leads to the preparation of the policies to decrease in the transportation industry. The researches on the guidelines of green house gas for heavy duty commercial vehicle are being conducted and the green house gas standards of passenger cars expect to be established after 2020. By adopting the emissions rating system, all vehicles are rated on a scale from 1 to 5 and the system expect to be used in Low Emission Zone (LEZ) in the future.

Regulations for driver safety have also been newly prepared and enforced. Automakers are providing information on complimentary repair service and quality to relevant authority and they can provide the information on automobile field quality in a more transparent way through the system of submitting manufacturers' data executed since 2017. Meanwhile, a so-called 'Lemon Law' expects to be enforced from 2019 to guarantee the exchange or refund of a new car if it repeatedly suffers from breakdown.

When it comes to tire related regulations, the standard of tire's minimum energy consumption efficiency is ready to be raised and the system of indicating noise-performance of tires is also planning to be enforced. In addition, the adoption of the standards of energy efficiency for the tires for trucks and buses is under preparation.

Under such market environment, the European automobile industry has continued its business to expand the trade with Korea and vitalize the domestic auto market, through enhanced investment and employment in Korea as well. In addition, its growing role in the Korean market leads to its active participation in various CSR activities.

According to the EU-Korea FTA, the safety standards of motor vehicles and parts have been harmonized with the international standard, through which trade barriers have been lowered and the FTA has been practically carried out. However, the industry is likely to face some challenges in its actual operation and application process and therefore, it needs to work closely with the government to resolve the challenges.

In regard to environment field, several systems including the system of corporate average greenhouse gas emissions, obligatory sales of low-emission vehicles and the fund for eco-friendly vehicles have been reviewed and conducted. In order to maximize the efficiency of such systems, automobile manufacturers should be given clearer guidelines for compliance by thoroughly examining whether each system has double regulations and actual effectiveness and how much they affect the competitiveness of the domestic auto industry. In addition, for the electric vehicles (EVs), which are the essential part of ecofriendly vehicle distribution, automobile manufacturers should make efforts in the distribution and the public should also put efforts in building relevant infrastructures as well as being a supportive role in such distribution.

The business surroundings of the current domestic automobile industry are about strengthening the management of automobile safety, protecting the environment and expanding customer rights. Accordingly, the government is pursuing several policies and systems in line with this direction. European automakers are also actively supporting such government policies, but it needs to be considered that some different conditions are applied to them as they are based overseas. In this sense, the Korean government and the European manufacturers need to continuously cooperate to achieve the common goals of creating a better regulatory and trade environment for the development of the automotive market in Korea.

Key Issues

Passenger Vehicles Committee

1. Enforcement Date of Crash Safety Standard Amendment

In April 2018, the legislation of some amendments was preannounced to the Rule regarding Performance and Standards of Vehicles and Vehicle Parts and it is planned to adopt the new standards of crash safety standard; partial frontal and pole side crash. The EU also plans to adopt these crash safety standard revisions, but its enforcement date is different from that of Korea, which can raise possibility of non-tariff barriers against the import of European vehicles into Korea. It is expected that Korea plans to enforce the new crash safety standards in September 2020 for new models and January 2022 for existing models; whereas in the EU, after 2022 for new models and after 2024 for all new vehicles.

Recommendation

It is necessary that the enforcement date for the new crash safety standards amendment of the Rule regarding Performance and Standards of Vehicles and Vehicles Parts in Korea is identically harmonized with that of the EU.

2. Test Standards of Traction Battery for EV/PHEV

48.7.1, 48.7.2 and 48.7.7 of the attached Table 1 of the enforcement regulations of the Automobile Safety Standards state the

standards of the safety test (drop test, salt water immersion test, and flammability test) for traction battery. However, such standards are very specifically tailored to Korea, the tests are not being carried out in any other countries. Moreover, automakers are questioning whether such safety standards are practically needed to assure the safety of vehicles. In the case of flammability test, in particular, its test conditions including temperature are different from those of other countries and they are considered to be rare occurrence in the field.

Recommendation

Considering the fact that some of the test conditions for traction battery are applied particularly to Korea only, we request to review the elimination of the test standards of drop test, salt water immersion test and flammability test from Vehicle Parts and 48.7.1, 48.7.2 and 48.7.7 of the attached Table 1 of the enforcement regulations of the Automobile Safety Standards.

3. Recognizing Parts Self-Certification According to Vehicle Self-Certification

According to the current 2-5 of Article 30 in Motor Vehicle Management Act, it is indicated that when a motor vehicle manufacturer has performed self-certification of a motor vehicle, the motor vehicle parts installed on the relevant motor vehicle shall be deemed to have undergone self-certification of parts. However, this article is not clearly interpreted for some cases, resulting in additional works for the parts self-certification process. One of the objectives of parts self-certification is to prevent the defective parts that do not meet the safety standards being sold in the market. Moreover, the parts which have gone through the process of vehicle self-certification by automobile manufacturers can be considered as satisfying the vehicle safety requirement. Accordingly, it seems appropriate that the recognition of parts self-certification specified in 2–5 of Article 30 of the Act should include parts installed in vehicles and the service parts with equivalent specifications.

Recommendation

It is necessary that the approval scope of parts self-certification indicated in the 2-5 of Article 30 in Motor Vehicle Management Act to include the parts installed on the vehicle and the parts with identical specification.

4. Recognizing UNECE Type-Approval According to the EU-Korea FTA

Article 8 of the Annex 2-C of the EU-Korea FTA states the recognition of UNECE Type-Approval certificate about the technical standards of Korea. However, the UNECE Type-Approval is limitedly recognized in the actual process of self-certification and follow-up management and is not fully accepted as the document that can guarantee technical standard of Korea.

Recommendation

We request the revision that UNECE Type-Approval certificate is practically recognized as the document to guaranteeing Korea's technical standards according to Article 8 of the Annex 2-C of the EU-Korea FTA.

5. Standard for Corporate Average Greenhouse Gas (GHG) Emissions

Automobile manufacturers are given the target goal regarding the corporate average GHG emissions for passenger vehicles by 2020. However, considering the fuel economy technologies and the portions of low-emission cars that automakers have, it seems challenging to achieve the target. Thus, more Electric Vehicles (EVs) need to be distributed for the achievement and apart from the efforts made by automakers to expand the sales of electric vehicles, building a reliable social infrastructure for EV operations is prerequisite prior to the EV sales. Eco-innovation systems are currently executed but more flexibility should be provided to the manufacturers for the achievement.

Recommendation

In order to achieve GHG Emissions target for passenger vehicles set for corporates, it is necessary that expanded policies need to be prepared to provide more flexibility to automobile manufacturers.

6. Recognizing Test Reports on Emission, Fuel Economy and Noise

Regarding the current test reports used for the measurement of emission, fuel economy and noise, the approval range for manufacturers' test reports is limited to the assured testing

facilities with confirmed testing facilities and domestic testing institutions. However, the test reports from European Type-Approval (TUV, VCA, RDW) are considered reliable and therefore, it seems necessary to recognize the test reports from European Type -Approval without having extra assurance of testing facilities.

Recommendation

It is necessary to expand the approval range so that the test reports for emission, fuel economy and noise measurement made from European Type-Approval Institutions (TUV, VCA, RDW etc.) can be recognized without having extra assurance of testing facility.

7. Recognizing the International Standard Process Regarding EcoAS Operation

In regard to the operation process of EcoAS (Eco-Assurance System of Electrical and Electronic Equipment and Vehicles) in Korea, there are limits in recognition of international standard such as IMDS, ISO and REACH since it operates centrally with seperately prepared domestic standard in follow-up management. However, IMDS and ISO need to be recognized since they are the processes internationally standardized for EcoAS operation.

Recommendation

We request for flexibility in recognizing an international standard system such as IMDS and ISO when operating EcoAS.

8. Specifying the List of Emission Related Components

As indicated in the Article 76 of the enforcement regulations of the Clean Air Conservation Act, Emission Related Components (ERC) are already specified but if there are parts that are not specified clearly, it poses difficulty on the procedure progress for change certification/reporting. Particularly, as shown in the Note 1 of the Table 20 from Clean Air Conservation Act, if it is defined as 'the product that has identical function or similar function due to the alteration made by technical advance', it is difficult for manufacturers to decide whether it is applicable to certification/reporting. If ERC are specified in more detail, automobile manufacturers are able to proceed with more thorough certification/reporting for alteration of ERC after deciding the ones subject to change certification/reporting more easily.

Recommendation

It is necessary to remove Note 1 of the attached Table 20 of the enforcement regulations of the Clean Air Conservation Act and have the amendment to designate the ERC parts subjected to certification/reporting more clearly.

9. The Term of Validity of Test Report on Vehicle Energy Efficiency

(1) of Article 9 of the Rule regarding Energy Efficiency and Rating Label of Vehicle indicates that the term of validity for the energy efficiency test report as 90 days. However, the automobile manufacturer proceeds emission certification with same test report, but it does not specify the term of validity. It seems that the validity of the test report that has passed 90 days does not get affected, thus, is seems unnecessary to set the term of validity for energy efficiency test report as 90 days.

Recommendation

We request to remove the term of validity of 90 days for the energy efficiency test report which is specified in (1) of Article 9 of the Rule regarding Energy Efficiency and Rating Label of Vehicle.

10. Notification of Recall for Not Delivered Vehicles

When the correction of manufacturing defects (recall) occurs, domestic vehicle manufacturers have to notify it based on whether a vehicle is delivered to a customer or not. On the other hand, import vehicle manufacturers have to notify it based on whether it has gone through the customs clearance. Therefore, even when the applicable vehicle is not delivered to a customer yet, import vehicle manufactures have to send out notification on its manufacturing defect correction (recall). For example, sending a mail notification to a vehicle owner or announcing it to the media. However, this process is not in accordance with the purpose of the notification which is to inform the correction of recall to the vehicle owner. And it takes unnecessary time and cost to proceed the notification process if there is no actual vehicle owner.

Recommendation

We request that by revising the conditions of vehicles subject to the correction of manufacturing defects (recall) specified

in the Automobile Management Act and change 'the vehicles manufactured and etc.' to 'the vehicles registered', so that the vehicles sold become the subject to the requirement if the notification on the correction of manufacturing defects.

11. Process of Reporting the Plan of Recall

In order for automobile manufacturers to report the plans of recall, they have to visit both the Ministry of Land, Infrastructure and Transport (MOLIT) and Korea Automobile Testing & Research Institute (KATRI) to conduct a face-to-face reporting. However, the reporting system has already been well-established to provide enough information and therefore, a face-to-face reporting process is unnecessary. The reporting to both the MOLIT and the KATRI is also considered redundant.

Recommendation

We hope that reports on the manufacturing defect correction plan has to be completed through the system. In addition, we request to unify the reporting channel into one (the MOLIT or the KATRI.)

Heavy Duty Commercial Vehicles Committee

12. 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 standards of seat belt anchorage, in particular, even though they meet the safety standards of the EU, Korea's safety standards are not recognized by the FTA equivalence rule.

Recommendation

We request that by revising the applicable articles of the EU-Korea FTA, semitrailer-towing tractors are allowed to be applied to the EU-Korea FTA.

13. Vehicle Width Standards

Article 4 of the "Rule regarding Performance and Standards of Vehicles and Vehicle Parts" states that a vehicle's width cannot exceed 2.5m. While conducting the research for the internationalization of safety standards, the KATRI plans to maintain the vehicle width standards in the current 2.5m but revise them for the items excluded from the measurement standards into the equivalent level of the EU. However, in case that the width of vehicle frame exceeds 2.5m, it does not earn any mitigating effects generated by harmonizing measurement standards. 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 that of 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 hard to apply the 2.55m standard to all vehicle categories, it seems to be an appropriate alternative that the 2.55m width standard is limitedly applied to trucks/special motor vehicles, double-decker buses and 3 axles buses.

Recommendation

We request the revision for the acceptable standards of Korea's vehicle width to 2.55m.

14. Mandatory Installation of LDWS and AEBS

2 of Article 14 and 3 of Article 15 of the Rule on Performance and Standards of Vehicles and Vehicles Parts currently state the mandatory installation of Lane Departure Warning System (LDWS) and Advanced Emergency Braking System (AEBS) for bus and trucks/special motor vehicles. Additionally, it indicates vehicles categories that are not included in the mandatory installation, but the vehicle categories which are not included are different from the standard of EU. The EU excludes off-road vehicles from the subject of mandatory installation.

Recommendation

We request exclusion of off-road vehicle from the mandatory installation of LDWS and AEBS 2 of Article 14 and 3 of Article 15 of the Rule on Performance and Standards of Vehicles and Vehicles Parts.

15. Recognizing Parts Self-Certification According to Vehicle Self-Certification

According to the current 2-5 of Article 30 in Motor Vehicle Management Act, it is indicated that when a manufacturer has performed self-certification of a motor vehicle, the parts installed on the relevant motor vehicle shall be deemed to have undergone self-certification. However, this article is not clearly interpreted for some cases, resulting in additional works for the parts self-certification process. One of the objectives of parts self-certification is to prevent the defective parts that do not meet the safety standards being sold in the market. Moreover, the parts which have gone through the process of vehicle self-certification by automobile manufacturers can be considered as satisfying the safety requirement. Accordingly, the recognition of parts self-certification specified in 2–5 of Article 30 of the Act should include parts installed in vehicles and the service parts with equivalent specifications.

Recommendation

It is necessary that the approval scope of parts self-certification, 2-5 of Article 30 in Motor Vehicle Management Act should include the parts installed on the vehicle and the parts with identical specification.

16. Green House Gas (GHG) Emission Calculation Program for Heavy Duty Vehicle

The Ministry of Environment (ME) currently plans to use HES program developed in Korea to estimate GHG emissions of heavy duty vehicles whereas European automobile manufacturers make the calculation via VECTO program used in Europe, from which the calculation difference between the two is expected. It seems that there will be difficulties for European automakers as the difference between the two systems (HES and VECTO) can provide different calculation result for GHG emissions even with the identical vehicle model. Thus, European manufacturers are considering the necessity of recognizing the usage of VECTO program.

Recommendation

We request that European automobile manufacturers are allowed to use VECTO program as a calculation program for GHG emissions.

Tires Committee

17. KC Mark Exemption Process for Tires with E-Mark

Article 84 of the management methods of the Electrical Appliances and Consumer Products Safety Control Act states that the tires of EU origin with E-Mark satisfying UNECE R-30/54 can be exempted from safety assurance. Table 1 of the Annex 2-C-3 of the EU-Korea FTA also indicates that the tires meeting UNECE R-30/54 requirement are recognized as satisfying its equivalent safety assurance of Korea. However, as the safety assurance exemption process is too comples to proceess, tire manufacturers choose to go through the general process of safety assurance reporting since it is believed to be more efficient.

Recommendation

In order for the EU tire manufacturers to receive the practical benefits provided by the EU-Korea FTA, we request to improve the current safety assurance exemption process to be simplified for the tires with E-mark.

18. Recognizing E-Mark for Tires of Foreign Origin

Article 84 of the management methods of the Electrical Appliances and Consumer Products Safety Control Act states that the tires of EU origin with E-Mark satisfying UNECE R-30/54 can be exempted from safety assurance registration. However, the exemption is limitedly applied to the tires of EU origin only, not to those of others. Although the tires are produced in countries outside of the EU, if they have E-mark, they are seen as being manufactured according to the equivalent technical standards to those of EU origin. Therefore, the recognized range of safety assurance registration exemption should also be expanded to those produced outside of EU, if they have E-Mark since they are believed to have equivalent technical standards.

Recommendation

We request to review that tires of non-EU origins, as long as they have already obtained E-Mark, are to be exempted from safety assurance reporting.

Beer, Wine & Spirits

Hyokyung Suh
Director
Beer, Wine &
Spirits
Committee

Overview of the Industry

The alcoholic beverage industry is regulated by a number of different government authorities: The National Tax Service (NTS) issues licenses on production and distribution, the Ministry of Food and Drug Safety (MFDS) regulates labelling, inspection and surveillance, while the Ministry of Health and Welfare (MOHW) is responsible for the implementation of the national Health Promotion Act in which advertising of liquor is controlled. For this reason, Korea's rules and regulations on alcoholic beverages directly affect production and sales activities as well as marketing and advertising.

In 2018, there have been a heated debate on the liquor tax in Korea. For several years, the need to revise a liquor tax system, has continuously been discussed. There have been researches on the analysis of the pros and cons of ad valorem and specific tax system, and the government agencies, research institutes, and industries have deliberated and debated on how to reasonably amend the liquor tax system. The adoption of the volume specific tax of beer was actively reviewed, but it was not included in the tax reform plan for 2019.

According to the notification on the revision of the liquor tax in 2017, the labelling requirements for distribution classification of certain types of liquor (fruit wine, distilled soju, brandy, general spirits, liquor and others) were abolished (i.e. integrating labelling 'for hypermarket' and 'for household' into 'for household'), which somewhat eased the burden of liquor producers and distributors on managing labelling and inventory. However, it is required that the labelling requirements not still amended are relieved.

The Korea Customs Service (KCS) announced that the quantity of principal imported liquor products[1] in 2017 was 3.8 million litre (equivalent to 9.0 litre per adult[2]), 38.1% higher than 2016. The import value increase rate was 8.0%, which shows that the liquor products with relatively low unit price were imported significantly.

The quantity of imported beer reached 3.3 million litre (equivalent to 7.8 litre per adult), an increase of 50.2% from the previous year. In fact, it has shown an increase rate of more than 20% every year over the last decade but in 2017, its rate recorded much higher than 43% (the highest record) from 2015. Leading exporting countries to Korea are Japan, China, and Belgium in order. The import volume of beer from European countries accounts for 47.4% (1.6 million litre) of the total beer imports and the rapid growth from Belgium (a 92% increase from the previous year) and France (a 127.4% increase from the previous year) is particularly noticeable. The import volume of wine was 28.0 million litre (670 ml per adult), an 8.1% decrease from the previous year whose main cause was less imports of white wine. Top exporting countries to Korea are, in order, Chile, Spain and Italy (import volume) and France, Chile and the US (import value). The import volume of whiskey was 1.8 million litre (428 ml per adult), a 14.3% decrease from the year before. It had been on a downward trend since 2010 but slightly revived from 2014. And since then, it has decreased in 2017 again. Leading exporting countries to Korea are the UK, the US, and Canada, in order.

The reason behind this rapid market expansion of imported beer can be attributed to social ambience where people want to drink less for healthier life style, coupled with the propensity to consume various products with different flavors. It is analysed that supermarkets and convenience stores are main sellers of imported beer, which is relevant to the current social trend that more people are enjoying drinking beer at home. Domestic liquor companies play a big role in the market growth of imported beer as it imports various kinds of beer.

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

2. Approximately 42,000,000 adults aged 19 and older

Key Issues

Creating Market Environment for Fair Competition

1. Limits on Price Range and Total Amount of Liquor Promotional Items

To clarify liquor giveaway standards and to mitigate the scope, the NTS amended regulations pertaining to the standards in July 2017 and claimed to have expanded promotion opportunities for companies. However, actual application of such revisions to importing companies showed that the scope was drastically reduced, resulting in limited promotion opportunities. In 2016, the Korea Fair Trade Commission (KFTC) abolished its notification related to supply of promotional items, which regulate the price range and total amount allowed for giveaways, because they anticipated following consequences on easing market barriers for new enterprises and bringing the price down for consumers. However, its anticipation has

not been fulfilled specifically in alcoholic beverages industry due to 'price range and total amount allowed for giveaways' remained in the NTS notification.

(i) 1% or Less for Liquor Tax Base Sorted by Liquor Type of the Previous Year

When companies, handling many types of liquor, wishes to import different types of liquor to expand their business or improve its business performance, they actively carry out sales promotion activities to raise their brand awareness for the first 2 to 3 years when introducing a new product in the market. If the total amount limit is confined to 1% of base for liquor tax by liquor type of the previous year, companies with poor performance in the preceding year or those without import record of liquor type concerned will be prevented from entering market itself, making fair competition impossible.

(ii) Prohibition of Consumer Giveaways Worth More Than 5% of Liquor Sales Price (Except Insulated Bags)

Such unrealistic price range allows almost no promotional items to be used which makes conducting sales promotion activities almost impossible. Insulated bags, one and only exception, are not that attractive item for promotional giveaways for most of the liquor types other than beer. Its manufacturing cost is quite heavy, which brings about the limit of adjusting its unit price in a case of producing it in a small quantity. This, therefore, can be a big burden on small and medium sized importing companies and restrain the activities of sales promotion and business in a free competitive market.

(iii) Reduction in Consumer Benefits

The current trends of alcohol consumption include light drinking for health and higher demand for a variety of flavors. Even though providing various giveaways to consumers can be an effective tool in cutting down an actual price and expanding product options, such opportunities are limited.

Recommendation

We request to adjust limits on price range and total amount of liquor promotional items, consistent with the initial objective of 'mitigating scopes for promotional items and further expanding promotion opportunities for companies.' It is also required to remove the terms

by liquor type and the standards of liquor tax base from the limit on their total amount, instead to adjust it to the limit relative to companies' total sales from the previous year. In addition, we hope that the price range of promotional items is adjusted upwards to more than 10% at least of liquor sales price and a variety of promotional items are allowed by abolishing the exclusion clause. We hope that domestic as well as foreign companies are given an equal chance for competition, and they should not be restrained from introducing a variety of products to consumers who have the rights to choose freely.

2. Allowing Digital Marketing for Provision of Liquor Promotional Items

The Liquor Tax Act allows the provision of liquor promotional items and sets up the limit on 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 Enforcement Decree Article 10 of 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 but its promotion is prevented. Also, it is considered exercising overly strict control over business activities.

Recommendation

As other laws allow it, it needs to be permitted that all consumers are able to get benefits without discrimination against their location or time through advertisements of liquor promotion. Accordingly, we hope that the National Health Promotion Act is revised to allow the promotional and marketing activities for the promotional items of alcoholic beverages.

Revision of the Labelling Requirements for Alcohol Use Classification

The labelling requirements for alcohol use classification implemented for the transparency of distribution since 2002 are now seen as an ineffective regulation when electronic tax invoices and credit cards are being used frequently. Rather, the requirements result in the

increase of production and logistics costs for label manufacturing and changing. It was notified in 2017 that the requirements were partially relieved, but the rest needs to be amended as well.

3. Complete Abolishment of Use Classification Labelling Requirements for Liquor with RFID Tags Attached

The labelling on whiskey and brandy, two major imported alcohols in Korea, is required to include its usage classification of 'for business', 'for household', and 'for tax-free.' Especially, for whiskey, enormous amount of expenses have been spent in attaching Radio Frequency Identification (RFID) tags to the products, to allow its distribution records to be tracked as they are registered in the liquor distribution data system of the NTS.

Recommendation

As the distribution channels of liquor with a RFID tag attached are electronically trackable, we recommend that labelling requirements for alcohol use classification to be completely abolished to remove double regulations.

4. Revision of Use Classification Labelling Requirements for Bottled Beer

The labelling requirements for alcohol use classification were revised in 2017 to remove the labelling of 'for hypermarket' and 'for household' for wine and canned beer. However, bottled beer is still required to have the labelling of 'for hypermarket' and 'for household', which makes it difficult to control its inventory and management.

Recommendation

We request to integrate the indication of 'for hypermarket' and 'for household' into 'for household' for labelling requirements for bottled beer.

Revision of RFID System

The NTS has run the 'liquor distribution data system' using RFID since 2012. According to this system, alcoholic beverages are produced and released with the bottle caps where RFID tags having product information such as serial No. provided by the NTS and product name are attached. Such product and transactional information are automatically recorded in the NTS network and accordingly, all distribution processes from production sites to retailers become trackable and consumers are able to verify whether whisky is genuine or not. RFID tags are applied to whiskey and the beverages whose main ingredient is whiskey.

5. Sharing of RFID Data Outcomes

The industry has been actively supporting the government's policy for transparent distribution and has been putting a lot of effort to have the RFID system implemented by making enormous investment and to maintain it in a market. However, the data collected through the RFID system is not being shared with the industry at all. As all the alcoholic beverages are distributed through wholesale or retail, it is not easy to analyse their sales information by region.

Recommendation

We recommend that the data collected through the RFID system to be shared with the companies. The industry should be able to receive the benefits of the RFID system, achievements earned through the cooperation between the government and the business. The companies should be allowed to obtain their sales data by city, district and region on a continuous or regular basis.

6. Country Location for RFID Tag Attachment Process

RFID tags are mostly attached to the alcoholic beverages imported from the production regions except for the ones bottled in Korea. As it is currently prohibited to ship out RFID tags overseas, tag attachment is allowed only after the products enter Korea. For import liquors, efforts are being made to reduce additional works done in Korea such as adding labels in Korean at production regions, but when it comes to RFID tag attachment, no alternative option exist.

Recommendation

We request to allow shipping out of RFID tags overseas as well as the attachment procedures to be carried at the production region for more efficient management of the products by the companies. In addition, it is suggested that importing companies help relevant regulations applied reasonably by reporting the amount of carrying out and in.

Chemical

Overview of the Industry

Since 1960, the South Korean chemical industry has been on a promising path in becoming a global chemical hub. It is currently Korea's major industry as it holds the third place in the manufacturing sector.

Moreover, in 2015 four Korean companies ranked among the world's top 50 chemical companies, proving that it was the world's 5th leading country in the chemical sector, particularly, in sales.

Adding on to this industrial development, the Korean government has developed regulations to protect public safety and health from chemical accidents.

However, some of the regulations have become stricter than international standards due to the fact that several small and big chemical accidents have occurred, which jeopardize the healthy development of the chemical industry.

In addition, more excessive systems have taken in place in some parts comparing with Globally Harmonized System (GHS) achieved throughout the successful settlement of EU-REACH for several decades.

As the global presence of Korea's chemical industry has increased, Korea needs to adjust its regulations and systems in accordance with the global ones considering a fair competition in order to improve the capacity of its chemical industry on a global stage.

If the gap between Korea's regulations and international ones get larger, it would eventually give a harmful effect on the global status of Korea's chemical industry, one of its major economic backbones.

Furthermore, Korea needs to be aware of the fact that the recent development of the chemical industry in South East Asia as well as China has directly influenced Korea.

Through a close cooperation, the government and companies need to make efforts to come up with legislations that can secure the objectives of regulations and protect the country's own industry.

Key Issues

K-REACH

1. Combined Volume Control

It is a big burden for a company importing or manufacturing new chemicals of less than 50 kg a year to be required to register compared to a company which imports or manufactures more than 50 kg. It will be likely for such companies to stop importing or manufacturing products containing new chemical substances if the burden of registration continues to be enforced.

Recommendation

Those who manufacture or import new chemical substances of less than 100 kg a year and existing ones of less than one (1) million tons a year should be excluded from a registration obligation.

Since such total amount mentioned above is not the amount applicable to one registrant but the amount accumulated at the national level, it is appropriate to increase the limit amount to 100 tons for existing chemical substances and 10 tons for new chemical ones. But if the proposal to increase the limit is not accepted, the hazard criteria to designate chemical substances shall be clearly defined such as Acute Toxicity Category 1, 2 or CMR Category 1, and also unless the registration is urgent such as CMR substances, grace period of at least three years is required considering the time consumption for the preparation of data and the relevant joint registration procedure.

2. Omission of Data to be Submitted When Applying for Registration of Chemicals

EPI Suites and ECOSAR, screening assessment programs for polymer compounds (molecular weight < 1,000), are being actively used in other countries including the US. The use of such screening methods is also described in the "Interpretive Assistance Document for Assessment of Polymers" released by the US Environmental Protection Agency (EPA). The required proportion of polymer compounds in all existing chemical substances of more than one (1) ton is too high.

Recommendation

The restriction on the use of the already available programs will require the generation of unnecessary test data. Allowing to use

the programs such as EPI Suite and ECOSAR is, therefore, strongly recommended in order to minimize the generation of unnecessary test data. It follows the Use of Vertebrate Animal Alternative Test under Article 4 of Act Duties of the State and Principle of Minimization of Vertebrate Animal Test under Article 16-2.

The Polymer Exemption criteria under Article 11 of Presidential Decree is similar to the exemption standard of the polymer manual of the US EPA and countries like Canada and Australia follow this manual. Accordingly, the omission of data should be recognized only by the submission of Notice List for low concern polymer under Subparagraph 6-2 as exempted from the registration which is notified by foreign governments such as the US, Canada and Australia.

3. Substances Subject to Intensive Management (SSIM)

(i) The criteria for designation of SSIM (Subparagraph 3-2) are more stringent than EU REACH SVHC due to additional Specific Target Organ Toxicity (STOT) endpoint and stricter PBT/vPvB criteria. Current SSIM criteria have gone well beyond what EU REACH has required for the SVHC-Candidate list. (i.e. the PBT and vPvB criteria are less flexible than EU ones, and STOT is not a criterion for SVHC since STOT is not as serious/hazardous as CMR, endocrine disruptor or PBT/vPvB.)

Recommendation

We request to remove STOT endpoint, and use EU REACH criteria for PBT and vPvB

(ii) There is no Risk Management Option Analysis (RMOA) step for designation of SSIM and Authorization Substance. It is very important to add in K-REACH the concept of RMOA which was introduced by the EU authorities after implementing EU REACH. In the EU, this step takes place after evaluation of the substance and before taking any risk management decision (i.e. designation of SVHC, restriction, or authorization). During this stage, the relevant authorities collect data from the industry which actually uses the substance, if there are alternatives, etc. to conduct a small socio-economic analysis. Based on these data, the authorities define what is the most appropriate risk management measure of the substance (i.e. authorization, restriction or another legislative tool outside EU REACH). As such step did not exist at the beginning of EU-REACH, several substances ended up with wrongly being put on the authorization list. As a result, this led to killing thousands of businesses (mainly downstream users) as no alternatives to some substances were put on the authorization list, and the authorities were not aware of such circumstances. This was the reason why in the EU, RMOA concept was introduced, aiming at collaborating with the industry early in the process, before risk management, to improve protection but also minimize unnecessary negative impact on the industry.

Recommendation

We request to include RMOA step as a key step before the decision for designation of SSIM takes place.

4. Exemption from Registration of Chemicals

According to the amendment of the regulation, surface treated chemical substances are required to apply for the verification of exemption registration after each filler and treating agent is registered. However, the registration deadline for existing chemical substances differ depending on the tonnage band of manufacturing and/or importing. Also, existing chemical substances imported and/or manufactured less than 1ton per year are not subject to registration. According to the current amendment, the exemption of surface treatment substances cannot be applied.

If a substance to be surface-treated or a substance whose surface is treated is a new chemical, exemption verification from registration cannot be applied even if it is already registered or notified.

Recommendation

Treated substance exemption, therefore, should be accepted if a new chemical substance is notified or registered and/or existing chemicals of more than 1 ton/year are notified. It would be reasonable to proceed with the process of confirming that the registration of the substance was completed within the grace period by KECO afterwards.

In the case of existing chemical substances of less than one (1) ton,

it is requested that treated substance exemption should be accepted without prior notification and registration.

5. Criteria of Amount in Provision of Chemical Substance Information

According to Paragraph 2 of Article 118 of EU REACH, the information deemed to undermine the protection of commercial interest includes full composition and precise use of chemical substances. Under emergency situations where an urgent action is essential to protect human health and safety or the environment, such information may be disclosed.

Under K-REACH, most of chemical substances are subject to registration. If the information of a substance is required to be provided to downstream users regardless of the content in the mixture, a company will lose its competency by delivering the component information of the mixture deemed as confidentiality of business information.

Recommendation

The information on component content is considered as confidential business information. Even if a chemical substance is registered according to Article 10 of K-REACH, if its relevant chemical substance does not contribute to the classification of the mixture where it is contained, it is not specified in the section 3 of Material Safety Data Sheet (MSDS). If the substance meets the classification standard in accordance with Article 31 of K-REACH and falls under the list categorized as a vPvB and/or SVHC candidate substance, the supplier of the substance is required to provide the information of such substance to a recipient.

Thus, K-REACH needs to follow this global standard. In addition, we recommend to list up substances according to the GHS classification criteria on mixture and provide such information to downstream users.

K-BPR

6. Data Requirements for Biocidal Product Authorization

According to "Guidance on the Biocidal Products Regulation - Volume III: Human health Part A: Information Requirements and Volume IV: Environment Part A: Information Requirements" of EU-BPR, no testing of a product/mixture needs to be conducted if there are valid data available on each component in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

Recommendation

It is strongly recommended that K-BPR adopts the abovementioned rule used in EU-BPR. There is no need to generate new testing data for a biocidal product if there is a valid data available for each component in the mixture sufficient to allow classification of the mixture as the cost and time required to be spent for it will become a huge burden to the industry. Along with that, the requirement also contradicts with the global trend of anti-animal chemical testing.

The data required for registration need to be minimized because it is including Confidential Business Information (CBI) such as net contents of all substances, components and raw materials.

7. Control Practice for Imported Treated Articles: Recognition for Similarity by Other Laws

If a biocidal product used in an imported treated article is identical with the product authorized under K-BPR or it is the biocidal product ensured as "safe" worldwide (i.e. approved by EU BPR or US FIFRA), it is considered as "safe" while complies with K-BPR.

Recommendation

The product types under EU BPR and US FIFRA are not consistent with the biocidal products referred in K-BPR. It is recommended to provide a clear guidance on the product types specified in similar laws in order to comply with imported treated article requirements under K-BPR.

Chemicals Control Act (CCA)

8. The Problems of the Universal Chemical Tracking System

Under the "Poison Centre Notification" of EU CLP, EU countries are required to set up poison centers for receiving information on the composition of hazardous mixtures in order to respond to emergencies, for example, by giving recommendations for medical treatment in a case of poisoning. However, it is reported that most of the emergency calls to the centers are related to accidental exposures involving consumer products while only a few calls are related to exposure to industrial chemical substances. Accordingly, it is relieved to notify chemical substances for industrial use only when the substances are listed in MSDS and they are given an exemption from notification until 2024. For consumer products, Korea has established Act on Safety Management of Household Products and Biocides, which includes provisions to request information on ingredients, etc. on a regular basis and it will be enforced from 2019.

Recommendation

The fact is that we cannot expect that overseas manufacturers willingly proceed with a chemical confirmation notification for local importers by appointing an OR. In the case of importing Mixture In Mixture (MIM), as an overseas manufacturer who owns the mixture composition does not export to Korea directly, it is free from the obligation of notification through an OR. Furthermore, the industry already admits that trade secret is never be protected in Korea, as revealed through various statistical surveys. If an overseas manufacturer proceeds with a chemical confirmation notification by appointing an OR, the OR will be acknowledged as an importer who has a legal liability thus the OR system will not be able to work as planned.

In addition, there is no guideline prepared for the implementation of PCN in the EU yet since it is only at the preparatory stage. For Korea, the idea of introducing a similar system without any relevant validation process might cause serious impact on the industry and might weaken the competitiveness of the chemical industry which affects economic growth of the country.

Existing chemical substances of less than 1 ton are managed by relevant regulations for the protection of safety and health of employees if the substances are subject to restriction pursuant to Occupational Safety and Health Act. In terms of consumer products, the manufacturers or importers are required to apply for safety confirmation every three years for prohibited substances. Also, the Ministry of Environment has newly designated substances subject to intensive management and any product containing such substances of over 0.1% as being applied for notification. Based on these regulations, we will have to look into the objectives of regulations on chemical substances and products set by the ministry. We believe that the regulation system should be designed to focus on effective management of hazardous chemical substances for the sake of protecting employees and consumers, not on the verification whether companies have submitted reliable data or not. A lot of regulations and systems are already in place for the management of chemical substances such as chemical substances statistical survey, emission survey, business license for hazardous substances, sales license for reagents, notification of substances subject to intensive management, notification of household products subject to safety confirmation, approval of biocides, registration of all new/existing chemical substances, etc. If an accident associated with chemical substances occurs, nevertheless, the government can still improve the system by giving penalties as a sign of alert and strengthen public education on safety in order to reduce the occurrence of accidents based on the current regulations, which could be one of the alternative options to be taken.

Cosmetics

Ansook Park
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Cosmetics
Committee

Overview of the Industry

As the country's next growth engine, the Korean cosmetics industry continues to show a strong, steady growth. In 2017, the trade surplus of Korean cosmetics industry exceeded KRW 4.0 trillion for the first time.

The cosmetics production in 2017 was KRW 13.5 trillion, a 3.6% increase from the previous year and the exports of the last year amounted to USD 4.9 billion (KRW 5.6 trillion), up 18.3% from the previous year. The average growth rate of exports over the past five years was 40.1%. As a result, the trade surplus was USD 3.8 billion (KRW 4.3 trillion), a 18.5% increase from the previous year, and exceeded KRW 4.0 trillion for the first time. This result could be attributed to diversifying export territories. Exports amount to China has increased by 23.1% from the previous year despite the trade tension arose from THAAD issue between the two countries. Export to South East Asia and Europe also increased (Vietnam: +96.9%, Indonesia: +60.8%, France: +40.1%, Poland: +101.1%)[1].

In order to maintain the growth of cosmetics industry to become a core industry in the future, the government needs to actively support and improve its regulation conditions.

1. Press release on 2017 Cosmetics Statistical Data, Ministry of Food & Drug Safety (2018)

Key Issue

1. Packaging of Cosmetics

Ministry of Environment has temporarily eased a set of regulations applied to cosmetics, including space ratio in product packaging and number of packaging (effective until December 31, 2018). Nevertheless, the regulations do not properly recognize the nature of cosmetics industry when compared to cases in other countries. In order to secure the on-going investment climate and Korean cosmetic industry's strength and international competitiveness, the regulations on packaging methods for cosmetics needs to be amended.

Recommendation

We request to review the exclusion of cosmetic products from the subject applied to the regulations on the space ratio in product packaging and number of packaging or change temporary to permanent easement of the regulation.

2. Act on the Safety Control of Dangerous Substances

According to Korean regulations on Safety Control of Dangerous Substances, liquids having a flash point of less than 250℃ are defined as dangerous substances, which applies to most of cosmetic products and quasi-drugs. Compared to the regulations of flammable liquids that are defined having a flash point below 93℃ in the US and the UN, and below 60℃ in Europe, Korea's standard of 250℃ is considered being too strict. Furthermore, in the EU, cosmetic and medicinal end products that are not subjected to <Classification, Labeling and packaging (CLP) Regulation ((EC) N° 1272/2008)>. Yet, when a product classified as not dangerous in the EU gets imported into Korea, it gets classified as a dangerous good. The regulations on the storage and distribution of products in accordance with the current dangerous goods safety management rules are unrealistic considering the low risk of finished cosmetic products.

Recommendation

It is recommended to exclude finished cosmetic products and quasi-drugs from the Dangerous Goods Safety Management Act as the products are safely managed in accordance with Korean cosmetic and pharmaceutical regulations.

3. Labelling and Advertisement of Natural/Organic Cosmetics

On March 13, 2018, natural cosmetics and organic cosmetics certification systems were introduced in the Cosmetics Act. There are various international organic/natural cosmetic standards and certification bodies (USDA NOP, ECOCERT, Cosmos, ISO, IFOAM etc.), and in most of the other countries, if a product meets one of these international certification standards, the cosmetic product can be advertised as organic or natural. But in Korea, even if a product is certified as organic/natural cosmetics by an international certification body, it still needs to meet additional standards required by the Ministry of Food and Drug Safety (MFDS) in order to advertise as an organic/natural cosmetic in Korea. This is considered undermining the consumers' right of choice.

Recommendation

If a product conforms to the organic/natural cosmetic standards certified in other countries (ex. ISO standards) and can be proved with the data, it should be allowed to be advertise as organic/

natural cosmetics in Korea as well. The country's system should be in harmony with the international standards and requirements.

4. Sun Protection Factor (SPF) Indication

As the SPF indication regulations are different in the EU and Korea, products are often required to attach additional label to modify its SPF value. For example, if the test result of a product is 19, it can be indicated as SPF 15 according to the EU regulations. However, in Korea, the exact same product is required to change its SPF level to 16, 17, 18 or 19 (within the –20% range). This causes unnecessary work for marketing authorization holders in Korea and creates confusion for consumers (different SPF value for overseas and domestic sales products).

Recommendation

It is recommended to revise the rules of SPF index (within the –20% range of the mean) and set the indication range wider and allow to indicate the index if it is lower than the measured value.

5. Labelling Requirements for Children's Cosmetics

On June 22, 2018, the amendment of the Enforcement Rule of the Cosmetics Act was proposed to label the content of restrictive ingredients in cosmetics with labels or advertisements indicating that they may be used by infants or children of 4 to 18 years. In other countries including the US and EU, there are requirements such as safety instructions, prohibition of use, or directions for use, but there is no requirement to specify the content of certain raw materials.

Such information is not useful for consumers who do not have expert knowledge of the raw materials, and it may cause confusion among consumers which might lead to unfounded decision that the products are not safe to use. The company may take into consideration to use listed preservatives that has been reviewed for a long time for safety approval, which are very important for the hygienic use of cosmetics, in cosmetic products for children. In addition, the age range for children's cosmetics is too broad as it includes adolescents. It is not in accordance with the purpose of strengthening the cosmetic safety standards of infant's and children's products since the applicable age group is not considering children's skin type.

Recommendation

It is not appropriate to indicate the content of the raw material designated for children's cosmetics. It is recommended to provide information, such as prohibiting the use of ingredients that are considered unsafe for children through additional risk assessment, or adding precautions of use, in order to be in harmony with the international standards and requirements

Also, the age range for children's cosmetics needs to be harmonized with the standards from other laws such as drugs regulation as well as cases in other countries. We request to reset the age range to 4~12 of age and exclude adolescents.

6. Government Designation of Test Institutes for Cosmetics Efficacy Testing on Human

The revision of Cosmetics Act was proposed by National Assembly that test institutes of cosmetics efficacy testing on human shall be designated and managed by the government. Also, the efficacy data for functional cosmetics and substantiation data for advertisements, shall be accepted only if it is prepared and issued by the government designated institutes.

But the matters concerning human efficacy testing are already defined in the 'Regulation on Screening of Application for Functional cosmetics' and 'Rules on claim substantiation for cosmetic labelling and advertisement' by MFDS, and the ministry is already conducting reviews upon these standards. It is unnecessary to revise and include additional requirements for facilities and experts in the Cosmetic Act. Also, there are no such cases where government designates cosmetics efficacy test institutes in other countries.

The data from functional cosmetics efficacy testing on human conducted by overseas test institutes has been successfully approved by MFDS for more than 15 years.

If such data issued by a foreign institute is not accepted because it is practically impossible for the Korean government to designate test agencies outside of Korea, it is considered to be

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discriminatory. Also, it creates issue of credibility and sustainability towards functional cosmetics review system.

Recommendation

The proposal of designation of human application institutions by the government, and acceptance of efficacy data for functional cosmetics and substantiation data for advertisements is duplicative regulation and creates unnecessary additional work for cosmetic companies. Also, we request to accept human efficacy test data for functional cosmetics conducted by overseas cosmetic test institute.

7. Cosmetic Ingredients Reporting System

According to the revised Cosmetics Act which will be enforced from March 14, 2019, responsible persons of cosmetic sales business shall report ingredients lists to the MFDS. The report of ingredients lists shall be done before distribution or sales of the cosmetic products. The importers are required to submit EDI entry notice including ingredient lists with its contents for customs clearance and need to receive approvals prior to importation. Whereas, local cosmetics manufacturers are required to report the ingredients lists only before distribution or sales, which is considered to be discriminatory against the imports.

Recommendation

The details of cosmetic ingredient reporting process will be prescribed by coming Ordinance of the Prime Minister.

It is recommended that the reporting of ingredients lists shall be done before distribution or sales of cosmetics for imported cosmetics too. Also, we request to review the requirements of documents and conditions for EDI approval of customs clearance for cosmetics defined in the 'merged notice' in the notification by the Ministry of Trade, Industry and Energy.

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 at an annual average rate of 3.5% from 2017 to 2020, and is forecasted to reach KRW 53.0 trillion won by 2020[1]. 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 travelled, both are factors that benefit European brands.

Since its entry into force more than seven 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 taking advantage of the FTA in their business with or in the Korean market.

The ECCK is pleased to note that the amendment of the Safety Control Act, which has taken effect from July 1 2018, has decreased industry's burden with regards to maintaining safety testing reports (eliminating KC mark and safety testing for 23 items). The further use of ISO values with regards to the quantity of Dimethyl Fumarate (DMFU) contained in child leather products (indicated in article 5.2.4 in the Annex1 on Child Leather Products of the Safety Standard of Children Products Subject to Supplier's Assurance of Conformity), which is something ECCK requested in last year's White Paper.

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. While the reasons behind the regulations are understandable, mandatory requirements and regulatory obligations are drafted or put into practice in a manner incompatible with international standards or norms. This has resulted in higher operational and market access costs, which in turn are reflected in higher consumer prices in comparison to other countries.

Korea has a remarkably high internet penetration[2], which allows for Korean consumers to be well-aware of product prices globally.

1. Korea Fashion Association (2018), Global Fashion Industry – domestic fashion market and the volume of east Asia fashion market

Korean consumers further take an ever-increasing number of outbound trips. These two factors combined make it attractive for consumers to purchase European products outside of Korea, rather than locally.

Key Issues

2. 93% of Korean individuals have access to internet: ITU (2017), Percentage of Individuals using the Internet,

1. Compliance with Local Labelling Requirements After Customs Clearance and Before Sales

Currently is it required for imported products to comply with local Korean labelling requirements before customs clearance. This is a huge burden on companies who are forced to maintain inefficient supply chains, contrary to local producers that are only required to comply before the products are made available for sale. A practical solution may be for a local labelling venue to be selected per company, where labels are applied after customs clearance.

Recommendation

In light of the adverse effects of the current requirement to comply with labelling requirements prior to customs clearance, ECCK would like to propose that it will be allowed for labelling to be indicated on products after their customs clearance, but before they reach the consumers. In doing so, the impact will be mitigated, foreign and domestic producers of consumer goods are treated more equally, and moreover the purpose of the requirement will still be respected.

2. Direct Shipment Requirement

Article 13 of the EU-Korea Free Trade Agreement (the 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

Recommendation

It is recommended for the European Union and Korea to agree on an amendment of the FTA that would allow for repackaging and redistribution in appropriate circumstances.

3. Price Labelling 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.

In addition, pursuant to Article 5-1 of the Implementation Guideline for the Price Labelling Obligation, the companies are required to indicate the sales price in a form and size that is clear and precise enough for consumers to easily read and understand it. The permissible methods for such price indication include label, tag, stamp and a collective list.

In practice, companies always provide consumers with a clear and precise sales price indication. It is however not always possible to do so in the narrow scope of the regulation. Companies, for example, place a list of collective product prices in close proximity to the products displayed or use various mediums to indicate the product price (for example for products where tags are attached to products, but placed inside of the items).

Recommendation

- The ECCK recommends that the font size on price labels should be aligned with globally accepted standards.
- It is recommended to allow companies to comply with the objective of the legislation (providing proper information to consumers) in manners that are outside of the limited methods provided for in the legislation.

4. Safety Control Act Sales Ban

The amended Safety Control Act enables local authorities to hand down a sales ban for certain products in case of non-compliance, including for relatively small and not dangerous forms of incompliance (such as labelling mistakes).

The simple fact that even a simple error of indication can hypothetically result in a sales ban could lead to an inconsistency in the application of the Safety Control Act and the unpredictability for industry.

Recommendation

In order to prevent unclarity, inconsistency and unpredictability both for industry and local authorities, ECCK encourages KATS to issue guidelines, as well as regular instructive communications with each local authority, which include that the sales ban should not be issued for cases of non-compliance that do not pose harm to consumers.

5. pH Restriction Level under the Safety Quality Labelling 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, which 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.

6. Method/Requirement of Indication

Article 6.1.2 in the Annex 1 of the Safety Standard of Consumer Products Subject to Safety Certification allows for companies to indicate a variety of information to identify products, including '..first sale season, lot number, style number, barcode number, QR code etc.'. ECCK has requested for the importing date to be added as a suitable indication method, to which KATS indicated that such is possible due to the inclusion of 'etc'. It is important that this is either included in the Regulation itself, or confirmed in writing.

Recommendation

In order to ensure predictability and consistency, it is essential that consistent standards are applied throughout all regulations. In particular, it is recommended that all acceptable information to identify products is specifically included in the Regulation where possible and further that any interpretation deemed acceptable by KATS and other officials is confirmed in writing.

7. Changes in Legislations

European companies have broad experience in operating in countries around the world by complying with various local laws and regulations. Because of such, European companies have 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. Particularly, engagement in a more proactive manner, either directly or through the ECCK could be very fruitful.

Additionally, it is practically very difficult for foreign companies to keep abreast of every single regulatory change. 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, a reasonable period of time between the publication of the regulatory change and its implementation should be provided for.

Changes in regulations are not effectively communicated by the

Fashion & Retail Committee

government, making it necessary for companies to learn about pending changes from service providers.

Recommendation

In order to increase the transparency of the legislative process and ensure European companies' compliance with laws and regulations and to have them attain the intended level of consumer protection in Korea, it is recommended that any envisaged regulatory changes are timely shared with ECCK in order to allow for insights to be provided before their enactment.

It is in this regard important to note that members of the World Trade Organization are required to notify other countries of changes in their regulation in order to avoid the creation of so-called 'technical barriers to trade'. These notifications should be made for legislations at draft stage in order to allow for any input by other countries to be properly reflected in the legislation, or for the legislation to be abolished in case it establishes the aforementioned technical barriers to trade.

Food

Hyokyung Suh
Director,
Food Committee

Overview of the Industry

Korea's food industry is supervised largely by two government ministries. The Ministry of Food and Drug Safety (MFDS) is in charge of making policies and amendments on food, health supplements, food additives · apparatus, along with food containers, package hygiene · safety management. The ministry also regulates manufacturing, import, distribution and sales of food. Meanwhile, the Ministry of Agriculture Food and Rural Affairs (MAFRA) takes responsibilities of overall food provision together with quality management, distribution, price stability of agricultural products. Its duties also include promotion of environment-friendly agriculture and fisheries and the management of and support for organic food. The MAFRA handled the EU-Korea Equivalence Arrangement on Organic Processed Food in February 2015.

The responsibilities pertaining to agro-livestock and fishery products safety have been transferred from the MAFRA to the MFDS since 2013. Processing of livestock products, previously subject to the Livestock Products Sanitary Control Act, is transferred under the Food Sanitation Act. Livestock processed products (processed milk, meat and egg products) are managed same as general processed foods under the standards and specifications of food. Also, labeling standards to be revised to the similar format to the foods. In March 2018, in accordance with the enactment of 'Labeling Standards for Foods and Advertising Regulations' (to be enforced from March 2019), the current laws for labeling for foods, advertisement standards and indications, advertising regulations, and administrative punishment and penalty etc., related to the laws were modified. The labeling regulations that were spread out through the Food Sanitation Act, Health Functional Foods Act and Livestock Products Sanitary Control Act are subjected to be intergraded and controlled as a single act. In June 2018, in order to strengthen the safety management regarding synthetic flavors, the list for permitted substances was modified and the article that grants recognition to globally accepted flavors was eliminated within the rule. The flavor substances that are recognized by the MFDS are only allowed to be used (to be enacted in July 2019).

In line with the enforcement of the Special Act on Imported Food Safety Control initiated by the MFDS in February 2016 in an attempt to enhance the safety of imported foods[1], overseas manufacturer

1. Agricultural products, processed foods, health functional foods, food additives, equipment or packaging

registration prior to customs clearance has been put in place, together with complete guidelines on exporting country's hygiene evaluation process and importing standard on livestock products (applies only to livestock products without previous import records). In addition, the Korean government can conduct hygiene inspection on overseas manufacturing factories. It is necessary to keep an eye on special laws being enforced to enhance safety control on imported food, especially when those laws are often stricter than the ones for local products.

According to the MFDS's Imported Foods Statistics, in 2016 the amount of imports (excluding livestock and fishery products) was recorded USD 14.7 billion, which has increased 2.1% compared to last year and the volume recorded 14.9 million ton, which has increased 1% compared to last year. The amount of processed foods imports was recorded USD 6.6 billion, which has increased 11.7% compared to last year and the volume recorded 58.0 million ton, which has increased 7.4% compared to last year. According to the 2016 imported foods price standards, the first importing country is China, which the amount of imports recorded USD 3.1 billion. This accounts 21% of the total foods etc. amount of imports and the EU (includes 28 countries) recorded USD 1.8 billion in total, which accounts 12%[2].

2. Reference: 2017 Food and Drug Statistical Yearbook (Statistics 2016)

Key Issues

1. Expansion of Non-GMO Labeled Products

While Europe and the US allow the use of "Non-GMO" labels signaling that foodstuffs do not use any GM crops (e.g. peaches, apples, etc.) or were not produced using GMOs (approved GMO ingredients such as soybean, corn, cotton, canola, sugar beet, alfalfa and potato), the labels in Korea are not allowed unless the following conditions below are all met.

1) Must be GM products approved for food, which is soybean, corn, cotton, canola, sugar beet, alfalfa and potato, and products manufactured/processed based from these ingredients only.
2) Products containing more than 50% of approved GMO ingredients subject to the labeling or those containing the largest quantity of the ingredients subject to labeling.
3) 0 allowance on adventitious or technically unavoidable GMO genes in the final products (while there is allowance of maximum 3% of GMO genes for the general products).

Since Non-GMO labels are given only when the aforementioned 3 conditions are all satisfied, processed food rarely gets the labels. For this reason, foreign companies often give up on exporting their products to Korea due to costs incurred from creating additional labels just for the Korean market.

Within the EU, GMO is not allowed and only maximum 0.9% GMO composition considered as an unintentional mix, which means that Non-GMO labelling is not restricted to any food only if it meets the general condition mentioned above.

In Japan, if packages already have obtained Non-GMO labels in English when imported, the original labels can be used if it meets allowance of maximum 5% of adventitious or technically unavoidable GMO genes in the products even if the ingredients don't comply with the government.

Recommendation

We request for expansion of raw materials allowed for "Non-GMO" labels (the range of food should be expanded from the existing seven (7) types of raw materials only to the entire food) and portion adjustment of raw materials allowed for "Non-GMO" labels (e.g. 50% → 10% / 1st priority → top 5 priority). Also, we suggest allowing a little bit of adventitious or technically unavoidable GMO genes in the final products. Also, in the case of products imported from the EU, it is hoped that discussions between governments led the result in allowing the existing Non-GMO labels of the exporting countries can be used as they are.

2. Improvement of EU-Korea Equivalence Arrangement on Organic Processed Food

The EU-Korea Equivalence Arrangement on Organic Processed Food took effect in February 2015. This means that as long as organic processed foods conform to terms and conditions of the Arrangement and are certified pursuant to respective laws either in Korea or the EU, they can be labeled as 'organic' and sold in the counterpart country. The Arrangement was valid for 3 years and supposed to be expired on January 2018. Thankfully, both parties

agreed to extend the period of application for an unspecified duration in February 2018. However, it is not applicable to final products that were delivered to Korea from a warehouse in a third country even though they were manufactured and certified in the EU. This is a major factor in increasing the logistics cost of organic processed foods because it does not benefit those who use warehouses in a third country.

Recommendation

When the EU-Korea Equivalence Arrangement is revised, we strongly request for renewal of the condition of direct shipment. We request for acknowledgement of the Arrangement for a product to transit via a third country if its manufacturing and certifying countries are both EU member states.

3. Coordination Between International Standards and Specifications for Food

It has been requested improvements in reducing technical barrier to trade in case some labeling is prohibited derived from inconsistency of local food standards and specifications of CODEX and other foreign countries.

(i) Food Labeling Standards on 'Natural'

- **In Korea**: According to the food labeling standards, in the case of foods that contain synthetic flavors, color additives, preservatives, or other artificial or added synthetic components or that went through a process other than the removal of inedible parts or the 'minimum physical process', the term "natural" shall not be used. 'Minimal physical processes' get divided into 17 different process including rinsing and define specific standards. Regarding the heat process, if the food went through higher than 60 degrees Celsius, it also gets excluded from natural standards.
- **In other countries**: CODEX, US FDA, EFSA, etc., do not clarify the process range over foods "natural" labels. But the International Organization for Standardization (ISO)'s recent publication of 'Definitions and technical criteria for food ingredients to be considered as natural' includes wide range of food processes such as physical, enzymatic and microbiological processes. Even the food processes not included within the range, as long as it's applied for the food safety then it's considered as natural range.

- **In Canada**: The Canadian Food Inspection Agency (CFIA) separates food processing process into minimum process and maximum process. To obtain "natural" labels for products, it is regulated that raw ingredients of the food is expected not to have submitted to processes that have significantly altered their original physical, chemical or biological state (i.e. maximum processes). Since the minimum processes don't affect foods' physical, chemical and biological characteristics so the food products are eligible for a natural claim and heating processes such as pasteurizing and sterilizing are considered as minimum processes.

Recommendation

In overseas, the range of "natural" is broader that the products that have been through processes, such as sterilization, pasteurization, etc. could be labeled as "natural". On the other hand, when the MFDS's 'minimal physical processes' is applied the food cannot be considered as "natural" in Korea even if the products went through processes such as sterilization, pasteurization, etc. for food safety purposes.

Through reviewing the current standards, we hope the number of misguided consumers and high shipping costs that are caused by standards that are incompatible to the global ones to be reduced.

(ii) Definition and Specifications of 'Natural Flavor'

- **In Korea**: According to the Standards and Specifications for Food Additives, the range of natural flavoring is defined that it is obtained from specified origin materials or adequate food ingredients through extraction, distillation, etc. It is regulated to use methods that do not cause chemical changes to natural flavoring, such as rectification, extract, oleoresin, etc., and mixed with more than 2 kinds and to keep quality, water, alcohol and vegetable oil can be added.
- **CODEX**[3]: Natural flavoring substances and natural flavoring complexes are obtained from material of plant or animal origin by 1) Physical processes (Allow the process which may result in unavoidable but unintentional changes in the chemical structure such as distillation, solvent extraction, etc.) 2) Enzymatic, microbiological Process 3) Traditional food-preparation processes (e.g. drying, roasting, fermentation) and 4) It includes flavoring complexes (e.g. essential oil, essence, extractive, protein hydrolysate, distillate or enzymolysis) containing flavoring

3. CAC/GL 66-2008

substances. Also, it is regulated that for the flavor substances' production, storage, process and usage the food ingredients that are not flavoring substance could be included and it could be labeled as "natural" in such case[4].

- **EU (EC No. 1334/2008)**: Natural flavoring is defined as chemical substances obtained from materials of vegetable, animal or microbiological origin, by appropriate physical, enzymatic or microbiological processes, either in the raw state of the material or after processing for human consumption.
- **US**: Natural flavors include natural extractives obtained from plants listed in the CFR and the flavoring constituents derived from plants originated material, meat, seafood, poultry, eggs, dairy products or fermentation products. Also, the form of natural flavors includes the essential oil, essence, oleoresin, protein hydrolysate, distillate or any product of roasting, heating or enzymolysis[5].

4. CODEX STAN 107-1981 and CODEX STAN 1-1985

5. FDA 21 CFR 101.22

Recommendation

Compare to other countries, Korea has limited numbers of substances that could be added to preserve recipe and quality and be qualified as natural flavoring. As a result, even the flavor that could be qualified as natural has to be labeled as synthetic flavor or mixed formulation accordingly to the Korean law. We hope to have substances, which are used for physical process and solvent extraction while identified as natural globally, to be re-evaluated in Korea.

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 and remains as a huge obstacle to importing. Korean labels of imported food are attached on its package based on prior reviews from importers and then mass-produced by overseas manufacturing factories. However, 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 manufacturing factories. The reasons for labeling modification are as below:

- In addition to differences in food standards between Korea and foreign countries, Korean labels are determined and reviewed solely by importers (e.g. different standards applied to indications of natural/synthetic materials and 'no artificial additives').
- Different information may be required upon the same product, depending on government officials in charge of importing (e.g. they may review in-depth on production process as well as secondary and tertiary raw materials).
- 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.

Recommendation

Considering duration of marine transport (6 weeks from Europe), expiration date of food (4~6 months), and requirements by clients (minimum 90 days left until expiration date), it is urgent to cut down time and cost for document review processes and maintenance works during customs clearance. We request the vitalization of pre-declaration system, which is the import declaration process such as document reviews and labeling requirements check is done in prior to the arrival. Also, implementation of the planned import declaration system that if the importers declare annually planned quantity of the products ahead of time and once it's confirmed, the quantity could be cleared the customs without further checking processes.

5. Sufficient Preparation Time Upon Regulation Amendments

Importing manufacturers are at a disadvantageous upon regulation amendments, considering that it takes longer for them to adapt to the changes than local manufacturers. Sufficient preparation time and deadline notices are necessary if the amendments are about non-safety issues such as administrative procedures. For imported food, it is often the case that products are imported with the Korean labels attached already, and the whole process from product packaging to shipment takes up to 3 or 4 months. Also, considering that those products are manufactured in a large quantity to reduce the unit price, frequent changes to the labeling systems cause a disposal of labels in stock, a severe waste of resources and high costs incurred from these additional management.

Recommendation

We request to the MFDS to take the initiative in regularizing the revision process in the labeling system. Afterwards, 3 years should be allowed for preparation prior to the changes.

Ansook Park
Director,
Healthcare
Committee

Healthcare

Overview of the Industry

With a rapidly aging population and the development of medical devices technology, the healthcare market continues to show a steady growth. In many other countries, including Europe, new drug development is being promoted with various policy supports to strengthen the country's international competitiveness. However, the pricing and reimbursement evaluation system based on PE evaluation in Korea is insufficient to reflect the value for innovation and social needs, and it still has problems of transparency and objectivity. If these issues are not considered, the patient access to new drug will continue to impede and discourage pharmaceutical companies to develop new innovative drugs.

Reflecting the healthcare system in Europe, it is recommended to do case studies relating to evaluation method for healthcare innovation, enhancement of patient access to new drugs, and medical value of new drugs. In Europe, most of the countries' healthcare system considers various sociological perspectives including disease severity, social costs, quality of life, and relative medical value for the assessment of the adequacy of new drug benefits. It is expected that this kind of approach to healthcare system will increase patient access to new innovative drugs and reduce the social costs.

The utilization of vaccines can be a great tool to support Ministry of Health & Welfare (MOHW)'s one of main policy directions 'strengthening of preventive healthcare', introduced to prevent the rise of disease burden and government budget expenditure caused by the aggravation of disease seriousness. Accordingly, MOHW and Korea Centers for Disease Control & Prevention (KCDC) needs to put policy-wise efforts to create healthier nation and effective budgetary control, by driving utilization of innovative vaccines that can improve vaccination rate, safety, clinical, and economic benefit etc.

The market size of the Korean medical devices in 2017 reached KRW 6.2 trillion (+5.5% from the previous year) and its average growth rate is 7.6%[1]. The technology in healthcare has been evolving and innovating at such fast pace, the Korean government is lifting the regulations restricting the growth of medical device industry. We support the Korean government's effort to improve regulations enhance industry growth.

1. Press release on 2017 Statistical Data of Medical Devices, Ministry of Food and Drug Safety (2018)

Key Issues

<Pharmaceuticals>

A. Market Access

Fair-Value

1. PE Evaluation

The implicit Incremental Cost–Effectiveness Ratio (ICER) threshold, 1 GDP/QALYs is still not at the optimal level. The Korean government increased the threshold up to 2GDP/QALY for cancer and rare disease, but the maximum ICER threshold for other types of diseases remains conservative, not rationally reflecting the diseases or patients' situation. Also, considering the fact that there are minority patients with cancer and rare disease with a very short survival time, it is also needed that recognizing other severe illness requiring more flexible level of ICER threshold, as it carries more burden of disease with higher social needs than cancer or rare diseases.

Recommendation

It is recommended to apply more flexible level for ICER threshold considering the severity of diseases, availability of alternative medicine options, quality of life, value of innovation, social needs, etc., without limiting the subject to cancer and rare disease or 1~2 GDP/QALY.

2. Expansion of PE Exemption Criteria

The scope of Pharmaco-Economics (PE) exemption scheme is limited to cases where there is high clinical significance (i.e. no alternatives available) or when it is hard to produce PE evidences for drugs (i.e. small patient pool with 200 or less). Consequently, there are rare disease with more than 200 number of patients that are neither covered by the PE exemption system nor eligible for the Risk Sharing Agreement (RSA) criteria, thus left in the blind spot for reimbursement listing.

The price of PE exempted drugs is determined based on the prices of A7 countries. The calculation formula of A7 prices was set long years ago and the price does not accurately reflect the real price structure of A7 countries as the numbers are outdated.

Recommendation

Given that the purpose of implementing PE exemption scheme was to recognize the necessity of clinical significance and the difficulties of limited PE evidences, the exemption criteria should be expanded to by including more categories such as rare diseases designated by the Ministry of Food and Drug Safety (MFDS) rather than limiting the scheme to excessively small number of eligible patients.

Also, it is recommended to recognize the current pricing structure in the A7 countries and create an objective index on pricing type and sources, and then readjust the calculation formula appropriately in cooperation with the industry stakeholders.

Patient Access

3. Risk Sharing Agreement (RSA)

Currently, RSA is only applicable for anticancer drugs and rare disease treatment and does not apply to latecomer drugs that did not have a chance to be listed under the system. The RSA helps patients with severe disease without any other treatment option to get more access to expensive new drugs that are hard to get access with conventional pricing and reimbursement system. Also, RSA system supports managing balanced healthcare budget control.

Recommendation

It is recommended to expand the criteria of applicable drugs under the RSA to all severe disease without treatment option. Also, we request to include latecomer drugs and strengthen treatment access for patients who are suffering for absence of right treatment.

Furthermore, it is recommended that RSA period to be guaranteed until generic drugs are available in the market and simplify the process for coverage expansion and eliminate mandatory PE assessment to obtain revaluation. To improve the refund process, it is recommended to unify the organizations in charge of RSA refund into the National Health Insurance Service (NHIS) and introduce minus tax invoicing system to resolve the problems of double taxation of value-added tax (VAT).

4. Refunding VAT Duplication (Over-burden) Issue

Introduced in 2014, RSA is a drug reimbursement system to improve patients' access to new medicines. The RSA is recognized as the key contributor for improving patients' access to innovative medicines, especially its refunding system allows maintaining the fiscal neutrality of NHIS budget control. The refunding system is one of schemes under RSA, where a signed company pays back the money to NHIS based on the RSA contract and quarterly notice from NHIS on NHIS reimbursement claims.

Despite the fact that pharmaceutical companies are paying VAT based on listed Maximum Reimbursement Price (MRP) and financially records the refund made to NHIS as sales discount in financial book, there is no related VAT adjustment process under the current regulations. Due to this reason, companies with refunding drugs are paying its VAT higher than the standard 10% VAT. For example, in the case of 30% refunding rate, the company's actual VAT rate is 19.4%, 94% higher than its standard 10% VAT charge. In Australia, the RSA system calculates VAT based on the net price instead of listed price, subsequently preventing unreasonable tax burden. In sum, there are no other countries except for Korea only with RSA refunding system to request higher VAT burden.

Recommendation

We request that by revising the related regulations of VAT Act, pharmaceutical companies are allowed to release the transaction report for the refunding amount to NHIS. Through this revision, companies can pay at 10% VAT aligned with the standard rule, eliminating the extra burden of VAT.

5. Pre-Reimbursement and Post-Evaluation

To improve and accelerate patient access to innovative oncology and rare disease drugs, the government introduced RSA (2013) and PE exemption (2015). However, patients' access to majority of innovative new drugs are still limited. The PE analysis requires various kinds of evidences, however, some drugs, in particular for rare disease treatment, are not possible to develop enough evidences before its launch. As a result, the long period of non-reimbursement creates huge financial burden, decreasing patients' access to treatment.

Recommendation

To handle this issue, the Korean government is considering the introduction of 'Pre-Reimbursement and Post-Evaluation' system aimed at rare disease drugs. According to the known concept of the system, drugs subjected to economic evaluation can select 'Pre-reimbursement' with refunding option after 'Post-Evaluation'.

The 'Pre-Reimbursement and Post-Evaluation' system can be a great help for patients who are in life threatening situation by accelerating patient access to innovative medicines with minimal impact on the NHIS budget. To save patient lives and protect them from catastrophic health expenditure, the system should be implemented for life threatening disease drugs including anti-cancer and rare disease drug.

Post Management

6. Price-Volume Agreement (PVA)

Under Price-Volume Agreement (PVA) system, drugs that have proved its cost-effectiveness or contribution on budget saving, are subjected to penalty of further price cut when the drugs are being widely used. This price cut system is contrary to the government's initial intention when they made reimbursement decision. Nevertheless, the government is currently planning to strengthen the price cut system under PVA to prepare financing for Moon care.

Recommendation

Strengthening of price volume base price cut system should be avoided on top of duplicated post launch price control system. We request to review the post-launch price control system, considering overall pricing and reimbursement as well as microanalysis of initial listing and post launch system.

7. Selective Reimbursement

Selective reimbursement is to reimburse non-reimbursed pharmaceuticals by introducing different co-payment ratio of 30%, 50%, and 80% by 2022. Pharmaceutical candidates for selective reimbursement will be selected by the healthcare authority bodies in accordance with the government's agenda of strengthening the health security. Despite the government driven policy, government

will apply same principle of mandatory pre-emptive price cut for selective reimbursement without considering higher patient co-payment compared to essential reimbursement.

Recommendation

Since the selective reimbursement is to ease the burden on the public by reducing the patients' co-payment on pharmaceuticals under government's healthcare agenda, it is reasonable to omit the additional pre-emptive price cut at expansion and to implement it promptly. Drug price cuts for selective reimbursement should be made through PVA post expansion based on actual health budget impact. Also, enough opinions of stakeholders should be preceded by specific rules and procedures for this new policy.

Discrimination

8. Premium Pricing for 'Innovative Drugs'

Korean government had announced pricing policy (named as 7.7 policy) providing pricing benefit for globally innovative medicine in July 2016 and amended in June 2017. However, the amended pricing policy fundamentally prohibits multinational companies to be eligible for the premium pricing scheme as it is only applicable to drugs under specific conditions; (i) acquired regulatory approval in Korea before any other country, or (ii) fully manufactured in Korea, or (iii) made social contributions over 3% of its total sales.

Recommendation

By simplifying the policy process and eliminating discriminatory provisions, the policy needs to be applicable to both local and multinational companies and fairly recognize the value of innovative drugs. Also, it should operate with greater predictability and transparency to recognize the spirit of EU-Korea FTA.

9. Unfairness of Innovative Pharmaceutical Company (IPC) Designation to Foreign Pharmaceuticals

On May 31, 2012, Pharmaceutical Industry Promotion and Support Act was established to mitigate the negative impact on Korea's pharmaceutical industry after the implementation of the Korea – US Free Trade Agreement. Under the Act, MOHW estimates and selects IPCs and provides the selected companies with

corresponding benefits in terms of tax credit, R&D investment and drug pricing etc. Currently, 44 pharmaceuticals and bio-ventures have been authorized as IPCs under the act, and only two (2) foreign pharmaceuticals among them are on the list. The major reason for the low share of foreign companies in the list can be found from the evaluation criteria that recognizes R&D investment and outcomes made only in Korea. At big hospitals, a number of pivotal clinical trials are run by multinational pharmaceutical companies. But due to differences in handling financial expenses between Korean and foreign companies, the clinical trials are not recognized as R&D costs which is the main criteria for selecting IPCs.

Such biased evaluation criteria cause tipping effect of benefit to some domestic pharma companies and vulnerable to discriminatory policy for foreign companies operating in Korea with holding Korean legal entity.

Recommendation

It is recommended to incorporate key indicators of R&D innovation into the IPC assessment criteria regardless of domestic or global investment. The freshness index of newly developed medicine, introducing new drugs into the market and contribution to public health, should be fairly evaluated to the IPC evaluation criteria.

10. Patent Term Extension for Drugs with Different Salts

Korean Intellectual Property Trial in 2016 and Appeal Board and the Korean Patent Court in 2017 decided that the follow-on drugs with different salts are not in the limits of Patent Term Extension (PTE) system. This decision completely undermines the fundamental purpose and value of PTE, because the follow-on products must rely on the innovator's safety and efficacy data for product license. Also, the regulation is not harmonized with other countries including the EU and the US, which allow PTEs to cover other drugs with different salts with same active compound.

Recommendation

In order to facilitate the development of new drugs and to meet the fundamental purpose of the PTE system, it is needed that the limits of the PTE for a novel compound patent has to be interpreted based on the "active moiety" (novel compound), including drugs with different salts.

Process

11. Transparency Improvement

i) PE evaluation; recently MOHW and HIRA began to share the meeting minutes of Drug Reimbursement Evaluation Committee (DREC) meetings in addition to the summary of evaluation result, as part of its efforts to develop the transparency of the PE evaluation.

Recommendation

In this regard, the meeting minutes of clinical review committee (cancer disease review committee) and the PE evaluation committee needs to be shared to improve the transparency of communication similar to that of other health technology assessment agencies in other countries such as NICE, UK. (at least with the company which submits the evaluation)

ii) Market-Based Actual Transaction Pricing (M-ATP) related price decrease; In April 2018, more than 7,000 drugs from 239 pharmaceutical companies had price reduction as a result of investigation on the actual trading price of drugs. However, the details about how weighted average prices was calculated from the actual transaction prices and quantities of each product was not shared with the companies, which made it impossible for the companies to conduct a study of the price cut decision and prepare countermeasures for preventing recurrences.

Recommendation

It is needed that the details about the calculation has to share with the companies before the implantation of M-ATP related price decrease and weighted average prices.

B. Vaccine

12. Fee Scheme for Combination Vaccine

DTaP based combo vaccines (Tetra, Penta, Hexa and etc.), developed to protect multiple vaccine-preventable diseases are prevalent in the US, Europe, etc. since the 1990s. The DTaP based combo vaccines can reduce the related stress for infants by reducing the number of vaccination and can improve vaccination rate with simpler injection schedule. 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.

Recommendation

In order to reduce injection frequency for infants and to improve vaccination rate, we request to revise the fee scheme for combination vaccines. The pricing standard needs to be based on the number of components for the fee scheme or introduce incentives system for hospitals that have contributed to the increase in vaccination rate.

13. Double Testing for Vaccines

Regarding the release testing for the pharmaceutical products, global manufacturers performs duplicated release testing, one at the manufacturing site and additional one at the importers local laboratory. On the other hand, local manufacturers are only required to perform single release testing at the manufacturing site. In addition, MFDS performs National Lot Release (NLR) testing for the biological products and for the vaccines subjected to MFDS NLR process, the test items performed by MFDS have been exempted for local importer testing.

In July 2018, MFDS announced their new development in the interpretation of local testing requirements for NLR products (vaccine products), requiring importers of biological products to perform a full release testing regardless of the NLR testing. The MFDS demands full local testing requirement of the imported products in addition to the NLR process, as the NLR is recognized as a quality verification process by the authority which should be separated from importer QC testing. In addition, during the local release testing of ethical drugs, an analytical column required for one test item failed to perform unexpectedly. No equivalent column was readily available due to the discontinuation of the column supply, consequently, product could not be released to the market due to incompletion of one test item. Product supply was impacted posing out of stock risk, and the MFDS consultation was sought for the exemption of one test item for this column supply issue. The MFDS position was confirmed to require completion of full testing of the imported product for the product release.

2. EU-Korea FTA clause: The Parties will consider the requests by either Party to accept conformity assessments of that Party when performed in accordance with the Good Laboratory Practices and Good Manufacturing Practices of pharmaceutical products and medical devices and when both Parties' corresponding practices are in accordance with international practices.)

Recommendation

According to the clause from EU-Korea FTA[2] regarding consideration of acceptance of conformity assessment of either party, we request to accept the manufacturing site test results and not to require the duplicated importer local testing for the imported products that are subjected to MFDS' NLR testing.

C. Regulatory

14. Approval of Manufacturing Business (Consignment Manufacture)

Multinational companies without local manufacturing facility cannot hold the product license for locally manufactured products and cannot directly get the license back for the locally manufactured products. Also, they are not allowed to the license contract with local manufacturer is terminated. Thus, multinational companies are required to find local license holder (transferee) which is a difficult task to fulfill in reality, and this is one of the barriers for multinational companies to invest and collaborate with the local industry.

It was anticipated that by expanding the scope of consignment manufacture, it would become the basis for establishing new growth engines of related industries through the transfer of advanced technologies and it would help to simplify the license transfer procedure for locally manufactured products.

Pharmaceutical Affairs Act was revised on October 24, 2017, and the following amendment which will be effective from October 25, 2018, was introduced to add "pharmaceutical drugs which transferred technology to Korean manufacturer among drugs marketed in foreign countries, and orphan drugs" to the scope of the subjects of consignment manufacture (Article 31, Paragraph 3, Subparagraph 3 and 4).

'Pharmaceutical Affairs Act
Article 31 (Approval of Manufacturing Business, etc.)
③ 3. Drugs marketed in overseas that are technically transferred to local manufacturer that is designated by the ordinance of the Prime Minister
4. Orphan drug or national essential drugs managed by Korea Orphan & Essential Drug Center according to article 91 ① <Effective on 25 Oct 2018>'

However, the amendment of Regulation on Safety of Pharmaceutical Drugs (Draft) was proposed on January 31, 2018, to designate "Drugs as prescribed by the Prime Ministerial Decree" in Article 31 Paragraph 3 Subparagraph 3 of the Act, as only to new drugs and orphan drugs that have been or will be granted post marketing surveillance (PMS).

This proposed enforcement regulation which limits the scope of the subjects of consignment manufacture has not been accepted during the public hearing or it has not been proclaimed yet.

In case the scope of consignment manufacturing is limited as indicated in the amendment (Draft), multinational companies are still restricted from investing or collaborating with the local industry.

Recommendation

We request not to amend the Regulation on Safety of Pharmaceutical Drugs to designate "Drugs as prescribed by the Prime Ministerial Decree" in Article 31 Paragraph 3 Subparagraph 3 of the Act as only to new drugs and orphan drugs that PMS have been granted or will be granted. Instead, it is recommended to give permission to all pharmaceutical drugs which transferred technology to Korean manufacturer among drugs marketed in foreign countries as a scope of Article 31, Paragraph 3, Subparagraph 3 of the Act.

15. Conditional Approval

We support the MFDS' decision to adopt a review system for accelerated approvals for earlier patient access in case of life-threatening diseases that are similar to the Accelerated Approval Program of FDA and the conditional marketing authorization of EMA. The conditional approval system is commonly based on surrogate endpoints like objective response rates in single-arm studies in patients with refractory disease. Approval conditions would be given to a certain period time for full approval to conduct confirmatory study result likely overall survival data results. Furthermore, it is encouraging that the MFDS is preparing a guideline for the review system and gathering opinions from industries.

(i) The confirmatory study required as an approval commitment cannot be in related populations, which are conducted usually in patients with less refractory or an earlier stage of disease in the EU and the US.

(ii) In most cases, it is not feasible to conduct confirmatory study in the same patient group due to several reasons like ethical issue to introduce control arm, availability of the drug in the market, low prevalence of the late stage and etc.

(iii) MFDS have a regulation to give full approval based on surrogate endpoints like objective response rates in case of very rare disease but so far, there has been not been a case where full approval was made based on this regulation.

Recommendations

- The confirmatory study to be conducted as an approval condition can be conducted in patients with less refractory or an earlier stage of disease as done in other countries.

- The approval condition should be more flexible to accept other alternative data like overall survival data from the patients follow up.

- In cases to address high unmet medical needs for very low prevalence, a regulatory review path should be established that full approval could be given based on surrogate endpoints like objective response rates.

It is encouraging that the MFDS introduced a system to enable earlier patient access by conditional approvals with surrogate endpoints results like objective response rate (ORR). Yet, more flexibility in approval conditions can significantly benefit the Korea patients with highly unmet medical needs, who are waiting for innovative medicines.

16. Additional Data Requested During Investigational New Drug (IND) Review Process for Early Phase Trials

More and more multinational pharmaceutical companies are focusing on R&D activities and increasing their investment in Oncology (Immuno-Oncology) and Immunology. In these therapeutic areas (TAs), various combination treatments could demonstrate considerable benefit in different populations, which resulted many innovative studies to be designed and conducted

simultaneously during a very early stage, phase I/IIa. In Korea, multinational companies still face serious difficulties in getting Clinical Trial Application (CTA) approval for this kind of early phase trial on time, since the MFDS request much more efficacy/safety data than other regulatory authorities in EU, US or Japan.

The MFDS frequently request for amendment of protocol for Korea aimed at patients in Korea only (i.e. eligible patient failed all available treatment options in Korea). Such requests take much longer to get CTA approval (negotiation with MFDS/central study team, or amending study design) and, as a result, prevents multinational companies from conducting more early phase trials in Korea. These early phase trials have more scientific and medical added value that phase 3 trials for the medical community.

Recommendation
We request to simplify the IND review by reducing the additional data requested in order to attract more early phase trials.

17. Slow Importing Process of Ancillary Supplies (medical device, electronic equipment, lab supplies etc) Used for Clinical Trials
With increasing complexity of study designs, more and more medical devices (ECG, actigraphy, etc.), electronic equipment (smartphone, ePro, Sensor Connector, etc.) or laboratory supplies are being imported and used for clinical trials. However, in Korea, importing process (documentation, paperwork, review time) for supplies are far more complex compared to the process in other countries. If the supplies are not approved for use in Korea, the process takes even longer, and sometimes Korea cannot conduct certain tests for the patients when it fails to import the supplies. This issue has been continuously raised to MFDS, but the process is very slow and cannot keep up with the fast-changing global study trends. As a result, the attractiveness of Korea for innovative clinical trials is being negatively impacted.

Recommendation
It is recommended to simplify the importing process of ancillary supplies (medical device, electronic equipment, lab supplies, etc.) used for clinical trials by considering these supplies as part of the R&D process and not as part of a normal importing process for goods and services.

3. EU-Korea FTA clause: The Parties will consider the requests by either Party to accept conformity assessments4 of that Party when performed in accordance with the Good Laboratory Practices and Good Manufacturing Practices of pharmaceutical products and medical devices and when both Parties' corresponding practices are in accordance with international practices.)

18. Local Labour Law Prevents Hospitals to Use Clinical Research Coordinator from Site Management Organization (SMO) to Work in Clinical Trial Sites
Due to serious lack of trained clinical research coordinator at major clinical trial sites (especially oncology centers) in Seoul and at local level in the provinces, some Korean sites cannot enrol new patient or open a new study. Despite that the current Korea Good Clinical Practice (KGCP) allows clinical research coordinators from SMO to work at the clinical trial sites on behalf of clinical trial site staffs, hospitals are not allowed them due to conflicting local labour law regarding temporary agency workers.

Recommendation
We request to resolve the conflict of laws between the SMO related regulation and local labour law to allow hospitals to recruit clinical research coordinator from SMO to work in hospital clinical trial centers.

D. Customs/Tariff

19. Quarantine Process Required for the Customs Clearance of QC Testing Reagents of Animal Origin
QC testing reagents need to be imported for local release testing and custom clearance for the imported QC testing reagents of animal origin requires quarantine process. For quarantine, duplicated certification statement documents are required from both the shipping country and the manufacturing country, where the two countries differ.

Recommendation
According to EU-Korea FTA[3] regarding consideration of acceptance of conformity assessment of either party, we request 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.

20. Tariff Exemption of Investigational Medicinal Product (IMP)
The IMP custom tariff exemption has been lifted in 2016 with the signing of the EU-Korea and US-Korea FTAs. However, many

multinational pharmaceutical companies operating in Korea are not getting the benefits of FTA as most of the IMPs are not directly imported from the US and the EU. Meanwhile, the custom tariff/ VAT has been significantly increased, recorded KRW 11.5 billion in 2016 and KRW 14.0 billion in 2017 among 28 pharmaceuticals.

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

<Medical Devices>

21. Value of Innovative Medical Devices
The value of innovative medical devices is still insufficient followed by the revision of the VAS system.

Recommendation
The government should strengthen transparency so that the revised VAS system can be practically applied.

22. Import Prices for Reimbursement Pricing Cut
The Korean government is using import price to lower the cost of reimbursement. It has no legitimate grounds and continuous reduction of price is causing a negative impact on the industry.

Recommendation
It is not appropriate to use arbitrary methodologies for pricing and the independent review process shall be operated transparent and fair.

23. Unique Device Identification (UDI)
The UDI is planned to be rolled out to class IV medical devices from July 2019, but the legislation progress is still quite slow, and the industry has difficulties to prepare the UDI introduction. The 3 guidelines on UDI generation, UDI marking, and UDI uploading were announced in June 2018, and the new Notification on UDI is still under the review process.

Recommendation
It is recommended that the finalized and detailed requirements of UDI to be provided in advance before its enforcement.

24. Transaction Price Information in Distribution Reporting
According to the proposed legislation, the transaction prices information is a part of Distribution Reporting which will be required to class IV medical devices from July 2020 and expanded to class I in 2023. The medical device industry has actively expressed their concerns, but there are no responses from the Korean government yet.

Recommendation
We request to provide an official response responding to the industry's concern so that the authority and industry can have discussions on any dissensus.

<Others>

25. Consent Rule for Digital Activity
Under applicable laws, Information and Communications Network Act, segregation/deletion of data is required for personal information collected from users that have been dormant in accessing the web site for one (1) year or longer. Although it is needed to confirm further, Korea is the only country which has this law. Companies are faced with losing its customer information every year which is considered overly strict.

Recommendation
Rather than deleting the customer accounts, we would like to propose for company to provide a clear opt-out option when the company engages with customers. And if it is not acceptable, we would like to ask to extend the period to five(5) year instead of one(1) year as the period of segregation or deletion of the data needed.

Insurance

Overview of the Industry

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

Members of the Committee are Allianz Global Corporate & Specialty SE Korea, AXA General Insurance, BNP Paribas Cardif Life Insurance, BNP Paribas Cardif General Insurance, Orange Life, and Swiss Reinsurance.

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

Key Issues

1. Establishment of Standard for Oriental Medical Treatment and Cost

The portion of oriental medical costs paid for Bodily Injury (BI) claims by insurance industry keeps rising every year (2014:19%, 2015: 23%, 2016: 28%, 2017: 31%). Even more so, the claims payment portion of oriental medical cost for outpatient claimants is 59%. Accordingly, average claims cost for minor injuries has sharply increased.

Claims payments for oriental medical treatments not covered by national health insurance are increasing. Among the total claims payments to oriental hospitals by insurance industry, the portion of medical treatments which are not covered by the national health insurance is steeply increasing every year (in 2016 and 2017, the portion of payments the insurance industry paid to oriental hospitals took 50% of the total; the portion has been increased from 34% in 2015 and 40% in 2016).

The oriental treatments not covered by the national insurance are mainly herbal medicine and oriental physical therapy (e.g. acupuncture), of which payment by the insurance industry increased by 163% in 2016 compared to 2015.

Insurance industry keeps asking Ministry of Land, Infrastructure and Transportation (MOLIT) to set standards for the treatments and costs. However, the announcement of the standard has been delayed for more than one-year months (according to the last pre-announcement, public notification of the standards should have been made on January 20, 2017).

Many insurance companies are working together , participating in the "Oriental Treatment Improvement TF" jointly created by GIAK and the P&C industry (BI assessors in motor insurance) to improve the oriental treatment cost practice in a practical and institutional way by establishing medical expense standards for oriental treatment (including non-covered treatment) and standards for country of origin labelling for oriental medicine ingredients and strengthening HIRA's review on oriental medicine treatment cost.

In the meantime, the industry also keeps setting forth its views regarding the issue to other subjected organizations (e.g. MOLIT, Financial Supervisory Service (FSS), Financial Services Commission, Health Insurance Review & Assessment Service and others).

Recommendation

The ministry needs to expedite the notification of the standards on oriental medical treatments and costs so that excessive treatments and false payment requests by oriental hospitals to insurance companies can be reduced. In addition, the standards on oriental medicine prescription need to be established. (54% of the payments to oriental hospitals are not covered by the health insurance.)

The establishment of the standards will reduce the burden of medical bills on the patients, prevent the medical cost differences on the same treatments among oriental hospitals and reduce the spending of unnecessary social expenses by preventing excessive treatments and duplicate physical therapies from both western and oriental hospitals.

2. Usage of the Cloud Services in Korean Insurance Market

In 2016, the FSS released a guideline for financial companies to use cloud services. Based on such guideline, Korean insurance companies would be allowed to use cloud services, with certain limitations and under certain conditions, being obliged to comply with various regulations; the items which influence the implementation of cloud service are as follows:

(i) Korean financial company must locate its data centre within Korean territory. This measure is to protect the financial company data including personal information of Korean citizens. <Regulation on 'Supervision of Electronic Financial Transactions, Clause 11, Article 11>

(ii) Non-critical data, not including customer unique identification information or personal credit information are allowed to use cloud service, while personal customer data is not allowed to use cloud service; data classified as non-critical must be reported to FSS before implementing in cloud service <Financial Security Institute's cloud guideline for financial company>

However, allowing only some information to use cloud services, most processes are broken and become inefficient. Moreover, the true benefits of using cloud services are not ripped if only partial usage is allowed. Inefficiencies arise and it is impossible to pass on savings and efficiencies to the customer.

Global companies have already implemented or been developing cloud platform to be more agile and reduce time to market for new products. In Korea, several insurance companies are trying to introduce the cloud service, but the regulations related to personal information protection allow only limited services.

Recommendation

FSS should set forth a regulation that allows insurance companies to move personal information to the cloud, including offshore, to use advanced IT technologies provided by cloud service, allowing many benefits to customers.

Non-critical data systems not including customer unique identification information or personal credit information such as HR, messenger, email and internal training system are already allowed to use cloud service. As the non-core business systems mentioned above are operated in cloud outsourcing, financial companies will be able to focus more on operating core-business system such as product domains.

Moreover, temporary operating systems which are required only for a short time with high performance such as artificial intelligence and big data not including customer unique identification information also could be operated in cloud service. With cloud service, there will be no hardware and software purchase for the temporary operating systems. It will bring cost benefit reducing unnecessary expense as a result.

From a security perspective, all the three axes of security (confidentiality, integrity, availability) are already covered with the existing regulation. To comply with them, due-care and due-diligence are already requested to and complied by insurance companies.

3. Excluding CPI from the List of Insurance Products Subject to Forced Sale

Related laws and regulations: Supervisory Regulation of Banking Business Act (Article 88 Paragraph 6 Items 1, 2) / Supervisory Regulation of Insurance Business Act (Article 5-15, Paragraph 9) / Detailed Supervisory Regulation of Insurance Business Act (Article 3-12, Paragraph 2). By its nature, Creditor Protection Insurance (CPI) product is closely related to loans. This product cannot exist without loans. The purpose of purchasing this CPI product is to cover the credit risks that could take place to banks (=lender) in case of the death of the loan borrower who is the policy holder for this product at the same time. In this sense, CPI has to be treated as a kind of the objects (e.g. real estates, financial products, suretyship certification) that banks can get to obtain security interests like collateral, pledge, etc. Also, CPI can be introduced to customers as a way of securing the credit risk of loans in the lending process, according to the regulations according to the operational manual of bancassurance business issued by FSS. Then, it is desirable to introduce. Also, just as customers have to subscribe fire insurance in order to avoid the risk of fire when applying for residing houses-backed loans/mortgage loans, CPI should be recommended to customers in order to cover the risk of death and other diseases.

Current supervisory regulations on Insurance Business Act and Banking Act prohibit the sales of CPI within one (1) month before or after the execution of loans. The Detailed Supervisory Regulation on Business Act lists out the activities and products that the Chairman of FSS set as its exemptions which are judged as having a small risk of protection of customers. This list includes group insurance, general insurance, and property insurance like fire insurance but does not include CPI. Compared with other insurance in the perspective of protection of customers, CPI is one of the insurance products which distort customers' interests the least in terms of premium size and which projects the customers' interests against financial institutions when accidents take place. In that sense, CPI should be regarded as conforming to the objective of the list of products prescribed in the Detailed Regulation of Insurance Business Act.

Recommendation

Based upon the above rationales, we request to include CPI in the list of Insurance Committee products which are set out as exemptions in Article 3-12 of the Detailed Supervisory Regulation of Banking Business Act.

4. Cross-Selling Between Life and General Insurance Products

The cross-selling between life and general insurance products prescribed under the Insurance Business Law (the "IBL") is not in the form of business collaboration between insurance companies. In other words, cross-selling under the current IBL is a system whereby an insurance agent has a discretion to choose to solicit products of a general insurance company in addition to the life insurance company which he/she is affiliated to or vice versa.

However, this cross-selling agent system appears to be contradicting to the exclusive agent system that is still effective under the current IBL Article 85, which prohibits an insurance company from entrusting an insurance agent belonging to another insurer and an insurance agent from soliciting for another insurer other than the ones/he belong to. This is so, given the rationale behind such exclusive insurance agent system, namely, to encourage insurance companies to train their agents as insurance professionals by investing in the education and management of their insurance agents. Notwithstanding the purpose of introducing the cross-selling system, i.e., to increase income source of insurance agents, insurance companies are facing difficulties in managing their insurance agents including education and supervision of them, as they don't have access to information on their insurance agents' cross-selling status, which may ultimately result in the risk of mis-selling to the insurance consumers.

Recommendation

It would be necessary to amend the relevant IBL and/or regulations thereunder to (i) allow insurance companies to choose their cross-selling partners, or (ii) require insurance agents who are engaged in cross-selling to disclose information on their cross-selling status and insurance companies involved, etc. to the insurance company they are affiliated to.

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

A large-sized General Agency ("GA") is often bigger than insurance companies in its agency distribution scale and is out of the

insurance companies' control. The current laws and regulations are unreasonable to the extent they require the insurance company to bear all liabilities for an unlawful act committed by such GAs or their officers and employees. In particular, the IBL provides that the insurance company shall be liable for any losses incurred to the policyholder, etc. in the course of solicitation, with the exception that the insurance company shall be exempted from such liability if it has duly fulfilled its duty of supervision. It is inappropriate to apply this provision per se to GAs.

Recommendation

Customer complaint resulting from mis-selling by an insurance agent affiliated to a GA shall be deemed as a complaint made towards the GA, not the insurance company. In light of the fact that insurance companies have limited control over GAs, it would be necessary to reduce the scope of insurance company's liability to customers caused by GA's unlawful behaviour.

6. Applying the Same Standards for the Forced Sales to Insurance Products as Banking Products

Related laws and regulations: Supervisory Regulation of Banking Business Act (Article 88 Paragraph 6 Items 1, 2)/Detailed Supervisory Regulation of Banking Business Act/Supervisory Regulation of Insurance Business Act (Article 5-15, Paragraph 9)/Detailed Supervisory Regulation of Insurance Business Act (Article 3-12, Paragraph 2).

According to Article 88 Paragraph 6 Item 2 of the Supervisory Regulation of Banking Business Act and Article 5-15 Paragraph 9 of the Supervisory Regulation of Insurance Business Act, the sale of insurance products made within one month before or after the execution of loan is classified as a forced sale being subject to prohibition, regardless of the size of insurance premium amount whereas the sale of banking products is subject to a forced sale when it is made within 1 month before or after the execution of loan put when the monthly instalment amount exceeds 1% of the loan amount.

The standards for forced sales being prohibited are different between banking products and insurance products, generating the unfairness in regulation for each product.

In this regard, the answers received from Financial Services Commission (FSC) were two points:

The first point was that bankers will be inclined to recommend insurance products over banking products because of the commission coming from the sales of insurance products.

However, as the maximum limit of the commission for bancassurance is no more than 50% of that of the other channels, the size of the commissions from selling insurance products through bancassurance will not be big enough to entice the banking staff into recommending insurance products over banking products. Under such a situation, if another restriction of monthly instalment having to be within 1% of the loan amount is adopted for insurance products, this will actually keep the commission amount that banks will receive very low.

The second point was that insurance products do not guarantee the principles like banking products do and that this will eventually bring in customer complaints. As banking staff basically concerns about the long-term relationships with their customers more than commission revenues, they will be cautious in selling insurance products in consideration of the possibility of complaints. And, the monthly premium of less than 1% of the loan amount belongs to a small amount, the possibility of complaints will not be high.

Recommendation

Same standards should be applied for the forced sales to insurance products as banking products. Alternative solution is to include insurance together with banking products in the Article 67, Paragraph 1, Item 4 of Detailed Supervisory Regulation of Banking Business Act, which put small amount of banking products as exemption to Article 88 Paragraph 6 Items 2 of Supervisory Regulation of Banking Business Act.

7. Bills Regarding Special Type Workers

Several bills to promote rights of the so-called Special Type Workers, including insurance agents, among others, are pending in the National Assembly. That is, amendment of bills of Labor Standards Act, Labor Union and Labor Relations Mediation Law, National Pension Law, Employment Insurance Law and Workers Compensation

Insurance Law were submitted. These amendment bills purport to grant Special Type Workers 4 mandatory insurances (i.e. national pension, employment insurance, workers compensation insurance and health insurance) and 3 basic labor rights (i.e. the right to form a union, right to collective bargaining and right to strike).

Of these, the amendment bill of the Employment Insurance Law has recently gone through a decision by the Employment Insurance Commission to provide mandatory employment insurance to the Special Type Workers, including insurance agents, among others. This not only contradicts the long-standing legal stance in this country that insurance agents are not "laborers"(Geunro-ja) or permanent employees, a legal position that should precede provision of any type of 4 mandatory insurances, but also is against the wish of a majority of insurance agents themselves, which account for over 70 % of the Special Type Workers. Also, it is puzzling to note that the results of the latest survey in which a majority of insurance agents take a negative view (only 16.5% favored) about the adoption of mandatory employment insurance are posted in the Website of the Ministry of Employment and Labor, together with the press release where the decision was announced.

Insurance companies offer numerous work opportunities for insurance agents through independent service contracts. From the perspective of insurance companies, this was possible mainly because they do not have the heavy burden of maintaining and managing insurance agents as their permanent employees. If these bills are implemented, it will impose a huge burden on insurance companies both financially and operationally, and as a result, the insurance industry may no longer be able to provide abundant job opportunities for agents in such flexible way as it is doing now.

Recommendation

A careful review should be done first on what is actually necessary to promote rights of insurance agents who account for the most number in the so-called Special Type Workers.

8. Bills Regarding Statute of Limitations (SoL) Applied to Insurance Benefit Claims

Regarding SoL applied to insurance benefit claims, amendments to Commercial Code of Korea (CCK) and Insurance Business Law (IBL) are pending in the National Assembly. The proposed revision of CCK requires that: (i) the SoL be extended to five years from three years; and (ii) the running of SoL is suspended if the beneficiary could not receive insurance benefits for reasons attributable to insurance companies or a procedure for mediation of disputes has been filed. The proposed revision of IBL provides that the running of SoL is suspended from the time when a beneficiary requested payment to the point when the insurance company replies to that.

Recommendation

The revision (i) of CCK needs to be carefully reviewed as frequent revision of law may undermine legal stability. The SoL applied to insurance benefit claims was extended to three years from the previous two years recently in 2014. In case the revision is adopted by the National Assembly, a supplementary provision should be added so that the new SoL of five years is applied to policies purchased after the revised law went into effect.

The revision (ii) of CCK and the amendment to IBL, both of which would allow separate conditions to suspend the running of SoL on insurance policies, needs to be cautiously reviewed as such amendment may impair the major legal principal that conditions for suspensions of SoL are strictly limited to protect legal stability.

9. Financial Consumer Protection Bill

The government submitted Financial Consumer Protection Bill ("Bill") to the National Assembly on May 23, 2017 in an effort to put various consumer protections policies into a single legislation. Similar bills pending in the National Assembly submitted by lawmakers will also be reviewed together with the government bill.

In case of the government bill, despite the different business characteristics within the financial sector, due to the "one size fits all" approach embedded in the bill, its negative impact on the business would be tremendous for insurance industry. For instance, the Bill would impose "suitability" requirement that has been applicable only to variable insurance, as being considered an 'investment product' under the Financial Investment Services and Capital Markets Act (FISCMA), even to protection type insurance that has no bearing upon investment. Also, the Bill would categorize insurance policy loan into a loan product in classifying financial products into four (4)

categories: savings, investment, protection, and loan. An insurance policy loan clearly is not a loan as it is not a standalone insurance product, merely being attached to the insurance policy.

Furthermore, the Bill allows purchase agreement of a financial product to be rescinded by a consumer for as late as five years after the sale/purchase if a financial company breaches any of the six market conduct principles: suitability; need-based sale; duty to explain; ban on unfair competition; fair solicitation; and advertisement rules. This would impair legal stability of insurance business, especially given the fact that insurance consumers are already granted such right of cancellation through the 'cooling-off' period or cancelation right due to mis-selling, which is available under insurance-related regulations. This would also pose the risk of abuse by customers in case of variable insurance, which entails investment loss by nature of the product, having nothing to do with market conduct of insurance companies.

According to Article 48 of the Bill, not the complaining customer but the relevant financial company is to bear the burden of proof if the customer argues s/he suffered a loss due to mis-selling and non-compliance of the duty to explain. We believe that this is unfair for financial industry and lacks legal ground as it contravenes the long-standing/established civil law principle that disputant or whoever brings the claim or dispute should prove one's claim/dispute. In addition, the above Article imposes strict liability on financial companies even though strict liability is rarely recognized other than product liability, medical tort or similar cases. The strict liability proposed in this Bill is expected to cause insurance fraud cases and black consumers. The damage ultimately will be attributed to innocent customers and insurance companies' cost to defend strict liability will eventually be shifted to consumers as well.

The Bill would also prohibit litigation if it involves a small amount, i.e. KRW 20.0 million or below as is currently prescribed under the Bill, or when mediation procedure is commenced. We believe that the threshold amount set for the prohibition of litigation is too high, not to mention that such prohibition is unconstitutional in the first place. The threshold amount would in fact encompass most of the civil disputes, and therefore, needs to be adjusted down.

According to the bill by lawmakers, the court may levy punitive damages on financial companies up to three times the amount lost by financial consumers. The adoption of such punitive damages may work as an unfair discrimination against the entire financial sector.

The bill by lawmakers also provides that consumers may file for a class action lawsuit when financial companies cause damages to a large number of consumers. It is a discriminatory measure against financial companies given that class action is not allowed in other industries such as the communications sector where disputes arise frequently.

Recommendation

Certain parts of the proposed Bill and its Enforcement Decree, for being introduced under the single regulation approach pursued by the Bill, not taking into account of the particular industry, or insurance from our perspectives, should be re-considered. Those parts include: market conduct regulations without regard to insurance products or insurance business; categorizing insurance policy loan as a type of loan product; cancellation right by reason of mis-selling granted for a prolonged period beyond what is already available under the current insurance regulations; and unfair shift of the burden of proof imposing strict liability to financial companies concerning claims of loss, among others.

Threshold amount for small amount disputes regarding prohibition of litigation needs to be lowered, if the prohibition cannot be entirely abolished. That is, if the threshold of KRW 20 million is to be maintained in the Bill, it should be lowered in Enforcement Decree down to KRW 5.0 million or less.

Whether or not to adopt punitive damages and class action lawsuit as is proposed in the bill by lawmakers should be reconsidered

Intellectual Property Rights

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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 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).

In the current global economy "knowledge is [...] the driver of productivity and economic growth"[1] and a nurturing and supportive IP environment is an essential condition for a vital and a successful economy[2]. The integral role of IP to countries' Gross Domestic Product, employment and trade has been confirmed by reports conducted by the European Union Intellectual Property Office (EUIPO) and the European Patent Office (EPO)[3]. The Moon administration has designated innovative growth as one of the key economic goals, with the Korean Intellectual Property Office (KIPO) committing to leading "the creation of strong and flexible IP protection policies"[4] to facilitate such growth.

Against this background, the ECCK is pleased to recognize a number of recent actions to provide a more supportive environment for IP in Korea. These include the amendment to the Unfair Competition Prevention and Trade Secret Protection Act to include trade dress protection and the introduction of protection measures against theft of ideas that have marketing value, as well as the establishment of an international chamber at designated courts as of June 2018, allowing for procedures to be conducted in English (subject to agreement by both parties).

While the current administration has mentioned the importance of IP, the overall perception of IP protection in Korea has gradually decreased, with Korea ranking 54th out of 137 countries in terms of IP protection (falling behind various European countries, as well as countries in Asia such as Singapore, Japan, and China)[5]. A similar sentiment was reflected in the Business Confidence Survey 2017[6], in which close to one third of respondents indicated that IP enforcement was not as effective as it could be. This has prompted the European Economic and Social Committee to call for the promotion of "initiatives and political measures to enforce the protection of intellectual property rights (IP) and the fight against counterfeiting"[7] by the European Commission and the European Parliament in their bilateral discussions with Korean partners.

The existence of regulatory hurdles with regards to the export of technology and the ambiguity as to interpretation of the regulations also has a stifling effect on innovation and the creation of IP. In particular the Act on Prevention of Divulgence and Protection of Industrial Technology and the Foreign Trade Act restrict the possibilities for international collaboration on a wide array of technologies (defined as 'National Core Technology' and 'Strategic Technology/Material').

The ECCK IPR Committee remains willing and ready to continue providing support to all parties involved in enhancing the Korean IP environment, ranging from increasing innovation by raising awareness of the importance of IP among all levels of society to enhancing enforcement of all types of IP.

In an effort to enable such improvements, a number of common challenges that could benefit from amendments in legislation or practice are listed below. ECCK welcomes the openness to cooperation from all relevant stakeholders in order to obtain tangible and sustainable improvements.

1. OECD (1996), The Knowledge-Based Economy, OECD Publishing.
2. OECD (2013), Supporting Investment in Knowledge Capital, Growth and Innovation, OECD Publishing.
3. European Patent Office (EPO) and Office for Harmonization in the Internal Market (OHIM) (2013) Intellectual property rights intensive industries: contribution to economic performance and employment in the European Union.
4. KIPO (2018) Annual Report 2017.
5. WEF (2017), Global Competitiveness Report 2017-2018.
6. ECCK (2018), Business Confidence Survey 2017.
7. EESC (2017), EU-Korea Free Trade Agreement – Trade and Sustainable Development Chapter.

Key Issues

1. IP Studies

IP supports innovation and creativity, leading to increased prosperity and competitiveness. It is therefore of paramount importance that the creation of IP is stimulated and that proper IP protection is assured, as any infringement of IP cascades down from the IP owner, affecting the economy as a whole. The assurance that legal protection is available for new creations sparks further innovation, while a lack of (theoretical or practical) protection for IP can in turn serve as a deterrent to innovation.

In order to facilitate the creation of proper policies "it is essential that all those involved have access to accurate facts and figures. Only then can we ensure that debate on IP's role in supporting

innovation and creativity is based on sound evidence"[8]. This has sparked the European Union Intellectual Property Office (EUIPO) to conduct a range of studies through which both the benefits of IP, as well as the impact of infringements of IP, are quantified. These studies have analyzed the contribution of IP to the economy, the size of the counterfeit trade, as well as the damage inflicted by the counterfeit industry in specific industries in the EU.

The quantification offered through these studies has increased awareness of the benefits conveyed by IP at all levels of society and serves as a motivation to establish a nurturing IP environment and thorough IP enforcement (through in-depth investigations, vigorous prosecution and deterring sentencing). They have further enabled a passive enhancement of IP protection through the avoidance of (support for) infringements of IP by the general public, as well as industry.

Recommendation

In order to enable the creation of supportive IP strategies in Korea and promote a culture of respect for IPR, it is recommended that the Korean government also conducts studies into the economic benefits of IP, as well as the repercussions of IP infringements.

It is further recommended to communicate the findings of these studies with the general public through campaigns as well as inclusion of IP courses in students' curriculum.

8. EPO and EUIPO (2016), Intellectual property rights intensive industries and economic performance in the European Union.

2. Lack of Interest in IP Enforcement

Varies agencies have received a mandate to enforce IPR and bring an end to IP infringements. Unfortunately, IP enforcement is generally not considered of high importance, with limited use of officials' ex officio powers to take action against IP infringements.

In particular enforcement actions against infringements of industrial design rights or sales of products that imitate the appearance of another party's product (for which criminal penalties were introduced in July 2017) do not appear to solicit high interest.

Recommendation

In order to improve IP enforcement, it is important that enforcement officials are motived, that a high level of capacity is built amongst enforcement officials and that expertise is retained even after the departure of officials. This can be done by enhancing officials' awareness about the importance of IP and the impact of IP infringements (supported by quantifications mentioned in point 1), placing an emphasis on tackling IP-related crimes and assuring fair recognition of successful IP enforcement activities. Moreover, the establishment of specific units dedicated to IP enforcement at all agencies mandated to enforce IPR would be welcomed.

In light of the international nature of the counterfeiting industry, the OECD has further pointed to the importance of "strengthening co-operation and expanding the scope of international frameworks"[9]. It is recommended that regular exchanges of information and practices with foreign law enforcement officials, as well as industry representatives are organized.

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

10. G7 ICT and Industry Ministers' Declaration: Making the Next Production Revolution Inclusive, Open and Secure.

3. Ineffective Sentencing of IP-Related Crimes

Effective enforcement of IPR is a fundamental aspect of potent IPR systems. As emphasized by the ICT and Industry Ministers of the seven largest advanced economies in the world, it is necessary "to have in place strong enforcement mechanisms for IP, including through international collaboration, to the benefit of IP right holders engaged in both large and small businesses, in light of serious risk of economic loss stemming from IP infringement including counterfeiting, piracy and misappropriation of trade secrets"[10].

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 wilful trademark counterfeiting or copyright piracy on a commercial scale [...] includ[ing] imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity".

In line with such provision the Korean Trademark Act, Design Protection Act and Patent Act allow for up to seven years of imprisonment or a financial penalty up to KRW 100 million in case of infringement. Unfortunately however, the actual sentences handed down in IP infringement cases remain low compared to

other developed nations. The level of sentencing in Korea was also indicated as a 'systemic deficiency' as it was "considered insufficient to ensure adequate deterrence" [11].

Particularly for actors involved in creating, distributing and selling counterfeit products "[p]enalties and sanctions are key deterrents [...], as these actors will prefer to trade in goods where the rewards are highest, and the risks are lowest" [12]. In countries such as France, Hong Kong, Singapore and the United Kingdom counterfeiting is met with actual prison sentences, whereas in Korea prison sentences are commonly handed down on a probation basis. Additionally, fines as low as a few hundred thousand Korean won are still handed down to sellers of counterfeit products.

Recommendation

It is recommended that awareness of the importance of IP is raised amongst all enforcement officials (supported by quantifications mentioned in point 1) 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.

In particular, enhanced understanding of the lucrative nature of the counterfeit industry will compel all involved to utilize the robust sentencing provided for in the respective legislation and issue truly deterring sentences, quelling the appeal of counterfeiting and curtailing repeat offenders.

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

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

13. OECD (2009), Magnitude of Counterfeiting and Piracy of Tangible Products: an Update.

14. OECD/EUIPO (2016), Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact.

15. Frontier Economics (2017), The Economic Impacts of Counter-feiting and Piracy.

16. WTO Press Release (April 2018), Strong Trade Growth in 2018 Rests on Policy Choices.

4. Border Seizures

Customs Offices are the first line of defence when it comes to contraband and counterfeit items. Particularly in light of the expansion of the global trade (the World Trade Organization (WTO) has forecast that global trade will continue to expand in 2018, following strong growth 2017) [13] and the increasing number of counterfeit products in the global trade (calculated to have taken up 1.95% of global trade in 2007[14], 2.5% of global trade in 2013[15] and calculated to further grow by 9% on an annual basis [16]), the role of the Customs Offices in assuring that illegal products are kept at bay cannot be overstated.

It is against this background that various Customs Offices have published annual reports on their seizures of counterfeit products. At the start of September 2018 the Korea Customs Service (KCS) has published its annual third report on counterfeit seizures by its officials[17]. This ECCK is very pleased to note this continuation as well as the fact that the report has been made available in both Korean and English. This underscores KCS' awareness of the fact that counterfeiting is a global issue, rather than a local concern, and further facilitates consumers, industry and organizations around the globe to take note of KCS' activities. This is further evidenced by KCS' seizure of counterfeit goods being exported from Korea, rather than merely those imported.

For a number of years the use of small consignments for the distribution of counterfeit products across borders has increased. This trend was also observed in Korea through an increased number of cases handled by KCS in 2015 compared to 2014. Given that 2017 saw an increase in both the number of imports and exports compared to 2016[18], the forecast increase of global trade in counterfeit products and the relatively high percentage of Korean consumers purchasing counterfeit products (40%)[19], it is surprising that the total number of counterfeit seizures conducted by KCS in 2017 compared has decreased by 26% compared to 2016.

While the report provides the total number of seizures as well as information on how these seizures are made up, the report contains three different indication methods to quantify the seized products. These are the number of items, the total weight of the seized products, as well as the products' combined value. The use of inconsistent and uncommon units makes it a challenge to get a proper understanding of the actual seizure results.

Recommendation

In order to protect consumers in Korea from counterfeit products, it is important that an adequate shipment examination rate should be 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.

To further maximize the impact of the essential publication on KCS' counterfeit seizures, it is recommended for such publication

17. KCS (2018), 2017 Annual Report: Intellectual Property Rights Seizures.

18. In a consumer survey conducted by ECCK in 2018 40% of consumers indicated to have purchased counterfeit products, ECCK (2018), Busan Consumers' Perception of Counterfeit Products 2018.

19. Regulation (EU) No 608/2013

to be aligned to the practices adopted by for example the European Commission and Japan in that it clearly indicates the total "number" of items seized (rather than the total "weight" of the seized items as the variety in items' weight dilutes the value of this information) and their combined "value".

5. Customs Recordations

In order to facilitate the seizure of products that infringe IPR before these products enter the country, it is possible in many countries for IPR owners to record their IPR at customs through so-called recordations. Doing so assists customs officials in their efforts to prevent the import of IPR infringing products. Article 235 (1) of the Korean Customs Act provides that import and export of products infringing a variety of IPR (including trademarks and industrial designs) is prohibited and for all of these recordations can be made.

At the end of 2017 close to 19,000 copyrights, 5,600 trademarks and 34 industrial designs were recorded at customs. While industrial designs are important business assets and their protection is thus actively sought after, the documentation required for their recordation at customs exceeds what is required for trademark recordations and is often impossible to provide. In particular, it is a mandatory to provide evidence of industrial design infringement (such as court decisions or evidence of charges brought by the Prosecution Service), whereas this is optional for trademark recordations.

Recommendation

In order to ensure an adequate level of protection against infringements of industrial designs, it is recommended that the requirements for their customs recordations are aligned with those for trademarks.

6. Seizure of IP Infringing Materials

In recent years a growing trend has been observed where different components of counterfeit products (such as canvas, metal parts, buttons, zippers, as well as labels) are shipped into Korea through separate shipments. Considered by themselves, it is difficult to assess the infringing nature of some of these components. Particular components however, such as canvas or labels, that directly infringe IPR (most commonly trademarks) should thus be subject to seizure by customs officials. It seems to be the case however that these components are not subject to scrutiny due to these not being considered 'goods'.

Recommendation

It is recommended that customs officials seize all materials that infringe IPR (regardless of whether these are final products or components) in order to also frustrate the local assembly of counterfeit products.

7. Free Trade Zones

As of the end of June 2018, Korea counted 13 'free trade zones' in which a total of 1,150 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.

In a 2015 report[20] Europol and the EUIPO, indicated that "transit points for transportation of goods from Asia to Europe, which act as major hubs for container traffic because of their large free trade zones [...], have also become significant enablers for the activities of counterfeiters". Further research by EUIPO and OECD has found that "the existence, number and size of [free trade zones] in a country correlate with increases in the value of counterfeit and pirated products exported by that country's economy"[21]. "[Free trade zones] are a particularly useful tool for counterfeiters, who tend to exploit them regularly in their operations"[22] and an EUIPO Europol report found that they "continue to be associated with a number of IPR crimes, and harmonised enforcement standards are still required in certain geographical areas"[23].

While transhipped containers take up the majority of the containers handled at the Busan Port, transhipments are rarely subject to inspection. Additionally, the fact that free trade zones are operated by various government entities, elevates the risk of abuse. The aforementioned EUIPO and OECD report found that based on the number and size of the free trade zones in Korea, an estimated USD 7 billion in counterfeit products was exported from Korea in 2013 (the fifth highest in Asia)[24]. Various cases have highlighted the fact that abuse of Korean free trade zones is not

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

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

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

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

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

merely theoretical, but an actual reality.

Recommendation

In order to curb the abuse of Korea's free trade zones it recommended that mechanisms are implemented that provide adequate control over transhipped cargo, and standards for IPR enforcement at free trade zones are implemented.

In light of the potential for abuse of free trade zones, a number of improvements were suggested by the OECD[25]. In line with these, ECCK would like to recommend that:

- Supervision of activities in free trade zones is improved;
- Competent enforcement authorities are allowed to conduct ex officio investigations in free trade zones;
- Cooperation with stakeholders is enhanced and codes of conduct are developed.

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

8. 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.

The local government officials' detailed knowledge about their region and commitment to improving the market environment for their consumers have proven to be invaluable to the initiative's success. Particular dedication has been displayed by the officials of Seoul Central District Office's Counterfeit Crackdown Task Force, which have conducted in total more than 2,000 seizures, seizing 320,000 products with a combined value of EUR 120 million at the end of 2017.

In addition to the seizure of illicit counterfeit products, the enforcement activities have had a chilling effect on any merchants considering the sale of counterfeit products. As a result, the open display of large quantities of counterfeit products has mostly been abolished on Seoul's Itaewon, Myeongdong and Namdaemun street markets.

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.

Additionally, the Prosecution Service has recently decided to limit its involvement in the investigation of IPR infringements and focus on prosecution. Unfortunately, it has not been possible for other authorities to increase their IP investigation activities in order to fill the gap, allowing for the sale of counterfeit products to steadily increase.

Recommendation

The involvement of Seoul's local government officials in curtailing the sale of counterfeit products has proven to be effective and it is recommended that the Prosecution Service enables local government officials of other large cities in Korea to investigate counterfeiting activities and seize the illicit products. It is important to note that the European Commission has also highlighted the need for "continued actions" on physical markets[26].

In addition to employing support from local government, it is important that the burden of these anti-counterfeiting activities is shared amongst all capable authorities in order to make a lasting impact. Cross-agency cooperation will result in more systematic, effective and therefore sustainable enforcement. Without such, it will simply not be possible to bring an end to the creation, distribution and sale of counterfeit products.

26. OECD (2011), The Role of Internet Intermediaries in Advancing Public Policy Objectives.

9. Pro-Active Measures by Online Intermediaries

Over the past decade the amount and the transactions made through online sources has increased globally. In Korea alone, the total value of all products sold online has risen fivefold from 2007 to 2017 (from over EUR 11 billion to close to EUR 59 billion). The counterfeit industry has keenly followed such trend and has also expanded to the online space in order to distribute their illegitimate products to (unsuspecting) consumers.

This online expansion of the counterfeit industry has prompted the issuance of a number of guidelines and best practice documents. In a publication of 2011[27], the OECD mentioned that online intermediaries play an increasingly important role in curbing the sale of counterfeit products and also pointed to an increasing wish for proactive, rather than reactive, measures by online intermediaries. The International Chamber of Commerce's Business Action to Stop Counterfeiting and Piracy (BASCAP) has also suggested a number of best practices for online intermediaries[28], which have also been adopted by a number of online intermediaries.

In Korea, while the Act on the Consumer Protection in Electronic Commerce, etc. has been amended in 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[29].

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 various online intermediaries play. In establishing such legislation, input should be gathered from all relevant parties involved.

It is also recommended that online intermediaries incorporate best practices from around the world on their platforms and increase communications and cooperation amongst themselves and with industry. Increased harmonization through the sharing of information amongst online intermediaries in Korea would further be welcomed.

It is further recommended for all online intermediaries to pro-actively limit the possibilities for counterfeit products to be sold through their services, which will result in a greater reliability of their services. The following three measures have been adopted by online intermediaries in various advanced countries and do not require the online intermediaries to engage in any assessment of whether the products sold are genuine or counterfeit:

- Adoption of key word filtering systems with constant update of such key words;
- Implementation of efficient and expeditious take-down procedures;
- Deletion of ID and account(s) of sellers caught offering counterfeit products for sale.

27. OECD (2011), The Role of Internet Intermediaries in Advancing Public Policy Objectives. http://dx.doi.org/10.1787/9789264115644-en

28. ICC BASCAP (2015), Roles and Responsibilities of Intermediaries. www.iccwbo.org/Data/Documents/Bascap/International-engagement-and-advocacy/Roles-and-Responsibilities-of-Intermediaries-BASCAP-Report-2015---Executive-Summary/

29. European Commission (2018) COMMISSION STAFF WORKING DOCUMENT - Report on the protection and enforcement of intellectual property rights in third countries. http://trade.ec.europa.eu/doclib/docs/2018/march/tradoc_156634.pdf

10. Provision of Evidentiary Materials to Calculate Damages

The possibility that IP owners initiate civil litigations, in addition to the criminal prosecution by the Prosecution Service, serves a further deterrent to IPR infringements. During such litigation, parties held to have infringed IPR can be ordered to financially compensate damages caused by their infringement. In such procedures claimants are required to submit evidence to prove the extent of the infringements and the damages incurred. In order to take account of the increased digitalization, the Patent Act allows since 2016 the submission of 'materials' instead of 'documents' (which refers to physical documents)

While the claimant carries the principal burden of proof, key evidence about the alleged infringement and the caused damage can be in the possession of the accused infringer. In order to avoid accused infringers' simple refusal to provide such materials, the Patent Act enables courts to order defendants to submit materials essential to prove infringements or to calculate the amount of damages. In case a party fails to follow an order to submit materials without any reasonable grounds, the court may deem that the claim of the other party on the record of materials is true.

Recommendation

It is recommended for all IP legislation (not only the Patent Act) to be amended to allow the submission of 'materials' instead of 'documents'.

It is further recommended that the Trademark Act, the Design Protection Act and other IP legislation, are amended like the Patent Act, to expressly allow courts to deem parties' claims true in case

requested key evidentiary materials are not produced by their opponents without any reasonable grounds.

11. 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, based on the defendant's profit, or based on 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 the circumstances of the case.

These four calculation methods are in line with global standards. In multiple countries (including Germany, Japan and the United States of America) the damages are most commonly calculated on the basis of what would constitute a reasonable royalty. The high burden of proving either the lost profits or the unjustifiably gained profits and the absence of the standards to decide on the quantification of reasonable royalties, make that in Korea damage awards are most commonly rendered based on what the courts deem to be a reasonable amount. To exemplify this, 70% of the trademark infringements procedures from 2000 to 2013 saw a calculation of the amount of damages based on the court's discretion[30].

30. 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 awards 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.

12. Statutory Damage

The Trademark Act does allow for statutory damage claims, provided these do not exceed KRW 50 million. Due to the lack of a minimum amount and the inclusion of a relatively low maximum amount, the current provision is not actively used in practice.

Recommendation

In order to increase the actual use of the statutory damage provision of the Trademark Act and to allow for this provision to have a truly deterrent effect, it is suggested that a minimum amount of compensation would be introduced and that the current maximum amount would be increased.

Kitchen & Home Appliances

Hyokung Suh
Director,
Kitchen & Home Appliances Committee

Overview of the Industry

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, ICT and Future Planning (MSIP), 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.

In order to comprehensively manage the safety control system of electrical appliances and industrial products, Electrical Appliances and Consumer Products Safety Control Act had been implemented since January 2017 by combining Electrical Appliances Safety Control Act and Quality Control and Safety Management of Industrial Products Act. However, as the industry has claimed that some irrationality existed in executing this combined Act, its revision has started to be implemented since July 2018. Its content is mainly about eliminating the obligation of putting a KC mark on some items with low risk purchased through an agent and streamlining a certification process as the certification related test duties for parallel import of electronics are removed.[1] Accordingly, an analysis indicates that the rate of overseas direct purchase is increasing, and its kinds of products are growing as well.

As the market is expanding, the import quantity is increasing as well. However, the importers face high non-tariff barrier to enter the Korean market. Above all, any food-related products including apparatus and containers must be tested in detail for each material and color to ensure the food safety. Electronic goods should be determined whether they must go through one or more required tests for verification as described below in order to be imported.

In terms of EMC Registration/Certification, the MSIP gives a KC mark and approval number differently according to the state: Conformity Certification, Conformity Registration or Provisional Conformity, as a result of the ministry-hosted conformity assessment for communications equipment. Goods requiring electricity and radio frequency are subject to the EMC Registration/Certification, including products with rechargeable battery such as Bluetooth.

In terms of Electrical Appliances and Consumer Products Safety Control Act, the MOTIE gives a KC mark and approval number differently according to the state: Safety Certification, Safety Confirmation and Supplier's Declaration of Conformity. Such classification depends on standards provided by the Manual for Electrical Appliances and Consumer Products Safety Control Act. The KC system provides an integrated national certification mark. In 2011, each different government office marks became under control of a unified mark. But the process of certification application is separately implemented by each office on its own discretion. The certification number is also given and marked separately.

Products approved from abroad after strict local tests are also subject to the Korean test process. Even though Korea has Mutual Recognition Agreement (MRA) to help streamline the process between signed parties, but the recognition scope remains very limited since most of the agreements are still at phase one (recognition for the local laboratories' test report). The local test report will help during the Korean certification process, but most companies tend to give up as it is very challenging to get the approval. It is hard to release products in time because the process is highly time- and cost-demanding. Test fees and charges are also a big burden for many companies.

Key Issues

1. Easing Test Standards for Household Scales

Requirements for a scale with a measuring capacity of 1kg or less are simpler than that are over 1kg, which needs formal approval. The procedure to obtain 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 regulatory hurdles and requests, household scales in the domestic

1. Parallel import is allowed only when a trademark's holder of a right of locally-exclusive use is registered. It is allowed only when the model subject to parallel import is identical with the one with safety certification.

market are limited in type and most of them have excessively-high capacity and prices, while detail precision is not even needed at home. In this regard, the regulation is considered to hamper the purpose of the FTA between Korea and the EU which has been aimed at giving Korean consumers an opportunity to have access to more various products at reasonable prices.

Recommendation

We recommend that the formal approval for household scales to be removed, considering most economies such as the EU, the US, and Japan do not require the approval for household scales.

2. Conformity Assessment for Electronic Goods

Conformity assessments for electrical safety and electromagnetic waves are considered non-tariff barriers. Currently, the MRA is effective in which countries agree to treat a test report or certification issued from another signing country as same with that of their own. That is, parties who signed the MRA recognizes 'conformity assessment results', produced by the other parties, as the result they conclude. The MRA is established to facilitate trades among countries by cutting cost and shortening the period of the test. Korea and the EU mutually agreed on the Phase One (Recognition for the local laboratories test report).

EU-Korea FTA: Annex 2-B / Electronics / Article 1 General Provisions / (d) promoting "one test" and where practicable, a supplier's declaration of conformity through elimination of duplicative and unnecessary burdensome conformity assessment procedures.

(i) Streamlining the Mutual Recognition Process of Electromagnetic Conformity Assessment Report

At present, international standards (IEC-CISPR) and Korean standards (KN) are different in the electromagnetic test for the same products. Likewise, these circumstances do not easily allow the "one test". The only way to certify the report from EU, the mutually agreed laboratory in the EU can host a test with KN. But it is rather less efficient than a test in Korea in terms of time and cost. There would be difficulties to deliver an accurate test method to the local people while they have no idea of the Korean standards. Moreover, if the test fails to respond to the requests for submitting modified samples, it could be too late to release new products in time. For these reasons, the European companies give up to apply their test report as it is to Korea and take the test in Korea again. The Korean standards are different from that of most of the countries which created a difficult trade barrier for the Korean importers.

Recommendation

We hope that the legislation regarding Electromagnetic Conformity Assessment to be reviewed on the basis of international standards so that the testing and evaluation can meet the purpose of the original regulation.

(ii) Expanding the Scope of Supplier's Declaration of Conformity

Europe defines both Electrical Appliances Safety Certification and EMC Registration/Certification as Supplier's Declaration of Conformity, in which suppliers self-declare their product safety and assume responsibilities. Korea requires suppliers to obtain confirmation or certification for safety from the government authorities. Since the conclusion of the EU-Korea FTA, the concept of Supplier's Declaration of Conformity has been first introduced to Korea. In terms of electrical appliances, suppliers conduct the conformity assessment on their discretion for items subject to Supplier's Declaration of Conformity among products determined to be safer. But it is doubtful if any progress, even gradually, was made compared to the initial stage, because only a few products have been added since then. As for conformity assessment for electromagnetic waves, all electrical products are subject to obtaining certification or registration and suppliers cannot prove the product safety on their own. Since January 2017, the MOTIE has made it mandatory for manufacturers or importers of electrical appliances subject to Supplier's Declaration of Conformity to report it to the Minister, the conformity has lost its meaning.

Recommendation

We request for active expansion of the list of Supplier's Declaration of Conformity for the safety verification of electrical products. We also suggest creating the list of Supplier's Declaration of Conformity to the electromagnetic conformity assessment list.

3. Reasonable Application on Environmental Assessment of Recycling

The purpose of EcoAS is to minimize environmental loads through systematic management of entire life cycle of electrical products, electronic devices and vehicles, from design and production to

disposal. EcoAS is explained as the system embraced the EU regulations; Restriction of the use of Hazardous Substances in electrical and electronic equipment (RoHS), Waste Electrical and Electronic Equipment (WEEE), End of Life Vehicle (ELV), however, in some cases, it is difficult to follow the system in Korea as an importer because it requires more evidence documents than the EU.

For example, in the case of Compliance announcement of Toxic Material Containment Standard, one of the documentary evidences required is documents or marks issued by the exporting country, such as RoHS certificate, WEEE documents or CE marking of the products. In the exporting country, once the basic model of a product line is compliant with RoHS and the certificate is issued, other series models in the relevant product line are also recognized as RoHS compliant products. However, in Korea, all series product models are required to submit proof documents for each model.

In Europe, self-declaration is universal, while in Korea, self-declaration documents are not accepted, but only certified documents of certified inspection agencies are recognized. Also, the CE mark is only accepted as being embossed or engraved on the actual item, whereas in Europe, CE marks are required to be included on the label of a product or on the packaging box for small size products.

Another example is Compliance of Material and Structure Improvement Rules where manufacturers and importers are requested to submit the product enhancement plans. Unlike the manufacturer, the importer is a buyer who imports goods from overseas. There is barely no chance for importers to be involved in the improvement process of the material structure of the product, therefore, it is irrational to be subject to a fine for incompletion of product contents details to be filled.

Recommendation

In case the basic model of a product line is certified, compliant with RoHS, it is requested to validate RoHS certificate of compliance for series model of the relevant product line. Also, we request the self-declaration documents as the documentary evidences for product series models are recognized as well as CE mark could be at least labelled or marked on the packaging unit is accepted. For Compliance of material and structure improvement, we request to exempt the obligation of improvement plan submission for importers.

4. Simplifying Food Inspection on Imported Apparatus and Containers for Food

When new apparatus and containers are imported, areas directly touched by food should go through the scrutiny for each material group. And, the re-examination is not required when importing the same products afterwards, but documents need to be submitted. Given the fact that such food apparatus or containers, mass-produced like industrial products, are being inspected by types of material and color, improvement on its regulations and procedures, of those are clearly apart from food, is needed.

(i) Minimum Weight of Imported Apparatus and Containers for Food

Any imported apparatus or containers for food weighing less than 100 kg (minimum standard notified by the MFDS) should go through the scrutiny process if the quantity exceeds the minimum standard. Given the fact that such food apparatus or containers are mass-produced like industrial products and are being reported according to types of material and color, it seems unnecessary for the need of the standards on minimum weight. In addition, repetitive scrutiny process incurs additional costs and time.

Recommendation

We request for the initial scrutiny result to work as a verification to be exempted from further scrutiny regardless of the minimum weight (100 kg).

(ii) Reviews on a Korean & English title of materials used in apparatus or container package in Korean Food Standards Codex

Korean Food Standards Codex and Korean Food Additives Codex cover materials used in apparatus or container package. However, the codex is not properly reflecting recent changes including English titles for new materials, marking it challenging for companies to put Korean labels. Examples are as follows.

- Differences in notation upon the same material: In case of notating stainless in Korean, 스테인리스 is how it is written in standard dictionary whereas it is written in 스테인레스 in Korean Food Standards Codex
- Not reflecting up-to-dated titles of newly developed synthetic materials (e.g. Tritan)

Kitchen & Home Appliances Committee

Recommendation

We request for regular updates on the Korean Food Standards Codex and Korean Food Additives Codex on materials used in apparatus or container package, as the industry and new materials are continuously being developed. In order to reduce confusion among companies and consumers, consistency in the materials' titles, when written in Korean, needs to be achieved.

Logistics & Transport

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Overview of the Industry

Shipping

According to the 2018 Baltic and International Maritime Council (BIMCO) report, the bulk carrier market's continuous recovery is expected this year as well. The dry bulk cargo market's demand increased by 5% last year, and fleets increased by 3.2%. Especially, the freight rates recovered in the second half of 2017 and profitability for bulk owner and operator has improved as China rapidly increased imports of oil and iron ore. The Baltic Dry Index (BDI) in 2018 recorded 1,214 in average, which is 4.6% higher than the same period of last year.

During the first half of 2018, due to the Iran sanctions and rise of oil price etc., the chartering of product tankers and oil tankers showed a continuous downward tendency. But the oil tanker sector has recorded the highest volume of scrapped oil tankers since 2008 so that the supply and demand is expected to be improved within this year after slowing down the growth rate of bottoms to around 1%. Meanwhile, the product tankers' growth rate, although its scrapped volume is not the same level as the oil tankers', is expected to be within 2% this year because the speed rate for new supplies has slowed down since the second quarter.

Because the shipping industry, on the other hand, is struggling with low fare and high oil price that it's more likely to struggle from trade conflict between the US and China. Although there is no remarkable impact on containership market right now, it is expected to lose 1% in total traffic of container shipments if the trade war gets worse. As the US has imposed the first additional tariffs on USD 34.0 billion worth of imports from China, China also imposed tariffs on imports from the US in response, which affected products that account 6% of the total trade between the two nations like engines, medical devices, semiconductors, etc. The uncertainty of the market increasing from trade conflict between the US and China is affecting the Korean shipping industry as well. The trade conflict between the US and China increases the uncertainty within the industry, which could affect the Korean market as well as the international one. The International Monetary Fund (IMF) recently lowered its global trade volume (products and services) growth forecast 0.3% from 5.1% to 4.8%. According to the industry officials, the domestic shipping companies are

affected more negatively because they are forced to focus on shipments from overseas.

On April 5, 2018, the Korean government announced 'Shipping Industry Revival Five-Year Plan' to revive the domestic shipping industry after Hanjin Shipping's bankruptcy. To revive its global competitiveness up to the fifth-largest in the world by 2022, the government plans to secure KRW 51.0 trillion for sales in the shipping industry, 1.4 million DWT in controlled fleets and 1.1 million TEU in ocean-going container space. First, the Korean government will run win-win cooperation fund that shipowners, operators and shipbuilders participate as an investor for shipbuilding. The participating investors get to share profits made from newly built ships. Moreover, the new plan would expand the national shipping system to ship domestic shipments to secure stable cargo bookings and implement shipowner and shipper verification system to provide incentives related to customs clearance for the shipowners and shippers who utilize the national ships frequently. Secondly, the government plans to build more low-cost, highly-efficient ships based on the financial support program by the Korean Ocean Business Corporation (KOBC) that was launched in July to restore competitiveness in the shipping sector. Furthermore, the government plans to expand its financial support through the KOBC for the small and medium sized shipowners who have had difficulties with the existing financial program. Also, it will increase support providing used ships, ballast water treatment facilities, container units and some subsidies for replacing old ships. Lastly, the KOBC will improve its financial structure to strengthen cooperation and management of shipping companies with the Korea Shipping Partnership (KSP) and offer risk management and investment consulting services for the companies.

Air Freight

In April 2018, the airline passenger traffic recorded 9.8 million, an increase by 12.5% compared to same period last year. The passenger transportation sector is keep rising due to increasing demand for international travel, expanding low-cost airlines' flight operations, and low oil price. Meanwhile, the air routes from China have not yet fully recovered from China's ban on selling package tours to Korea, but the number of routes increased 43.9% compared to same period of last year. According to the Korea International Trade Association (KITA), the amount of airfreight export took 30.5% of total export volume in 2017, which is USD 175.0 billion. Airfreight export continues to grow, thanks to the advanced export industry, expansion of e-commerce market and diversification of air transport. Focused on the semiconductor, wireless communication instruments and computer took almost 70% of the total air freight export. The export rate of high valued products like medicine and cosmetics also has increased. The export of cosmetic products has increased as the result of the 'Korean Wave', which delivered better reputation to consumers and helped to increase the products' quality. In case of medicine, more than 80% of the total exports were shipped by air freight due to higher value was developed. In the first half of 2018, the air freight sector recorded 370,000 tons, an increase by 4.2% compared to same period of last year, from increased demand of international passengers and interest in semiconductor. The airfreight sector is expected to increase steadily as demand for semiconductor, IT products and special cargoes continues to increase in overseas direct purchase and global economy recovery.

International Express Shipment

In order to accommodate the rising number of overseas direct purchase, the Korea Customs Service (KCS) newly established an express logistics center at Incheon International Airport so that it can support customers to receive overseas direct purchased products faster. Besides, the KCS is planning to establish a marine express shipment center near Incheon Port by 2021 to process overseas direct purchases delivered by ships swiftly.

When consumers purchase products from international cities close to Incheon such as Weihai, China, and use car ferry for shipments, the shipping cost will be lower, which will lead the volume of shipment to be increased as well.

The Korea Consumer Agency (KCA) has surveyed 1,000 consumers who have made overseas purchases. According to the survey result, Korean consumers spent about KRW 2.2 trillion for overseas direct purchases, which has increased 29% from the previous year and recorded the highest amount at all time. The most purchased items were clothes (40.7%), dietary supplement (38.9%) and bags, purses and accessories (34.8%). Major customers and product of global express companies

are commercial sample for global companies and commercial documentation or letter for banks. Meanwhile, most of B2C shipments are handled by local express companies.

Key Issues

1. Concern About Unfair Market by Korean Government's 'Shipping Industry Revival Five-Year Plan'

The Korean government announced the 'Shipping Industry Revival Five-Year Plan' to revive domestic shipping industry after Hanjin's bankruptcy. The government is planning to provide aids to the local shipping companies so that they could compete with the global shipping companies. At first, the government revealed various financial support plans, including managing win-win co-operation fund so that shippers can order ships with investment from shipbuilders and shipowners, and providing financial support for replacing old ships. Moreover, it converts bidding standards for public freight from the lowest bidding system to the comprehensive screening bidding system which was provided by the five power companies and the Korea Shipowners' Association in February 2018, and it includes the plans of preferential loading for Korean cargoes so that domestic ships could be used for transportation of strategic materials, etc. The plan aggravates existing chicken games in the shipping industry by encouraging the domestic shipping companies to fill their container ships to build unnecessary ships and creates concerns unfair market for global shipping companies and raises deficit concerns among those companies. Furthermore, the plan could cause international trade conflicts as criteria of the comprehensive screening bidding system is provided by five power companies and the Korea Shipowners' Association, which is more likely to be in favor of domestic companies.

Recommendation

In order to prevent unfair competition and discourage unnecessary price competition, government should seek ways to help domestic shipping companies and global shipping companies to grow through cooperation and coexistence.

2. Korean Government's Leading Counteracting System Regarding Adoption of Initial Strategy for Reduction of Greenhouse Gas by IMO

The International Maritime Organization (IMO) adopted the initial strategy for reducing greenhouse gas based on the decision of intersessional working group for greenhouse gas during the 72nd session of the Maritime Environment Protection Committee (MEPC). However, the adopted initial strategy only reflects counterparts' opinions without any complete agreement of all member countries. Moreover, the initial strategy is a part of the plan to reduce greenhouse gas and it includes a possibility for a new regulation will take place. The strategy shows required measures by each term, the short-term is 2018~2023, the medium-term is 2023~2030 and the long-term to take place after 2030. Accordingly, the IMO has plans to include additional measures to reduce greenhouse gas emissions from ships, and the improved IMO strategy that includes additional measures to be adopted in spring of 2023.

Shipping industry, henceforward, should prepare a countermeasure considering the characteristic of management regarding new regulation not only on greenhouse gases but also on sulphur content in fuel oil. The shipping industry should prepare a countermeasure not only for the IMO's regulations on sulfur content in fuel oil but also for the future regulations regarding greenhouse gas after considering the characteristic of the management.

Recommendation

Regarding environmental regulation of the IMO, we recommend the government to find out industries' problems and capability of related industries to ship's life-cycle and then establish opinion about reducing greenhouse gas emissions from ships.
Also, the government should form a regular counteracting system between the industry in order to create an environment that could establish a preemptive policy on the IMO regulation that may occur in the future.

3. Current Global Policy According to Increase in E-Commerce Transactions and Improvement of Korean Policy Direction

The significant growth of cross-border e-commerce, which has dynamically driven by innovative technologies, presents many great opportunities and several challenges to international

trade. It can't be deny that e-commerce is a major growth driver and provides a great opportunity to small and medium sized enterprises. Meanwhile, the customs authority is facing the emerging challenges that are link to the protection of intellectual property rights, the security and safety of citizens, the revenue collection and illegal using of another name and so on. For these challenges, the World Customs Organization (WCO) is reviewing and recommending balanced changes to support sustainable development and it has taken some measures. In July 2018, as the first example, the Australian authority has introduced the Vendor Collection Model (VCM) for e-commerce products for fair competition with domestic businesses and secure revenue. Also, the Taiwanese authority has introduced the frequent importer control and real-name authentication system this year. Following these changes, the KCS has announced its plan to introduce real-name authentication system to prohibit the cases of illegal usage of other's name and prevent undeclaration for tax exemption.

The KCS's new policy is supported to prevent illegal cases and violators. However, one of reasons for consumers and shippers to commit the crime with e-commerce transaction in the first place is because B2C products' costs are lower compared to the domestic product prices. Therefore, concerns still exits about the efficiency of this measure to tackle the abuse of de-minimis clearance since the price competitiveness would still remain so that consumers and shippers will continue to commit illegal acts. Instead, the restriction could cause delay for business products and commercial documents customs that require urgent attention.

Recommendation

Instead of imposing sanctions for express distribution services and e-commerce companies to add submission duties to the MOEF and the KCS, reviewing Australia's VCM is recommended to eliminate fundamental causes. If adopting the real-name authentication system is inevitable for the KCS, then we recommend reducing the duty on business products or commercial documents.

4. Simplify the Scopes of De-Minimis Only to Range of Value

Most countries have a list of goods for tax exemptions specified in the WCO's "Guidelines for the Immediate Release of Consignments by Customs". The advantages of such list and appropriate standards help the customs authority. Despite the WCO's recommendation, the KCS adopts additional standards in their de-minimis regime, which allows only for personal purpose or business sample as well as price standards below USD 150 (USD 200 from US or Puerto Rico as per Korea-US FTA). The current regime has been making a big burden to express logistics companies to clarify clearances within a limited operation time and with a few shipment information such as weight, description, and name of consignee which were given by shipper. Also, the vague guidelines for business samples could risk the importers to become potential criminals and bring a dispute with consignees.

Recommendation

It is recommended to revise the de-minimis regimes to be based on only the cost of the goods. The most efficient system is the one based solely on the value of goods and it's recommended by the international association in terms of efficiency.

Marine & Shipbuilding

Hwonnarae Ha
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Marine &
Shipbuilding
Committee

Overview of Industry

According to the Export-Import Bank of Korea, the number of newbuilding orders of the world is 6.23 million CGT, which increased 61.4% compared to same quarter of last year. The increase of demands for handling with strengthened environmental regulation, low price of ships and expansion of LNG business are the main reasons of increased quantity in the newbuilding market. However, growth of order quantity in the second quarter of 2018 seems to be slowed down after significant increase in the previous quarter. In May 2018, the total order quantity was 1.07 million CGT, which increased 16.6% over the same quarter of last year.

In the first quarter of this year, the Clarkson Newbuilding Price Index was recorded 127.33, which has increased 2.3% compared to the previous quarter. Thanks to continuously improving order market condition, the index has been keeping upward trend since 2017. In the first half of this year, the three Asian countries (Korea, Japan and China) were recorded 87% of the market share. Among the order amount, China contracted 570,000 CGT, which is followed by Korea (530,000 CGT) and Japan (60,000 CGT). Nevertheless, cumulative total for the first half of this year, Korea still took the first place with 4.96 million CGT, accounting 40%; China accounting 36% with 4.39 million CGT; Japan accounting 12% with 1.48 million CGT. The reason for this result is the order amount of advantageous types for Korea such as oil tanker, LNG carrier and vessels were increased, and three major shipyards aggressively participated in biddings. Those types accounted 87% of total amount of orders in the first half of this year in Korea.

However, the 10 domestic medium sized Korean shipyards, such as STX Offshore & Shipbuilding, Sungdong Shipbuilding & Marine Engineering, Daehan Shipbuilding etc., recorded 273,000 CGT for twelve ships in the first half of the year. During this period, total price of ship order decreased 45% to USD 470 million. The substantial factor of the decline is the decreased amount of order for small and medium sized ship, which is the main product of those companies, due to the higher valued added and enlargement of ships worldwide. Additionally, banking industry is reluctant to offer Refund Guarantee (RG) to the small and medium sized companies. In practice, STX Offshore & Shipbuilding canceled four formal contracts after having problems with RG. The shipbuilding tonnage of medium sized company is finished with only ten tankers and five tankers in the first quarter and the second quarter respectively.

Marine &
Shipbuilding
Committee

On the other hand, Hyundai Heavy Industries (HHI) officially announced that it will suspend its offshore plant headquarters operation from this August.

Both DSME and SHI's last order projects were from 2014 and 2017 respectively. The Korea Shipping & Offshore Plant Association official said that oil price in July rose to 70 USD and it's clear to say that the price is higher than the first half of the year, but the price level is not enough to vitalize business. Plus, bidding competition with low prices with competitors such as China and Singapore would be a factor of difficulties to obtain orders in offshore plant market.

Key Issues

1. Unfair and Impractical Purchase Terms and Conditions

Unfair practices of local shipyards against the suppliers are prevalent. Such practices include processing delivery of goods prior to signing a contract, frequent requests for layout changes, cutting unit prices without mutual consent and requiring an additional contract to avoid legal liability.

This is especially challenging for a participating biding supplier when using E-based purchasing systems because the supplier should accept general terms and conditions as a precondition which contain rules that global companies find hard to accept. These preconditions in the E-based purchase system, which force to accept general terms and conditions of buyers, cause unfair competition between local suppliers and global ones.

In July 2018, the Fair Trade Commission announced the revised subcontract-law that specifies prohibition of requesting management information and the rights to request increased cost if irrigation cost rise according to the minimum wage.

The revised subcontract-law includes 'Recognition Range of Technology Data', 'Expansion of Range of Retaliatory Action' etc. and many are interested to see if the law can solve the unfair contract coercion problems between local shipyards.

Recommendation

For global companies to compete in a fair condition with domestic companies that participate in a bidding by accepting unreasonable conditions to win the contract, we request to adopt a standard purchase agreement that could be reasonably accepted by both sellers and buyers. Also, continuous monitoring in the revised subcontract-law is recommended.

2. Policy for Localization of the Shipping and Marine Plant Equipment

As the economic downturn in the domestic shipbuilding and offshore divisions have intensified, the promotion of localization of shipbuilding equipment and offshore plant equipment centered on large shipyards is being continued. However, excessive localization aimed at replacing imports could lead the shipyards and suppliers to form a 'cozy relationship', which may lead to illegitimacy and possible unfair competition.

Recommendations

The localization strategy should be promoted through technology cooperation between international equipment companies with original technology and domestic equipment manufacturers, which could prevent any possible patent disputes with international companies that hold original technology and help to avoid the potential safety accidents by indiscriminate technology replications.

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

When purchasing equipment from Korean shipyards, the domestic shipbuilding equipment companies are causing cutthroat competition by practicing the lowest price bidding system that bids below the production cost, which is not acceptable by global corporations.

This leads to the fallback of the product quality and ultimately the downturn of the R & D investment, which will destroy the industrial ecosystem of shipbuilding equipment.

Recommendations

For the fair competition between domestic shipbuilding equipment suppliers and overseas shipbuilding equipment companies, the price bidding system standards must be improved to apply the company selection criteria reflecting technology, quality and business experience rather than just choosing from the lowest price.

4. 52 Hours Work Per Week

The Korean shipbuilding industry is worried about the implementation of the 52 hours work week, which started from July 2018. Within the shipbuilding industry, working nightshifts and even on legal holidays is inevitable and the law is most likely to be violated when order numbers increase. Therefore, flexible working arrangements are necessary.

Although, the problems that are related to the change do not appear clearly in the marine equipment industry since the shipbuilding industry itself has slowed down, the government needs to prepare countermeasures to the working time for a long-term perspective.

Recommendation

We request the government to prepare solutions for the possible issues following the implementation of the 52 hours work week. Also, flexible working arrangements are necessary reflecting the industry's characteristic.

Green Working Group

Overview of Industry

Today, methods of economic growth that depend on fossil energy such as petroleum, coal and natural gas (NG) have led to climate change unprecedented in human society due not only to advanced nations, whose economies have gone beyond the mature stage, but also to the dramatic economic development in recent years of developing countries such as China and India, which consume considerable energy. Considering the clear warnings sent by the meteorological system and the fact that humans are the major cause of climate change, the Earth currently faces a crisis. To avoid the worst outcome of climate change, the breadth of the world average temperature rise must be suppressed within 2 ℃.

In order to overcome all these possible crises, Korea has improved access to environmental services and become a world leader in climate change mitigation technology. However, it will need to accelerate its green growth reforms to temper the effects of a decade of vigorous economic expansion that has pushed up energy use, resource consumption, greenhouse gas emissions, air pollution and smart cities, according to a new OECD report.

Korea's Presidential Committee on Green Growth explains green growth as follows: "Green growth is designed to reduce greenhouse gases and environmental pollution. At the same time it is designed to maintain environmental preservation and economic growth. Industrial development and economic growth, which have been under way so far, caused side-effects such as energy depletion and environmental damages. However, green growth protects environment and makes new industries and jobs with clean energies such as solar, wind, tide/wave/ocean, hydro power and green technologies instead of fossil fuels like oil and coal. It becomes a new driving force of national economic growth. The key to green growth pursues economic growth by minimizing the use of natural resources and environmental pollution so that it makes a virtuous cycle."

To accomplish these missions indicated, Korea needs appropriate frame green growth policies. It now needs to turn its vision into action by making progress toward practical and tangible outcome cooperating with industry side which play a key role to execute / implement it physically.

Key Issues

1. Green Energy Transition

Particulate matter air pollution is increasing due to increased coal consumption. Korea should aim to reduce reliance on nuclear energy and coal power plants. There are barriers to implement as following:

(i) Lack of public support and participation:
Even if there are regulations enforced to facilitate Green Energy Transitions, lack of public support and participation jeopardize both government / industry sides to utilize their strategic approach / technology solutions. Green Energy Transition must be supported by each individual sector.

(ii) Lack of financial support and investments:
Despite clear benefits of Green Energy Transition, investment remains deficient.

(iii) Insufficient renewable energy policy:
The 2nd Energy Master Plan (2014-2035), The 5th Energy Use Rationalization Plan (2013-2017) and Energy Vision 3020 have been enforced, there are still grey area which need to be interpreted clearly by government.

(iv) Weak renewable energy policy implementation agency

Recommendation

- Mainstream the energy transition:
The government should bring people's attention to mainstreaming the energy transition. Sufficient benefits need to be regulated by government side.
- Provide financial supports (e.g. feed-in-tariff scheme (FIT)):
Not only the investments, general financial support should be supported by the government, such as FIT, to facilitate industry's technology to get utilized by public/individual sectors.
- Establish an energy transition institution:
To implement it with inadequate method and resource. the definition of "Green Energy Transition" should be clearly defined by governmental institutions. Then, the implementation of the industry's technology will be possible in accordance with the definition and plan.
- Build up a regional energy transition cooperation scheme:
In line with the institution mentioned above, regional energy transition cooperation scheme needs to be implemented due to

various types of regional circumstances.

2. Renewable Energy Vision

Driven by increasing environmental awareness and soaring oil prices, the Korean government has shown great interest in policies and investments related to new and renewable energy (NRE). Against this backdrop, various programs are being carried out to utilize NRE to achieve energy self-sufficiency, GHG emissions reduction and climate change adaptation.

The Korean government initially implemented the feed-in tariff (FIT) scheme, an incentive program to promote voluntary participation in NRE distribution in early 2000, a time marked by the rapid commercialization of NRE. However, after 10 years of implementation, the government transitioned from FIT to the Renewable Portfolio Standard (RPS) policy, which regulates the proportion of NRE within the total power supply. Moreover, the Korean government also proposed to implement the Renewable Fuel Standard (RFS) policy, effective in 2015, which requires oil refineries to blend biofuel in their products. Various policies to incentivize voluntary distribution of NRE in the non-industrial sectors are also being carried out at the local level. Such diverse policy measures represent the Korea's efforts to address the financial gaps in the NRE industry to help create an enabling environment for energy self-sufficiency. While NRE is still deemed to be less economically viable with huge gaps in technology development, its future growth prospects are immense. Thus, boosting investment, R&D, and other enabling policies is critical to tap this potential.

Recommendation

It is clear that the growing financial burden of providing FIT subsidies was the major reason for its termination. In addition, the design of the FIT scheme led to a surging number of solar PV installations, which had comparably low returns in terms of power generation. The government should establish effective legislation with industry side to set rational goal rather than only encouraging numbers in statistics. If the industry get involved at the beginning of regulatory decisions, the government will have better outcome from their regulations while industries find solutions.

3. Creating Shared Value (CSV)

Korea is a fast-growing major economy, and as such, has a significant impact on billions of people around the world through the sourcing of raw materials as well as the natural environment its industry depends on.

Both government and industry side need to rethink each aspect of their value chain, evaluating their impact and identifying unique opportunities where economic value can be created while solving social and environmental problems.

Today, many companies tend to mistake CSR and philanthropy for Creating Shared Value (CSV), limiting the scale of their investment and the impact on their society and environment. CSV is about identifying opportunities that can be done to make profit while meeting the needs of the society.

Recommendation

Implementing the core CSV strategy driven by the government will allow the industry to pursue sustainability and compliance, and its social responsibility will deliver positive impact in the long term. Also the industry will have a better understanding of the governmental shared value, which will help them implementing technology and strategy to comply with shared value in their own way.

Taxation Working Group

Key Issues

1. Per Article 11 of the Adjustment of International Taxes Act, taxpayers exceeding a certain size are required to submit a Master file, Local file, and Country by Country Report (collectively Comprehensive Report on International Transaction or CRIT).

Recommendation
When a taxpayer submits the CRIT, it needs to be exempt from the filing requirement for duplicate information (such as Declaration of Transfer Pricing Method, Summary of Foreign Affiliates Income Statement).

2. The Base Erosion and Profit Shifting (BEPS) initiative has been introduced into Korean tax laws and transfer pricing adjustments are increasing. Accordingly, it is expected that Mutual Agreement Procedure (MAP) cases will also increase. However, the responsible personnel for MAP (including advance pricing arrangement or APA) in the National Tax Service (NTS) are limited and therefore the MAP process can be significantly delayed.

Recommendation
There is a need for an enhancement of the resources responsible for MAP cases (including APA) to resolve transfer pricing issues in a timely manner.

3. Foreign invested companies who have filed APA applications are sometimes examined for transfer pricing issues that are covered in the APA application during tax audit without specific reasons.

Recommendation
From a legal point of view, transfer pricing issues that are covered by an APA can also be examined during a tax audit. However, considering that the NTS has been promoting APA actively and the statute of limitation remains open for one (1) year after the APA is concluded, it needs to be enforced in the law to prohibit examination of transfer pricing issues that are covered in the APA application unless there are specific reasons (such as facts are different from the APA application or there is a suspicion for tax avoidance, etc.)

4. Per Article 94 of Corporation Income Tax Law (CITL) Corporate Tax Act and Article 133 of the Presidential Decree of the CITL, a person who regularly maintains and habitually delivers assets of a foreign corporation can be a dependent agent PE. However, the provisions of a relevant tax treaty override local tax law and therefore if the treaty excludes such person from being a dependent agent PE, there may not be a PE for corporate income tax purpose. However, the definition of a business place for VAT purposes still refers to the Article 94 definition of a PE and VAT is not a tax covered by tax treaties. Therefore, there can be an argument that there is a business place for VAT purpose whereas there is no PE for corporate income tax purposes.

Recommendation
It needs to be clarified that there will be no business place for VAT purpose when there is no PE for corporate income tax purposes.

5. Per Article 44-3 of the CITL, a merger between domestic sister companies that are wholly owned by the same domestic parent company is eligible for automatic tax-free treatment without further conditions needing to be met. However, a merger between domestic sister companies that are wholly owned by the same foreign parent company is eligible for tax free treatment only when certain conditions are met.

Recommendation
For equality between domestic and foreign companies, it is recommended to amend the law to allow automatic tax-free treatment for mergers between domestic sister companies that are wholly owned by the same foreign parent company.

6. Multinational companies frequently engage in intercompany financing transactions for efficient cash management. In this regard, regulations on intercompany financing transactions under the Law on Coordination of International Taxation (LCIT) and Law on the Coordination of International Tax Affairs (LCITA) are not reasonable. More specifically, when a domestic company makes a loan to foreign related parties, the default interest rate is stipulated by the head of the NTS, which is higher than market rate. On the contrary, when a domestic company borrows from foreign related

parties, LIBOR (for 12 months) plus 1.5% is deemed as arm's length interest rate.

Recommendation

It is more reasonable to have the same deemed arm's length interest rate for both borrowing and lending.

7. Under Article 21-2 of the Presidential Degree of the LCIT and Article 11 of the LCIT, foreign invested companies are only required to submit a Master File and Local File if they exceed certain size thresholds whereas foreign invested companies that meets certain conditions are required to submit country by country report regardless of their size.

Recommendation

In order to reduce the compliance burden for small foreign invested companies, it is recommended to limit the country by country report requirement to only foreign invested companies that exceed a certain size threshold.

8. 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.

9. Korean branches of foreign banks are subject to the thin capitalization rules. In addition, such branches are also subject to

a disallowance of interest expense when their capital amount is less than a deemed capital amount calculated under Article 129-3 of the Presidential Decree of the CITL.

Recommendation

It is considered that the thin capitalization rule is sufficient to regulate excessive borrowing, and it is not fair to impose additional regulations on branches of foreign banks compared to domestic banks.

10. Under Article 24 of the VAT Law, when a taxpayer provides services to a foreign company, the services can be eligible for zero rate VAT if such service falls under the list of qualified services in the relevant Presidential Decree. In this regard, it is difficult in practice to determine whether or not certain services fall under the list of the qualified services and there therefore exists uncertainty in applying zero rate VAT.

Recommendation

In order to remove uncertainties in applying zero rate VAT and for the sake of taxpayers' convenience, it is recommended to change the list of qualified services from a positive system to negative system.

11. 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.

Appendix

Abbreviation

Abbreviated	Expanded
AEBS	Advanced Emergency Braking System
APA	Advance Pricing Arrangement
BASCAP	Business Action to Stop Counterfeiting and Piracy
BDI	Baltic Dry Index
BEPS	Base Erosion and Profit Shifting
BI	Bodily Injury
BIMCO	Baltic and International Maritime Council
BOD	Business Operating Division
BPR	Biocidal Products Regulation
CBI	Confidential Business Information
CCA	Chemicals Control Act
CFIA	Canadian Food Inspection Agency
CFR	Code of Federal Regulations
CITL	Corporation Income Tax Law
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic or toxic to Reproduction
CODEX	Codex Alimentarius collection of food standards
CPI	Creditor Protection Insurance
CRIT	Comprehensive Report on International Transaction
CSR	Corporate social responsibility
CSV	Creating Shared Value
CTA	Clinical Trial Application
DMFU	Dimethyl Fumarate
DREC	Drug Reimbursement Evaluation Committee
DTaP	Diphtheria, Tetanus & Pertussis Vaccine
EC	European Commission
ECG	Electrocardiography
EcoAS	Eco-Assurance System of Electrical and Electronic Equipment and Vehicles
ECOSAR	Ecological Structure Activity Relationships
EDI	Electronic Data Interchange
EFSA	European Food Safety Authority
ELV	End of Life Vehicle
EMA	European Medicines Agency

Abbreviated	Expanded
EMC	Electromagnetic Compatibility
EPA	US Environmental Protection Agency
EPI	Environmental Performance Index
EPO	European Patent Office
ERC	Emission Related Components
EUIPO	European Union Intellectual Property Office
EUR	Euro
EV	Electric vehicle
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FIT	Feed-In-Tariff
FSC	Financial Services Commission
FSS	Financial Supervisory Service
FTA	Fair Trade Agreement
FTZ	Free Trade Zone
GDP	Gross Domestic Product
GHG	Greenhouse Gas
GHS	Globally Harmonized System
GMO	genetically modified organism
HES	Heavy-duty vehicle Emission Simulator
HIRA	Health Insurance Review and Assessment Service
IBL	Insurance Business Law
ICER	Incremental Cost–Effectiveness Ratio
ICT	Information and Communications Technology
IFOAM	International Federation of Organic Agriculture Movements
IMDS	International Material Data System
IMF	International Monetary Fund
IMO	International Maritime Organization
IMP	Investigational Medicinal Product
IND	Investigational New Drug
IP	Intellectual property
IPC	Innovative Pharmaceutical Company
IPR	Intellectual property rights
ISO	International Organization for Standardization

Abbreviated	Expanded
KATRI	Korea Automobile Testing & Research Institute
KATS	Korean Agency for Technology and Standards
K-BPR	Act on Chemical Consumer Products and Biocides
KCA	Korea Consumer Agency
KCDC	Korea Centers for Disease Control & Prevention
KCS	Korea Customs Service
KECO	Korea Environment Corporation
KFTC	Korea Fair Trade Commission
KGCP	Korea Good Clinical Practice
KIPO	Korean Intellectual Property Office
KITA	Korea International Trade Association
KOBC	Korean Ocean Business Corporation
KRW	South Korean Won
KSP	Korea Shipping Partnership
LCITA	Law on the Coordination of International Tax Affairs
LDWS	Lane Departure Warning System
LEZ	Low Emission Zone
LIBOR	London Interbank Offered Rate
MAFRA	Ministry of Agriculture Food and Rural Affairs
MAP	Mutual Agreement Procedure
M-ATP	Market-Based Actual Transaction Pricing
ME	Ministry of Environment
MEPC	Maritime Environment Protection Committee
MFDS	Ministry of Food and Drug Safety
MIM	Mixture in mixture
MOEF	Ministry of Economy and Finance
MOHW	Ministry of Health & Welfare
MOLIT	Ministry of Land, Infrastructure and Transport
MOTIE	Ministry of Trade, Industry and Energy
MRA	Mutual Recognition Agreement
MRP	Maximum Reimbursement Price
MSDS	Material Safety Data Sheet
MSIP	Ministry of Science, ICT and Future Planning
NG	Natural gas
NHIS	National Health Insurance Service
NICE	The National Institute for Health and Care Excellence
NLR	National Lot Release

Abbreviated	Expanded
NOP	National Organic Program
NRE	New and Renewable Energy
NTS	National Tax Service
OECD	Organisation for Economic Co-operation and Development
ORR	Objective Response Rate
PBT	Persistent, Bioaccumulative and Toxic
PCN	Poison Centres Notification
PE	Pharmaco-Economics
PMS	Post Marketing Surveillance
PTE	Patent Term Extension
PVA	Price-Volume Agreement
QALY	Quality-Adjusted Life Year
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RFID	Radio Frequency Identification
RFS	Renewable Fuel Standard
RG	Refund Guarantee
RMOA	Risk Management Option Analysis
RoHS	Restriction of the use of Hazardous Substances in electrical and electronic equipment
RPS	Renewable Portfolio Standard
RRA	Radio Research Agency
RSA	Risk Sharing Agreement
SMO	Site Management Organization
SPF	Sun Protection Factor
SSIM	Substances Subject to Intensive Management
STOT	Specific Target Organ Toxicity
SVHC	Substances of Very High Concern
TA	Therapeutic area
THAAD	Terminal High Altitude Area Defense
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UDI	Unique Device Identification
UNECE	The United Nations Economic Commission for Europe
USD	United States Dollar
USDA	United States Department of Agriculture
VAT	Value-added tax
VCM	Vendor Collection Model
VECTO	Vehicle Energy Consumption Calculation Tool
vPvB	very Persistent and very Bioaccumulative
WCO	World Customs Organization
WEEE	Waste Electrical and Electronic Equipment
WTO	World Trade Organization

Organizations

Abbreviated	Expanded
BIMCO	Baltic and International Maritime Council
CFIA	Canadian Food Inspection Agency
EC	European Commission
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EPA	US Environmental Protection Agency
EPO	European Patent Office
EUIPO	European Union Intellectual Property Office
FDA	Food and Drug Administration
FSC	Financial Services Commission
FSS	Financial Supervisory Service
HIRA	Health Insurance Review and Assessment Service
IFOAM	International Federation of Organic Agriculture Movements
IMF	International Monetary Fund
IMO	International Maritime Organization
ISO	International Organization for Standardization
KATRI	Korea Automobile Testing & Research Institute
KATS	Korean Agency for Technology and Standards
KCA	Korea Consumer Agency
KCDC	Korea Centers for Disease Control & Prevention
KCS	Korea Customs Service
KECO	Korea Environment Corporation
KFTC	Korea Fair Trade Commission
KIPO	Korean Intellectual Property Office
KITA	Korea International Trade Association
KOBC	Korean Ocean Business Corporation
MAFRA	Ministry of Agriculture Food and Rural Affairs
ME	Ministry of Environment
MEPC	Maritime Environment Protection Committee
MFDS	Ministry of Food and Drug Safety
MOEF	Ministry of Economy and Finance
MOHW	Ministry of Health & Welfare
MOHW	Ministry of Health and Welfare
MOLIT	Ministry of Land, Infrastructure and Transport
MOTIE	Ministry of Trade, Industry and Energy
MSIP	Ministry of Science, ICT and Future Planning
NHIS	National Health Insurance Service
NTS	National Tax Service
OECD	Organisation for Economic Co-operation and Development
RRA	Radio Research Agency
UNECE	United Nations Economic Commission for Europe
USDA	United States Department of Agriculture
WCO	World Customs Organization
WTO	World Trade Organization

Automotive Committees Key Issues

Passenger Vehicles Committee

1. Enforcement Date of Crash Safety Standard Amendment
2. Test Standards of Traction Battery for EV/PHEV
3. Recognizing Parts Self-Certification According to Vehicle Self-Certification
4. Recognizing UNECE Type-Approval According to the EU-Korea FTA
5. Standard for Corporate Average Greenhouse Gas (GHG) Emissions
6. Recognizing Test Reports on Emission, Fuel Economy and Noise
7. Recognizing the International Standard Process Regarding EcoAS Operation
8. Specifying the List of Emission Related Components
9. The Term of Validity of Test Report on Vehicle Energy Efficiency
10. Notification of Recall for not Delivered Vehicles
11. Process of Reporting the Plan of Recall

Heavy Duty

12. HS Code of Semitrailer-Towing Tractors
13. Vehicle Width Standards
14. Mandatory Installation of LDWS and AEBS
15. Recognizing Parts Self-Certification According to Vehicle Self-Certification
16. Green House Gas (GHG) Emission Calculation Program for Heavy Duty Vehicle

Tires Committee

17. KC Mark Exemption Process for Tires with E-Mark
18. Recognizing E-Mark for Tires of Foreign Origin

Beer, Wine & Spirits Committee Key Issues

Creating Market Environment for Fair Competition

1. Limits on Price Range and Total Amount of Liquor Promotional Items
2. Allowing Digital Marketing for Provision of Liquor Promotional Items

Revision of the Labelling Requirements for Alcohol Use Classification

3. Complete Abolishment of Use Classification Labelling Requirements for Liquor with RFID Tags Attached
4. Revision of Use Classification Labelling Requirements for Bottled Beer

Revision of RFID System

5. Sharing of RFID Data Outcomes
6. Country Location for RFID Tag Attachment Process

Chemical Committee Key Issues

K-REACH

1. Combined Volume Control
2. Omission of Data to Be Submitted When Applying for Registration of Chemicals
3. Substances Subject to Intensive Management (SSIM)
4. Exemption from Registration of Chemicals
5. Criteria of Amount in Provision of Chemical Substance Information

K-BPR

6. Data Requirements for Biocidal Product Authorization
7. Control Practice for Imported Treated Articles: Recognition for Similarity by Other Laws

Chemicals Control Act (CCA)

8. The Problems of the Universal Chemical Tracking System

Cosmetics Committee Key Issues

1. Packaging of Cosmetics
2. Act on the Safety Control of Dangerous Substances
3. Labelling and Advertisement of Natural/Organic Cosmetics
4. Sun Protection Factor (SPF) Indication
5. Labelling Requirements for Children's Cosmetics
6. Government Designation of Test Institutes for Cosmetics Efficacy Testing on Human

7. Cosmetic Ingredients Reporting System

Fashion & Retail Committee Key Issues

1. Compliance with Local Labelling Requirements After Customs Clearance and Before Sales
2. Direct Shipment Requirement
3. Price Labelling requirement
4. Safety Control Act Sales Ban
5. pH Restriction Level under the Safety Quality Labelling Standard
6. Method/Requirement of Indication
7. Changes in Legislations

Food Committee Key Issues

1. Expansion of Non-GMO Labeled Products
2. Improvement of EU-Korea Equivalence Arrangement on Organic Processed Food
3. Coordination Between International Standards and Specifications for Food
4. Improvements on Food Import Clearance Process
5. Sufficient Preparation Time Upon Regulation Amendments

Healthcare Committee Key Issues

Pharmaceuticals

1. PE Evaluation
2. Expansion of PE Exemption Criteria
3. Risk Sharing Agreement (RSA)
4. Refunding VAT Duplication (Over-burden) Issue
5. Pre-Reimbursement and Post-Evaluation
6. Price-Volume Agreement (PVA)
7. Selective Reimbursement
8. Premium Pricing for 'Innovative Drugs'
9. Unfairness of Innovative Pharmaceutical Company (IPC) Designation to Foreign Pharmaceuticals
10. Patent Term Extension for Drugs with Different Salts
11. Transparency Improvement
12. Fee Scheme For Combination Vaccine
13. Double Testing for Vaccines
14. Approval of Manufacturing Business (Consignment Manufacture)
15. Conditional Approval
16. Additional Data Requested During Investigational New Drug (IND) Review Process for Early Phase Trials
17. Slow Importing Process of Ancillary Supplies (Medical Device, Electronic Equipment, Lab Supplies etc.) Used for Clinical Trials
18. Local Labour Law Prevents Hospitals to Use Clinical Research Coordinator from Site Management Organization (SMO) to Work in Clinical Trial Sites
19. Quarantine Process Required for the Customs Clearance of QC Testing Reagents of Animal Origin
20. Tariff Exemption of Investigational Medicinal Product (IMP)

Medical Devices

21. Value of Innovative Medical Devices
22. Import Prices for Reimbursement Pricing Cut
23. Unique Device Identification (UDI)
24. Transaction Price Information in Distribution Reporting

Others

25. Consent Rule for Digital Activity

Insurance Committee Key Issues

1. Establishment of Standard for Oriental Medical Treatment and Cost
2. Usage of the Cloud Services in Korean Insurance Market
3. Excluding CPI from the List of Insurance Products Subject to Forced Sale
4. Cross-Selling Between Life and General Insurance Products
5. GA's Own Liability and Exemption of Insurance Company from GA's Own Misconduct
6. Applying the Same Standards for the Forced Sales to Insurance Products as Banking Products
7. Bills Regarding Special Type Workers
8. Bills Regarding Statute of Limitations (SoL) Applied to Insurance Benefit Claims
9. Financial Consumer Protection Bill

Intellectual Property Rights Committee Key Issues

1. IP Studies
2. Lack of Interest in IP Enforcement
3. Ineffective Sentencing of IP-Related Crimes
4. Border Seizures
5. Customs Recordations
6. Seizure of IP Infringing Materials
7. Free Trade Zones
8. Open Sale of Counterfeit Products
9. Pro-Active Measures by Online Intermediaries
10. Provision of Evidentiary Materials to Calculate Damages
11. Damage Calculation Methods
12. Statutory Damage

Kitchen & Home Appliances Committee Key Issues

1. Easing Test Standards for Household Scales
2. Conformity Assessment for Electronic Goods
3. Reasonable Application on Environmental Assessment of Recycling
4. Simplifying Food Inspection on Imported Apparatus and Containers for Food

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Logistics & Transport Committee Key Issues

1. Concern About Unfair Market by Korean Government's 'Shipping Industry Revival Five-Year Plan'
2. Korean Government's Leading Counteracting System Regarding Adoption of Initial Strategy for Reduction of Greenhouse Gas by IMO
3. Current Global Policy According to Increase in E-Commerce Transactions and Improvement of Korean Policy Direction
4. Simplify the Scopes of De-Minimis Only to Range of Value

Marine & Shipbuilding Committee Key Issues

1. Unfair and Impractical Purchase Terms and Conditions
2. Policy for Localization of the Shipping and Marine Plant Equipment
3. Practice of the Lowest Price Bidding System in Domestic Shipyards
4. 52 Hours Work Per Week

Green Working Group Key Issues

1. Green Energy Transition
2. Renewable Energy Vision
3. Creating Shared Value (CSV)

Taxation Working Group Key Issues

1. Article 11 of the Adjustment of International Taxes Act
2. Base Erosion and Profit Shifting (BEPS) Initiative and Increase of Mutual Agreement Procedure (MAP) Cases
3. Examination of APA Application During Tax Audit Without Specific Reasons
4. Article 94 of Corporation Income Tax Law (CITL) Corporate Tax Act and Article 133 of the Presidential Decree of the CITL
5. Article 44-3 of the CITL
6. Law on Coordination of International Taxation
7. Article 21-2 of the Presidential Degree of the LCIT and Article 11 of the LCIT
8. Article 43-2 of the Presidential Decree of the CITL
9. Article 129-3 of the Presidential Decree of the CITL
10. Article 24 of the VAT Law
11. Recent change in Article 24 of the VAT Law

ECCK EUROPEAN CHAMBER OF COMMERCE IN KOREA

European Chamber of Commerce in Korea

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