

Ready For A New Partnership

The EBC Report on the Japanese Business Environment
2018

The European Business Council in Japan
The European (EU) Chamber of Commerce in Japan

European Business Council in Japan European (EU) Chamber of Commerce in Japan

The EBC is the trade policy arm of the following European national chambers of commerce and business organisations in Japan:

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The European Business Council (EBC) is the trade policy arm of the 17 European national chambers of commerce and business associations in Japan. Established in 1972, the EBC works to improve the trade and investment environment for European companies doing business in Japan.

The EBC currently represents some 2,500 local European companies and individuals who are members of their national chambers of commerce. Around 350 company executives participate directly in the EBC's 24 industry committees, whose work aims to improve the local business environment in a wide variety of economic sectors.

The EBC speaks from a platform based on member consensus, representing the common view of companies from a major economic region in the world and one of Japan's most important trading partners.

The EBC works closely with the Delegation of the European Union in Japan and the embassies of European countries to co-ordinate policy proposals and facilitate European business in Japan.

For more information on the EBC and its activities, please contact the EBC secretariat at the following address:

Sanbancho POULA Bldg. 2F
6-7 Sanbancho, Chiyoda-ku, Tokyo 102-0075
Tel: 03-3263-6222
Fax: 03-3263-6223
E-mail: ebc@ebc-jp.com
Web: <https://www.ebc-jp.com>

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Editor and Principal Author: Bjorn Kongstad

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**Sanbancho POULA Bldg. 2F, 6-7 Sanbancho, Chiyoda-ku, Tokyo 102-0075
Tel: 03-3263-6222 Fax: 03-3263-6223
E-mail: ebc@ebc-jp.com Web: <https://www.ebc-jp.com>**

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Messages



Message from the EBC

Welcome to “Ready For A New Partnership”, the 2018 Report of the European Business Council in Japan (EBC).

Just as previous years have been exciting so has 2018 in regards to the Europe-Japan relations. This was the year when the EU-Japan Economic Partnership Agreement (EPA) was finally signed. Europe has now two distinct agreements with Japan: the Switzerland-Japan Free Trade Agreement and the EU-Japan EPA.

The importance of the EPA to both EU and Japanese business is enormous. From an EU perspective, it promises to boost exports in sectors such as food products, clothing and shoes, pharmaceuticals, medical devices, vehicles and machinery. The result will be increased growth and more jobs, not only in companies that already have a presence in Japan but also in those entering this market for the first time thanks to the EPA. The benefits will be felt across the EU and Japanese economies and significantly, amongst consumers, who will enjoy a wider choice of competitively priced, quality products.

The EBC greatly appreciates the hard work on both sides to reach this point. We are proud of the contribution we have been able to make to the process in offering insights and information from our own experience, and we are keen to continue our support, as the Agreement is finalised and preparations are made for its implementation. In fact, for the EBC, this is the most important phase, because, in the end, an agreement is only as good as its implementation. For EU business, this means that tariff reduction and removal must be completed on time; current non-tariff barriers must be lifted and not replaced by others; public procurement markets must become open and accessible; and geographical indicators and intellectual property must be respected. What is more, the spirit of the EPA must be translated into action within the machinery of government, with the authorities promoting closer cooperation between EU and Japanese companies and ensuring both sides are represented in policy discussions. For this purpose, the EBC and its Committees will dedicate significant time and resources to monitor the EPA implementation.

Yet the work of the EBC does not end with the EPA: a significant number of issues hindering EU business in Japan lie outside the scope of the agreement. Some of these issues are specific to the EU, but very many affect all companies, domestic and foreign, and serve only to delay new products, inflate costs, and restrict consumer choice. EBC expert Committees will, therefore, continue to highlight them and make practical recommendations for how they should be resolved. The EBC does want to underline this message, that a great portion of our recommendations will benefit companies and consumers independent of nationality.

The EBC work is made possible by the continuing support of its stakeholders, especially the European national Chambers of Commerce, their corporate members that join also EBC and other business organisations represented in Japan. Together with the Delegation of the European Union to Japan and the European national embassies in Tokyo, who keep offering their unique insights and guidance, we all work towards making European business more successful in Japan.

We also gratefully acknowledge all sponsors and supporters who have made this publication possible and whose names are listed at the end of the Report. The EBC is committed to helping Europe and Japan reach new levels of mutual trade and economic growth. We approach 2019 with new optimism as Europe and Japan are entering a new partnership.

Michael Loefflad
Acting Chairman, European Business Council in Japan
European (EU) Chamber of Commerce in Japan
(Representative Director & President, DKSH Japan, Ltd.)

Francesco Formiconi
Executive Director
European Business Council in Japan
European (EU) Chamber of Commerce in Japan

Message from H.E. Dr. Patricia Flor, the Ambassador of the European Union to Japan

It is my pleasure as the new Ambassador of the European Union to Japan to address “Ready For A New Partnership”, the much-awaited 2018 report of the European Business Council (EBC) on the business environment in Japan.

This is a very important moment for the EU - Japan relations. The signature of the Economic Partnership Agreement (EPA) - which will enter into force early next year - sends a clear message to the rest of the world that the European Union and Japan stand together to oppose protectionism, and will cooperate even closer to promote an open, fair, sustainable and rule based trade which benefits both societies.

But first and foremost, the EPA - which covers 37% of world's trade and is the biggest trade agreement ever concluded by the European Union - creates new opportunities for European companies to boost their exports and expand their business in Japan. By eliminating or significantly reducing custom duties, removing non-tariff barriers, simplifying export-import related procedures and enhancing EU-Japan economic cooperation, the EPA will open up the Japanese market of 127 million affluent consumers to a wide range of European goods and services.

We should not forget, however, that the conclusion of the EPA is only the first step. In order for the EPA to bring tangible economic benefits, we need to make sure that European companies - both small and large - are well aware of its existence and know how to make use of it. Subsequently, we will closely monitor EPA's implementation and promptly address any difficulties that European companies may face during its application.

The EU Delegation to Japan greatly appreciates the ongoing cooperation with the EBC on supporting European business in Japan. As far as the EPA is concerned, I believe that by disseminating knowledge about the agreement within the European business community in Japan, and by closely following its implementation, the EBC will play a key role in ensuring its success. The EU Delegation to Japan is looking forward to a close and fruitful cooperation with the EBC in that respect.

Patricia FLOR
Ambassador of the European Union to Japan
Head of the Delegation

Introduction



INTRODUCTION

If everything goes according to plan, 2018 will be the last year where European and Japanese businesses trade without a free trade agreement. At the time of writing, the European Parliament is debating the Economic Partnership Agreement (EPA) with an aim of taking a vote in mid-December on ratification. In Japan the process is similar with the Diet scheduled to ratify the EPA in the current session. Long has the European Business Council in Japan (EBC) advocated for a trade agreement between EU and Japan. Long too has the EBC been closely involved in the preparation for an agreement and also closely involved in the negotiations, continuously providing the European Commission with issues that affect European industry in Japan and technical expertise.

With this in mind, it is not surprising that a majority of the issues included in this report touches on the EPA in one shape or form. This can be issues that are finally solved through the agreement or issues that have been included in the agreement but where the outcome is uncertain. With the agreement, EU supplier will have a much improved market access in the food and beverage sectors. Many food products will see removed or drastically reduced tariffs, and the wine sector, both for still and sparkling wine will see completely removed tariffs from day one. The shoe and leather industry will also see reduced tariffs. Tariffs that have long made European products far more expensive than they need to be. We have already seen changes and improvements to the pharmaceutical and medical devices markets. The same can be said for labelling requirements for garments. Several of the issues for European automobile manufacturers have also been implemented, which is not to say that all issues have been dealt with. Japan will also further open up its public procurement market, and especially the railway equipment manufacturers is scheduled to see positive changes.

That being said, the success of the agreement is very much down to its implementation. It is here that both the EBC and this report come into play. As the reader will see, many of the EBC committees comment on the many benefits and positive changes that the agreement will bring, but also on the challenges and pitfalls that might appear if it is not implemented in the spirit of the agreement. This means it must be consistently monitored and robustly implemented on time and in good faith: there is no point in removing barriers, only to replace them with others. Consequently, the EBC will be devoting considerable energy to monitor the progress of the EPA, not only as it works its way through the political process but also, ultimately, as it enters into effect.

Moving away from the EPA, there are some dark clouds on the horizon which Japan has to tackle head-on in the near future – demographics and in particular the labour shortage. Since 2011, Japan's population has decreased for each year. More and more companies are experiencing difficulties in recruiting personnel. This is in particular felt in the service sector which tends to be more labour intensive. Japan is, as this report is being produced, introducing legislation in the parliament that will open up for labour immigration. This is a much needed reform and something that is welcomed by the EBC and brought up in the Human Resource chapter. The EBC fully understands the sensitivities regarding immigration, but it is still adamant that no stone can be left unturned.

To summarise and to end on a positive note because the EBC does believe that the future is bright, with the EPA, the EBC is convinced that the EU and Japan will enter into a new partnership which will promote increased trade and integration, not only as figures go, but also as two open economies that believe in free trade. This is very much needed in the current environment of more inward-looking policies around the globe. The EBC trusts that the ideas and recommendations in this report will prove a positive contribution to the thinking of the Government of Japan, Europe and all others who genuinely wish to see Europe-Japan trade and investment reach its full potential.

How this report is organised

Following this introduction, 28 chapters, each written by an EBC sector/expert committee, summarise the key issues and developments in the Japanese business environment over the past year, and are accompanied by concrete recommendations for reform.

ABOUT THE EUROPEAN BUSINESS COUNCIL

Founded in
1972

The European Business Council in Japan (EBC) is the trade policy arm of 17 European national Chamber of Commerce and business associations in Japan and has been working to improve the trade and investment environment for European companies in Japan since 1972. The EBC was registered with the Ministry of Economy, Trade and Industry (METI) in 2008 as the European (EU) Chamber of Commerce in Japan.

24
Industry
committees

The EBC currently represents around 2,500 local European corporate and individual members through their respective national Chamber of Commerce. Some 350 executives of more than 200 companies participate directly in one or more of the EBC's 24 industry committees, whose work covers a wide variety of economic sectors.

The EBC committees identify the issues keeping the companies from achieving their full potential in Japan and use the vast array of EBC's lobbying tools, including the annual EBC Report on the Business Environment, to bring change by eliminating the problems.

200
companies

The EBC works closely with the Delegation of the European Commission in Japan, the national European Embassies, and other business organisations to co-ordinate policy proposals and make recommendations to the Japanese Government on how to create an open environment for trade and investment in Japan.

Be Part of the Change - Join the EBC

The EBC is a key actor in bringing change for good to the Japanese economy. By participating in existing EBC committees, or by forming new committees, companies have the opportunity not only to learn about the important changes taking place in Japan, but also to play a critical role in influencing the change themselves.

Joining an EBC committee gives you:

- influence on issues addressed in political forums;
- access to key information in your sector (implementation of the EPA);
- valuable contacts with other European professionals;
- advice in formulating and resolving your regulatory concerns under the EBC umbrella;
- a direct channel to the Japanese Government officials and politicians.

To reach out to the EBC, please contact:

Francesco Formiconi, Executive Director
fformiconi@ebc-jp.com
03-3263-6225

Bjorn Kongstad, Policy Director
bkongstad@ebc-jp.com
03-3263-6224

Business Fundamentals

**Financial reporting
Human resources
Intellectual property
Legal services
Retail & wholesale
Tax**

Dr. Dirk Hermans

Chair, Financial Reporting Committee

(Director, Accounting & Finance Advisory, Deloitte Touche Tohmatsu LLC)

c/o Deloitte Touche Tohmatsu LLC

Shin Tokyo Building, 3-3-1 Marunouchi

Chiyoda-ku, Tokyo 100-0005

Phone 03-6213-1231

Fax 03-6213-1235

FINANCIAL REPORTING

Introduction

Another successful year, with an increasing number of Japanese listed companies voluntarily adopting International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB). The Tokyo Stock Exchange (TSE) lists a total of 195 companies that have adopted or are to move to IFRS, and increasingly some of the larger ones, thereby representing about a third of the total market capitalisation. Further, TSE expects adoption of IFRS to continue to increase in the next few years and soon represent half of the market capitalisation. The EBC acknowledges the progress made since 2010 when Japan allowed its listed companies a range of accounting options, including voluntary adoption of IFRS. This unique approach allows companies the freedom to decide the basis of accounting, but also allows them the ability to choose the time to transition away from Japanese Generally Accepted Accounting Standards (J-GAAP) to IFRS. Listed companies have been well supported in this transition to IFRS by the relevant Japanese authorities like the capital markets regulators, accounting standard setters, and major stock exchanges.

The EBC notes the progressive efforts of the Accounting Standards Board of Japan (ASBJ) to enhance the use of IFRS, and understands that the creation in 2015 of Japan's Modified International Standards (JMIS) was intended to support such efforts by adopting a local flavour of IFRS. This included only two exceptions: accounting treatment of goodwill by a process of amortisation over a duration of time, and requiring the recycling of certain elements through the Statement of Other Comprehensive Income and not the Profit and Loss Account. However, Japanese companies clearly prefer IFRS and not JMIS, as IFRS provides better global peer comparison and greater acceptance as qualitative financial reporting. Accordingly, the EBC would recommend that Japan and the ASBJ consider limiting further development of JMIS and focus its resources on the original goal of working to converge J-GAAP with IFRS. It is not to say that the efforts put into developing JMIS were not completely unused, as the IASB as the standard setters for IFRS is reconsidering if the amortisation of goodwill should be included in IFRS, and have noted Japan's position.

In the meantime, the existing challenges remain for multinational companies headquartered in Europe that have significant subsidiaries domiciled in Japan. For Japanese statutory purposes these subsidiaries will likely continue to report under J-GAAP, as published by the ASBJ, while having to maintain a dual set of detailed accounting records to be able to produce IFRS based financial information for reporting to their parent for group reporting purposes. While some significant differences have existed like depreciation periods and methods for assets, valuations principles and methods, etc., this has become further complicated with the recent and more significant changes in IFRS effective from 2018 onwards and in areas like recognising revenues from customers, and the recognition and accounting for financial instruments. Further, with future changes like the accounting for leases (2019) and accounting for certain industries/activities like insurance (2021), there is an increasing distance between IFRS and J-GAAP that needs to be bridged. These recent changes to IFRS have taken a lot of management time and companies resources, and any move to reduce the accounting differences will reduce undue management distraction, resource commitment, and administrative burden of maintaining the two very distinct sets of accounting records. This convergence of accounting standards will not only be useful to just European companies operating in Japan, but also for the increasing number of Japanese listed companies who have moved or are moving to IFRS as their primary reporting to the investors, as it will reduce the burden of dual reporting in J-GAAP for their regulatory reporting. Therefore, the efforts to reduce the differences between the two accounting frameworks of J-GAAP and IFRS, would improve the quality of reporting, while also reducing the volume and complexity of reconciliations currently required between the two standards. There will also be a direct contribution to corporate governance, an area of growing emphasis in Japan, as listed companies would be operating with just one set of financial reports that will be easier to comprehend, bring greater transparency, and thereby allow better governance.

The EBC acknowledges that any effort in convergence would need due consideration of Japanese corporate and tax laws. Alignment efforts are generally hindered where tax and financial reporting requirements differ significantly, so the EBC recommends that regulators avoid unfavourable tax consequences (from a time, cost and tax perspective). Undoubtedly, efforts to converge the two accounting frameworks would also benefit the increasing number and larger listed Japanese companies that have adopted or planning to adopt IFRS.

Key Issues and Recommendations

■ Approach of convergence

Yearly Status report: partial progress. ASBJ has been facing delays in its efforts to converge the standards at the pace that IFRS has been changing, especially in the more recent and significant areas. It has therefore become increasingly burdensome to IFRS adopters that include both European companies operating in Japan and an increasing number of Japanese listed companies, to maintain dual records, commit resources and management attention. ASBJ should continue to look to innovative ways to help companies and users of financial information by incorporating into J-GAAP, if not converge by updating J-GAAP to IFRS, particularly in areas where there have been recent and significant changes to IFRS that are already implemented or soon to be implemented.

Recommendation:

- ASBJ should look into bridging the differences via an appropriate combination of the following two approaches to convergence, and continue their innovative manner to addressing these challenges. The EBC acknowledges that ASBJ has to consider and address the concerns of the large number of Japanese companies that use only J-GAAP, and that incorporating sweeping changes to J-GAAP emanating from the recent changes to IFRS, would challenge the need for changes and also the ability of such companies to commit significant resources required to adopt them.
- ASBJ should continue to look to achieve convergence by replacing as much of the current J-GAAP with the recent updates to IFRS and eliminating prior differences
- ASBJ could consider addressing the more recent and significant changes in IFRS, by looking at ways to blend IFRS into J-GAAP, thereby allowing some of the existing practices of J-GAAP as well as all of current IFRS to coexist, where and to the extent possible. Once key elements of both standards are carefully blended into the updated J-GAAP, companies can be allowed to elect an accounting policy choice that best suits their situation. Essentially this approach would be aligned with how listed companies are currently making free choices to their financial reporting, by adopting standards they believe is better for them and also choosing the time to convert.

This blended approach to convergence has recently been used with a fair degree of success for the changes in J-GAAP for revenue from customers (issued in 2018), and needs to be actively pursued to bridge the differences in other existing and emerging areas like:

- The long standing differences in the determination of useful lives and the allowable depreciation methods for of property, plant and equipment
- The guidance of fair value measurement and disclosure in IFRS 13 effective from 2013 in IFRS
- The recognition, measurement and accounting for financial instruments effective in 2018 in IFRS
- The account for leases per IFRS 16 that is to be effective from 2019 in IFRS
- The accounting for insurance arrangements that is to be effective from 2021 in IFRS

■ Speed of convergence

Yearly Status report: partial progress. The ASBJ has to focus on reducing the time taken to achieve convergence, given the difference between J-GAAP and IFRS is growing while the pace of revision of the J-GAAP standards is increasingly falling behind. This makes maintaining even more details within the two sets of accounting records by companies that are dual reporters, and is not a desirable situation for such European and listed Japanese companies reporting in IFRS.

Recommendation:

- In updating the J-GAAP standards to IFRS, there could be two dates to them being effective and enable the transition. The primary effective date being the mandatory adoption of the updated J-GAAP standards by all companies in Japan using only J-GAAP, and such date could be several years from issuance of the updated standards to allow the time to comprehend and change, assuming the updating is done soon to address the ongoing delay in issuance of such updated standards. The alternative date being voluntary early adoption by companies that could be as close as possible to the current IFRS adoption date, to the extent possible. IFRS preparers would then be able to reduce the duration and complexity of maintaining dual records by electing to adopt the updated J-GAAP early.

Ms. Sonya Ito

Chair, Human Resources Committee
(HR Manager, Japan and South Korea - Herbert Smith Freehills)
c/o Herbert Smith Freehills
Midtown Tower 41st FL, 9-7-1 Akasaka
Minato-ku, Tokyo 107-6241
Phone 03-5412-5412
Fax 03-5412-5413

HUMAN RESOURCES

Introduction

The EBC Human Resources Committee has been monitoring Japan's demographic outlook for many years. Whilst the government is taking greater initiatives, unfortunately a shortage of skilled and unskilled labour, an ageing population, and a declining birth rate, together still present significant challenges for the long-term vitality of the economy in general, as well as domestic and foreign business networks. Given the low unemployment rate, only limited sourcing is possible from within the group of active job seekers.

The EBC is therefore pleased to see the various initiatives by Prime Minister Abe's Government to increase the participation of women in the labour market. The Government's initiatives include an overhaul of the current income tax break given to taxpayers whose spouses do not work (or work only limited hours), to remove the incentive for spouses to work part-time. The Government also called on companies to employ more women and increase the number of women in executive positions. Furthermore, Prime Minister Abe has talked of improving support for working parents, which is clearly a step forward in the right direction, however it does require concrete follow-up for a successful outcome. The Government needs, for instance, to find creative ways to offer more public child-care centres and private child-minding services, and to support and encourage men to take child-care leave.

On a positive note, the EBC commends the Government and the Ministry of Justice for improving Japan's attractiveness to foreign professionals through a new system covering re-entry permits and the extension of visa periods. This new system is complemented by efforts to admit greater numbers of highly skilled workers. Together these measures will benefit individual companies and the economy as a whole. There are indications that the Government is contemplating introducing online visa applications, which would be a welcome step as the processes, including for extensions and changes of visa status, are currently very time-consuming. In addition, the Japanese Government is in its final stages of implementing a system that will open up immigration of less-skilled workers. Figures such as 345,000 workers have been mentioned. The EBC believes that despite the sensitivities and the challenges to integrate these workers into Japanese society, such a policy is both needed and unavoidable. The EBC therefore appreciates the Government's initiative.

As for labour regulations, the EBC applauds the Government for introducing a longer period under which over-time can be balanced. As this change has only recently been introduced, it is not clear exactly how this will be implemented by industries. However it is clear that this will lead to a more flexible working style, something the Japanese Government is promoting and the EBC supports. At the same time, the improved three months could still be considered as a rather short period of time, as many projects run for a longer period.

Regarding pensions, Japan's Defined Contribution Pension Law of 2001 enabled employers to offer more flexible and attractive pension schemes to employees. Given the current demographic trend and the inevitable stress this will place on the Japanese social security system, it is imperative that further incentives are created to encourage individuals to prepare financially for their own retirement. Meanwhile, Japan must ensure that its efforts to open up to more skilled foreign workers are not undermined by its pension regulations. Amendments are still required to enable such workers to get a full refund of all mandatory Japanese pension fund contributions when they finally leave the country, rather than the current limit of the last three years of premium payments. The Government should also act quickly to conclude social security agreements with all remaining EU Member States, as well as with Norway and Iceland, to lessen the burden on both employers and employees, and to avoid double payments. It should be added though that the decrease from 25 years to 10 years of payment of pension premium is something that the EBC support and praises.

Key Issues and Recommendations

■ Immigration legislation and policies

Yearly status report: good progress. Japan needs to take a more proactive approach to immigration policies. Several sectors are currently restrained by the shortage of available labour. This holds true for both skilled labour and unskilled labour.

Recommendations:

The Government of Japan should:

- Move forward with introducing on-line visa applications and visa extensions;
- Lower the requirement for industry experience from ten to five years for those who do not have a relevant university degree;
- Quickly implement the proposed policies of allowing visas to non-high skilled workers;
- Formalise visa procedures for partners that are not married or are in same-sex partnerships.

■ Labour market regulations and diversity

Yearly status report: some progress. Japan's future prosperity depends greatly on maintaining an adequate workforce that can support its ageing population and drive its economy. By far the easiest way to increase the working population would be to increase female participation. The EBC strongly urges the Japanese Government to continue to place more focus on flexibility for both employees and employers. This is needed both in terms of time management as well restructuring of staff.

Recommendations:

- Remove the spouse special income tax credit (*haigusha-tokubetsu-kojo*).
- Vastly increase and improve the infrastructure necessary to ensure sufficient child-care facilities, systems and staffing to support female participation in the workforce and male participation in the home.
- Encourage companies to set up child-care facilities by offering them identical or similar financial contributions to those given to public day-care centres.
- Introduce employment legislation that encourages the creation of a competitive workforce based on performance and not on long-term employment. Adequate protection of employees is required, but employers also need a legal framework within which to remove non-performing workers.
- Japan should allow for longer periods during which over-time can be balanced, up for six months to better align with longer projects and seasonal developments.
- Allow for easier corporate restructuring, while setting up clear rules for compensation of regular employees whose jobs disappear.
- The Japanese Government and universities in Japan should promote the set-up of internship programmes for university students.
- Amend the employment legislation to expand the "highly skilled system" to include employees who earn less than the current system regulating highly skilled professionals, while keeping adequate protections of employees. People with high skills and high motivation want to work based on output instead of work hours.

■ Pensions

Yearly status report: gradual progress. Social security agreements have been concluded or are being negotiated with several European countries, to the benefit of their citizens, whose mandatory contributions to Japanese pension plans can now be refunded in full. This is important not only with European countries but also with neighbouring countries, as this will make it easier to recruit foreign graduates from Japanese universities.

Recommendations:

- Extend the payback period as well as expand pay-back to include the company contributions for ex-pats that leave Japan before being able to benefit from payouts from the Japanese pension system.
- Japan should move towards introducing more bilateral social security agreements, with a focus not only on European countries but also neighbouring Asian countries, as nationals from these countries are becoming more and more common to combat the labour shortage in Japan.

Mr. Laurent Dubois

Chair, Intellectual Property Rights Committee

(Representative, Union des Fabricants)

c/o Union des Fabricants

SK Bldg. 3F, 1-5-5 Hirakawacho

Chiyoda-ku, Tokyo 102-0093

Phone 03-3239-3110

Fax 03-3239-3224

INTELLECTUAL PROPERTY

Introduction

In Japan, luxury brand products reach consumers via one of the following two sales channels, regular distributors or dealers in parallel imports. (Please note that the sale of parallel imported goods is not illegal in Japan.) While luxury brands strive to develop sales through regular shops or internet sites, the need to protect the image of their product seems to hinder them from being active to further engage in e-commerce by using any other actors for distribution. As in many other countries, the top producer and exporter of counterfeit goods distributed in Japan is China, accounting for 92.2% of all fake goods flowing into the country.

In 2017, more than 50,000 fake items were stopped at the border by Japan Customs. Given that it is impossible for Customs to examine all imported goods, this figure is probably only the tip of the iceberg of fake items imported in Japan. As buying counterfeit products “for personal use” is not forbidden in Japan, fake items cannot be fully stopped by Customs even if items appear to be obviously fake.

Until recently, many Japanese consumers purchased fake items knowingly. However, the main efforts today are focussed on how to prevent consumers from accessing fraudulent websites (mostly operated abroad) which are deceitfully selling counterfeit products to consumers who are deceived either into buying counterfeits despite their wish to purchase authentic products, or into buying products that will never be delivered, or which intend to collect buyers’ information such as credit card information. The Government has ordered a third-party to study the feasibility of blocking access to websites selling counterfeits fraudulently in particular.

Relevant ministries and agencies are making considerable efforts to protect IPR (Intellectual Property Right). The Consumer Affairs Agency has set up a Cross-Border Consumer Center to provide assistance to consumers who have unwittingly purchased counterfeit products. The Center publicises on its website the names of online stores selling counterfeit items. Moreover, the National Police Agency protects consumers by providing the global Anti-Phishing Working Group with information about websites selling counterfeit products so that alerts can be displayed in web browsers.

Major online retailers Yahoo! and Rakuten are also playing an important role in combating counterfeit products. For example, these online retailers are endeavouring to clean up websites by regularly exchanging information on counterfeits and criminal dealers with brands, via IP rights-holders’ associations. Further, in order to “clean up” their shopping websites, site operators make a test purchase to verify the authenticity of the products, with the cooperation of the relevant brand, when an item posted for sale is suspected of being a counterfeit product because of, *inter alia*, its extremely low sale price or information given by a consumer. If the said item turns out to be counterfeit, the shop who has put the counterfeit product for sale may be banned from the shopping website with immediate effect. As for the fast-growing Flea market, some websites, who have been focusing on the eradication of counterfeit goods, have obtained satisfactory results similar to those of existing auction services. On the other hand, some websites have been left far behind in the efforts to fight against counterfeit products which continue to flood the market.

Finally, concerted efforts are being made by different sectors in Japan to set up a framework to eliminate counterfeit products. Some of their approaches are more advanced than those implemented in Europe or the USA. However, problems still remain. Specifically, it is necessary to implement ‘internet blocking’ to protect consumers from illegal websites or to consider how to prevent counterfeit products “for personal use” from penetrating into the market. This should solve the issue of increasing sale of counterfeits on the internet.

Key Issues and Recommendations

■ Strengthened and continuous actions to eliminate counterfeit products from online malls in Japan and abroad

Yearly status report: no progress. While major Consumer to Consumer websites have succeeded in reducing the percentage of counterfeit products to less than 1%, some Business to Consumer websites have not taken appropriate measures with the cooperation of relevant IP right-holders yet. This in spite of the approval in principle of such measures against counterfeit products. The delay in taking action by shopping websites can be explained partly by the fact that most uploaded image data are showing authentic products exclusively and that it is often necessary to make an actual test purchase to determine the authenticity of the product. Additionally, countermeasures against counterfeit products have not yet taken place in respect of the internet flea markets, where counterfeit products account for around 20% of the total merchandise on sale. Overall, initiatives against counterfeit sales websites, fraudulent websites and spoof websites are progressing far too slowly. Measures already put in place by the relevant Japanese ministries and agencies, including the freezing of bank accounts used by the operators of such websites, publication of their URLs, and display of alerts via security software or browsers and web blocking. However, web blocking, which is a fundamental solution to the problem, has not been implemented yet while the Government has already decided to consider its deployment in “2018 Intellectual Property Strategy Program”. Given that public awareness of the need to protect IPR and consumer interest are undoubtedly rising, now is the time to take bold and swift action to combat the sale of counterfeit products.

Recommendations:

- Japan’s Specified Commercial Transaction Law should be amended to strengthen checks on brand goods sold online, with a view to eliminating counterfeit goods from Business to Consumer websites. In addition, the Government should encourage internet service providers, distributors and IP rights-holders to establish their own anti-counterfeit guidelines to promote private sector initiatives in this field.
- Radical measures should be taken against counterfeit sales websites, fraudulent websites, and spoof websites hosted by foreign servers, for example: blocking access to them or removing them from search engines.
- Although the government has already endeavoured to call for the joining of non-participants ISP companies to the dialogue forum where SP companies and right-holders discuss countermeasures against counterfeit products, this policy should continue in the future.

■ Tighter definition of “for personal use”

Yearly status report: sign of progress. The fact that the importation and purchase of counterfeits “for personal use” are lawful in Japan offers a loophole to dealers importing fake goods for commercial purposes. As a result, the Customs Authorities, after having wasted manpower and time to detect counterfeit products, have no choice but to grant importation. According to the above “2018 Intellectual Property Strategy Program”, the Government has already decided to begin to consider how to restrict the importation of counterfeit products “for personal use”. Revising the Trademark Act to restrict commercial transactions appears to be a highly controversial solution. Dealers importing numerous counterfeit watches by postal mail several times a year, for example, could be stopped simply by defining the minimum period of possession (such as one year) or the maximum number of items presumed to be “for personal use”. Given that the importation of counterfeit products for “personal use” may not be prohibited by the Trademark Act, it is necessary to take every measure to prevent such dealers from stating that goods are “for personal use” by amending relevant laws and regulations accordingly.

Recommendations:

- The importation of counterfeit products, even “for personal use”, should be restricted by applicable laws and regulations.
- The current situation should be improved by tightening the definition of “for personal use” or by setting the maximum number of items authorised to be imported under “personal use”.

Ms. Rika Beppu

Chair, Legal Services Committee

(Partner, Squire Gaikokuho Kyodo Jigyo Horitsu Jimusho)

c/o Squire Gaikokuho Kyodo Jigyo Horitsu Jimusho

Ebisu Prime Square Tower 16F.

1-1-39 Hiroo, Shibuya-ku, Tokyo 150-0012

Phone 03-5774-1885

Fax 03-5774-1818

LEGAL SERVICES

Introduction

The EBC is delighted to hear of prospective changes in the laws of Japan in respect of the work experience requirement for foreign-qualified lawyers to register as *gaikokuho-jimu-bengoshi* (foreign-qualified lawyers or “*gaiben*”). Currently three of work experience is required, out of which two years have to come from overseas. The Ministry of Justice's Review Committee for the Registered Foreign Lawyers System is now proposing that the overseas experience element is reduced from two years to one year, as well as the ability of *gaiben* and *bengoshi* to establish a corporation together, subject to the implementation of the change in the law.

1. Further to deliberations by the above mentioned Committee which took place throughout 2015 and culminated in a Report being issued on 5 July 2016, we understand that the following changes to the Act on Special Measures concerning the Handling of Legal Services by Foreign Lawyers (Act No. 66 of 23 May 1986) (the “Act”) are on the agenda for the parliamentary session in the fall of 2018.

1.1 The current three-year work experience requirement (two years of which must be experience gained outside Japan) will be changed to three years (one year of which must be experience gained outside Japan).

1.2 It will become permissible under law for *gaiben* and *bengoshi* to establish a *hojin* (corporation) together.

1.3 The scope of “international arbitration cases” under the Act will be clarified so that *gaiben* will be able to be involved in such cases. For example, (1) the condition that an “international arbitration case” must have Japan as its chosen arbitration venue, as well as (2) the condition that the case must involve at least one party whose main business location or head office is overseas is due to be changed to (1) the chosen venue of arbitration does not need to be Japan, and (2) the majority of the shares or voting rights of at least one of the parties are held by an entity or individual whose address is overseas.

2. Transparency of the *gaiben* registration system and making the registration process simpler: We would welcome any updates from the forum which has been set up for discussions between the Ministry of Justice and the *Nichibenren*, taking into account opinions from registrants as necessary. This with a view to making the registration process and timing more transparent, simpler and faster.

The EBC welcomes the prospective changes to the law and implementation thereof to reflect the items in paragraphs 1.1, 1.2 and 1.3 above. Going forward, the EBC will continue to recommend that any requirement for work experience prior to registration as a *gaiben* should be abolished. The EBC will continue to take a close interest in the roll-out of the recommendations as a whole, not least because the ultimate success will depend on the process being conducted fairly, with proper participation by foreign lawyers and due consideration given to the views of the foreign legal community.

Key Issues and Recommendations

■ Recognition and approval as a foreign lawyer in Japan

Yearly status report: reasonable progress, pending enactment of the prospective changes in the law. In order to become registered as a *gaiben* in Japan, a foreign lawyer must have three years of professional experience in his/her respective home law, of which two must have been obtained outside Japan. This rule is in stark contrast to the rules governing *bengoshi* who are not required to have any post-qualification experience before being recognised. The EBC believes that this practice is not only discriminatory, but also makes little sense, as foreign lawyers are already recognised by their jurisdiction of qualification. If there is to be such a rule, what is important is the experience in home jurisdiction law, not where it is practised. The procedure for admitting foreign lawyers as *gaiben* also still imposes undue costs on foreign firms and individuals. A streamlined application form has, in general, shortened the process, but the requirement for approvals from both the Ministry of Justice and committees at the *Nichibenren* and local bar associations inevitably gives rise to delays. After over 30 years of operation, the *gaiben* system is in need of a thorough overhaul. An overhaul of the system could resolve a number of the current frustrations.

Recommendations:

- The rule requiring a specific number of post-qualification years of experience should be abolished. At the very least, experience in home jurisdiction law should be recognised regardless of where it has been practised.
- Continuing focus is needed on accelerating the application procedure for *gaiben* registration to the greatest extent possible.
- An overhaul of the existing system should be undertaken to enable changes such as the registration of firms, rather than individuals, which would do much to eliminate frustrations with the existing system.

■ Branches

Yearly status report: reasonable progress, pending enactment of the prospective changes in the law. Legislation was finally passed in 2014, permitting a *gaiben* law firm to incorporate itself as a *hojin*, and thereby become eligible to open more than one branch. However, the 2014 legislation did not permit *gaiben* and *bengoshi* together to establish a *hojin*. The effect is to severely limit the usefulness of the new legislation.

Recommendation:

- Amend the legislation to permit *gaiben* and *bengoshi* to establish a *hojin* together. Even better, abolish the restriction on branching, which is archaic and does not suit the needs of either domestic or international law firms.

■ Limited liability

Yearly status report: no progress. The EBC continues to recommend the introduction of a limited liability structure for lawyers in Japan, in line with the practice in many other countries, for the benefit not only of foreign but also Japanese lawyers. For foreign lawyers, this could be achieved by permitting them to operate through a branch of their home entity, rather than as separate individuals.

Recommendation:

- A limited liability structure should be made available in Japan for both foreign and domestic law firms, and foreign firms should be able to practise in Japan through branches of their international firms. This could be achieved by an overhaul of the existing *gaiben* system to permit foreign lawyers to operate in Japan through branches of their home entity.

Mr.Karl Hahne

Chair, Retail & Wholesale Committee

(President & Representative Director, Häfele Japan K.K.)

c/o Häfele Japan K.K.

14-17 Kami-shinano

Totsuka-ku, Yokohama 244-0806

Phone 045-828-3117

Fax 045-828-3119

RETAIL & WHOLESALE

Introduction

The Japanese retail market remains one of the largest and most vibrant in the world. After many years during which the presence of European retailers was more or less limited to the luxury sector, the last decade has seen the rapid establishment of new European retailers both in fast fashion and home interiors. Their success clearly benefits Japanese consumers by offering them greater choice, often better prices and, frequently, completely new products previously not available on the market. It also benefits the Japanese economy at large, by creating considerable employment and helping to revitalise cities that were previously in decline. Japanese retailers and wholesalers themselves gain from the presence of European competition as it provides incentives to further strengthen their global competitive edge.

With the implementation of the EU-Japan EPA, the market access for European products and services will improve. Tariffs will be reduced. In most cases it will go down to zero already on the day of entry into force. The EBC is also hoping for a more harmonisation of standards and regulations between the two economies. Where harmonisation is difficult or requires time to implement mutual recognition of standards, approvals and test result shall be established to improve the situations. The EBC would like to point out that the protection of the consumer will not be reduced as both economies have robust systems in place to achieve this.

European wholesalers and retailers still face considerable barriers in the Japanese market that make it difficult to take advantage of global-scale logistics. This creates higher costs and therefore higher prices for Japanese consumers. The Government of Japan still continues to insist on applying unique national rules and regulations to products that have already met European standards. Japan's reluctance to accept EN (European) and ISO standards or CE (*conformité européenne*) markings delays the introduction of new products to the market and increases import costs. While sharing the Government's concerns regarding consumer protection, the EBC believes that European rules more than adequately address these same concerns, ensuring safe and good-quality products. Mutual recognition of rules and regulations therefore makes sense and would create a level playing field for all players. Just one example of the barriers encountered by European retailers and wholesalers is the unique labelling rules, specified by Japan's Consumer Affairs Agency (CAA). Other examples include non-acceptance of non-SI units (International System of Units), importing process for food contact products (UCP) regulated by Food Sanitation Law, and non-recognition of global standards and European approvals. Furthermore, non-harmonised procedures for importing, certifying and labelling consumer products are unnecessarily costly and complex.

The Japanese Electrical Appliance and Materials Safety Act, known as the *Denan* Law, is a further source of unnecessary cost and complexity for retailers and wholesalers. The Ministry for Economy, Trade and Industry (METI) lists various groups of products that fall within the scope of this Law. However, it is often difficult to decipher whether a specific product is covered or not, resulting in uncertainty about test requirements. In addition, there has been a lack of harmonisation in this field, and where the Japanese equivalent to the IEC (International Electrotechnical Commission) standards is used, it is not always based on the most recently updated IEC standard.

Finally, the EBC is also concerned about Japan's Antimonopoly Law, following an apparent relaxation of prohibited vertical restraints with no safe harbour, and enforcement of the Subcontractor Law, without bright-line rules, against retailers and wholesalers. As a result, application of the Law has become more unpredictable and non-transparent, thereby increasing the difficulty of compliance. There is a real risk that this situation could be exploited and the market manipulated, so we urge the Japan Fair Trade Commission (JFTC) to issue as soon as possible clear written guidance that facilitates compliance.

As stated above the EBC looks forward to the implementation of the EU-Japan EPA and believes this will further reinvigorate the Japanese retail and wholesale sector to the benefit of the Japanese consumer.

Key Issues and Recommendations

■ Prohibitive import, testing and certification procedures

Yearly status report: some progress. To the detriment of trade, the Government of Japan continues to insist on applying unique national rules and regulations to many products that have already met European / international standards. The EBC requests that the MHLW harmonises positive list for utensils, container and packaging (UCP) in the Food Sanitation Act with other countries.

Recommendations:

- MHLW should make certain that the current draft positive list for food contact products is harmonised with other countries. It is furthermore of important that the list is also offered in English.
- Japan should recognise EU related timber regulations as equivalent to the Clean Wood Act.
- Japan should accept inclusion of common non-SI units on measuring devices when SI units are also used.
- Japan should simplify its *Denan* Law, avoid introducing further unique Japanese requirements and make certain that detailed information on standards and their application are readily available in English.

■ Labelling

Yearly status report: slight progress. The revised Household Goods Quality Labelling Act introduced some improvements, however requirements remain too detailed and inflexible for retailers and labels too complex for consumers.

Recommendation:

- The Labelling Act should be reformed to aid the consumer in understanding the product and to introduce flexibility for the retailer.

■ Shoe quotas

Yearly status report: progress. With the implementation of the EPA, shoe quotas will be eliminated. In the meantime, management of such quotas is not transparent and allocations are not always awarded to real importers of shoes, leading to significant market distortions.

Recommendation:

- Until the EPA enters into force, METI should monitor the system, reject applications from entities not trading shoes, release their quotas, and implement stricter penalties for infringements.

■ Limitations on selling liquor via telecommunication channels

Yearly status report: no progress. The retail sale of liquor across prefectural borders via any telecommunication channel (including the internet) is restricted. Furthermore, grandfathering old licences is unfair to new entrants.

Recommendations:

- Japan should abolish the telecommunication channel limitation within the liquor retail licence system.
- Japan should stop the practice of grandfathering licences.

■ Competition law/Anti-trust legislation

Yearly status report: no progress. Japanese Competition Law includes recognition of “market power” with minor shares in vertical restraint, and “superior bargaining power” irrespective of dependence, which differs from global practice. The Subcontractor Law lacks bright-line rules, and “yellow card” infringement notices lack explanation.

Recommendations:

- Japanese Competition Law/Subcontractor Law should be harmonised with global practices.
- The “yellow card” system, not transparent and lacks both a legal basis and bright-line rules, should be abolished.

Mr. Hans-Peter Musahl

Chair, Tax Committee

(Partner, Ernst & Young Tax Co.)

c/o Ernst & Young Tax Co.

Hibiya Mitsui Tower, Midtown Hibiya, 1-1-2 Yurakucho, Chiyoda-ku

Tokyo 100-0006, Japan

Phone +81-90-9848-6525

TAX

Introduction

The EBC welcomes the Japanese Government's continued efforts to increase Japan's attractiveness to investors. Reforms to date have reduced the overall effective corporate tax rate from 35.6% to 31% for large companies in metropolitan areas and to 35% for SMEs. The Government plans to help restore the country's finances through an increase in the consumption tax rate from 8% to 10%. Japan still trails behind many European countries, including EU Member States, in transitioning its tax profile from a focus on taxing income to a focus on taxing consumption.

Nevertheless, public statements made by Prime Minister Abe have indicated that Japan aims to take a lead amongst global economies in contributing to growth and to reboot the economy to the greatest possible extent. Since none of its policies to date involve significant curbs on expenditure, the growing deficit in the Government budget will at some point have to be made up from increased tax revenues. Consequently, the widening of the tax base that has occurred in recent years is set to continue. Regrettably, despite specific policies such as the reduction in the corporate tax rate, the Government's overall approach will inevitably have a negative impact on the attractiveness of Japan to potential overseas investors.

This negative impact is reinforced by the Government's increased focus on taxation of wealthy individuals and those with above average income, imposing inheritance, gift and income tax rates as high as 55% or more. The EBC appreciates recent inheritance tax reforms that benefit short and mid-term residents. Also, the repeal of the extraterritorial inheritance and gift taxation of long-term residents is welcomed, which the EBC had asked to consider. However, the Asian investment hubs of Hong Kong and Singapore will, overall, remain more attractive tax jurisdictions for individuals, particularly for those wishing to reside long-term in the region.

Bilateral trade and investment between Europe and Japan benefits significantly from mutual elimination of double taxation, as provided for in recent tax treaties between Japan and individual EU Member States and in the arbitration provisions of the multilateral instrument developed under the OECD's Base Erosion and Profit Sharing (BEPS) Action Plan. However, Japan's treaties with the majority of Member States (i.e. Bulgaria, Czech Republic, Finland, Hungary, Ireland, Italy, Lithuania, Luxembourg, Poland Portugal, Romania and Slovakia) still lack exemptions in respect of areas beyond the scope of the multilateral instrument, such as elimination of withholding tax on dividends, royalties and interest. No treaties have been agreed with Greece, Croatia, Cyprus and Malta.

In summary, while the EBC considers that some of the tax reforms undertaken so far by the Japanese Government are heading in the right direction towards encouraging and supporting inward investment, others are likely to work directly against those goals. Consequently, the growth anticipated by the Government may be difficult to achieve. This situation will persist as long as the significant fiscal deficit remains to be addressed and tax revenues are used as the supposed solution to this problem.

Key Issues and Recommendations

■ Tax policies to promote innovation

Yearly status report: little progress. Innovation-intensive industries are a key driver of growth and employment. R&D and innovation promotion tax incentives are widely recognised as an effective instrument for encouraging R&D activities and related (foreign) investments. While Japanese rules give some tax consideration to R&D and innovation expenses incurred in Japan, the current tax credit is generally too restrictive in scope (both in terms of access and benefit) to be a deciding factor in a foreign company's choice between potential R&D locations. Having said that, the decision to award higher credit rates to increased R&D expenses or newly started activities is welcome and foreign companies reviewing their R&D policy in Japan could benefit from this, provided that R&D cost are not borne centrally by the headquarter but locally by a Japanese entity. In general, however, Japan still needs to revise its current R&D tax policy if it wishes to maintain and improve its international attractiveness as a location for R&D activities. In this respect, it should be noted that many other countries have in recent years introduced some form of “back-end” Intellectual Property (IP) regime that applies to income earned after the creation and exploitation of IP. Furthermore, the current R&D credit regime is not available to companies that are not locally expensing R&D cost or are loss-making, and so is of little benefit to many foreign and start-up companies.

Recommendation:

- Revise the current R&D tax policy to maintain and improve Japan's international attractiveness as a location for R&D activities, paying particular attention to the specific position of foreign and start-up companies.

■ Directors' compensation

Yearly status report: new issue. Recent tax reform has provided some degree of relief from unfavourable directors' compensation tax rules that limit the deductibility of performance-based directors' compensation. However, in practice the relief only applies to listed companies issuing securities reports. In particular, small and medium-sized enterprises and foreign affiliated companies are unable to take advantage of the reforms, with the result that these companies have to pay performance-based directors' compensation from their after-tax income.

Recommendation:

- Remove barriers to relief for small and medium-sized companies, as well as foreign affiliated companies, to enable the deduction of reasonable performance-based directors' compensation.

■ Extended tax return filing periods

Yearly status report: some progress. Japanese rules require companies and individuals to file tax returns no later than two to three months after the end of the calendar or fiscal year. The extremely short deadlines in Japan compromise the quality of tax filings and the working and family lives of those preparing the returns, while driving up expenditure on overtime. Not surprisingly, international comparison of the cost incurred for tax compliance shows that Japan has the highest level among developed countries. The 2017 tax reform introduced measures intended to provide relief to corporates but not to individuals. However even for corporates measures this has proven impractical and have yet to be adopted by many Japanese taxpayers.

Recommendation:

- Extension of tax return filing periods for individual income taxes should be granted until May 30 as in other European countries. Where professional service providers are involved, a further extension by six months should be allowed. Also, the law should allow individuals to apply for extensions in exceptional cases.

■ Income and Inheritance Taxes

Yearly status report: progress with drawbacks for long-term residents. With top rates of more than 55%, Japan's income, inheritance and gift taxes are the highest in Asia and, indeed, in the world. Foreign nationals are exempt from Gift and Inheritance Tax for the first ten years of their stay in Japan. However, anyone who becomes a long-term resident is fully subject to Gift and Inheritance Tax. Moreover, Japan's top inheritance tax rate applies to inheritance between close family members, and starts at much lower thresholds and allowances than in other countries. Japan's Gift and Inheritance Tax is negatively impacting the ability to retain long-term residents, potentially triggering a loss in foreign intellectual capital and foreign investment.

Recommendation:

- Align the categories of foreign nationals who are subject to Gift and Inheritance Tax with the categories of foreign nationals who are subject to exit tax, so that only foreign nationals who can reside permanently in Japan are subject to taxation on global assets.

■ Accountability

Yearly status report: no progress. The overall lack of transparency and systematic accountability in the domestic tax regime continues to impede the development of business in Japan.

Recommendations:

- The tax authorities in Japan should be obliged to accept and process applications for tax rulings, and tax law should enshrine the right to request and obtain tax rulings. The system should be more user-friendly.
- Consider the merits of introducing a system offering Horizontal Monitoring, Risk Rating and Senior Accounting Officers, which have each helped to improve efficiency in the UK and The Netherlands.
- Transparency would be enhanced, if the tax authorities allowed for communication in English.

■ Tax treaties

Yearly status report: progress. Japan recently concluded new tax treaties respectively tax treaties in principle with Spain, Austria, Denmark, Estonia and Latvia which will come into force soon. The EBC welcomes treaties that include the exemption of withholding tax on royalties and qualified dividends and interest. However, its treaties with 12 other EU Member States still need to be renegotiated and no treaties have been concluded with four countries, among them Greece and Croatia. Furthermore, employees' contributions to social security systems within the EU and Japan should be treated as tax deductible on a mutual basis.

Recommendations:

- Any new or revised treaty should address the issue of withholding tax on royalties and qualified dividends and interest, and contain arbitration provisions if not already covered by the multilateral instrument.
- Treaties should be agreed with those countries having no agreement with Japan at present.

■ Centralise local tax

Yearly status report: new issue. Taxpayers who operate throughout Japan have to file local tax returns in numerous municipalities and have to make dozens, sometimes hundreds of tax payments three times a year, and to apply for tax refunds where applicable.

Recommendation:

- The EBC recommends to centralise the administration of local taxes by the national Government or, as similar to Consumption Tax, centralise tax payment by the local Government where the head office of the tax payer is located.

■ Abolishment of stamp tax

Yearly status report: new issue. Stamp duties as low as 200 JPY require significant additional administrative efforts for internal processes and payment. The cost of administration is not in proportion to the tax revenues. An abolition of the tax is also requested by numerous domestic business associations and publicly debated in the tax reform discussion.

Recommendation:

- The Government should consider to abolish the imposition of stamp tax.

Financial Services

**Asset management
Banking
Insurance**

Mr. Nicolas Sauvage

Chair, Asset Management Committee
(Representative Director, Amundi Japan Ltd.)
c/o Amundi Japan Ltd.
Hibiya Dai Bldg. 20F, 1-2-2 Uchisaiwai-Cho
Chiyoda-ku, Tokyo 100-0011
Phone 03-3593-5900
Fax 03-3593-5932

ASSET MANAGEMENT

Introduction

In the middle of 2018, the Japanese press, and not only the specialized one, reported two pieces of “shocking” news for the asset management industry:

The Bank of Japan, compiling statistics about the financial savings of Japanese households, recognised that they had overestimated ownership of funds by Japanese retail investors by almost 1/3, or 33 trillion yen (250 billion euros)! The reason for this over-estimation is that some large AUM (Asset Under Management) invested in private placement funds by Japanese financial institution(s) were counted as retail AUM for many years.

Indeed, this is a shock as it further confirms the low penetration rate of funds in Japan, and the urgency to build financial assets for households to prepare for their future. Share of funds in Japanese households’ financial savings remain below 5%, while in Europe, numbers vary between 10 to 20% according to each country, and this is well above 30% in the US. This is a problem not only for the individual households but also for the Government and society as a whole as more people will be dependent on the Government to provide for them to a higher degree after they stop working. It will also mean that there will be a lower supply of capital available for companies from where to fund growth.

The Japanese regulator, the FSA (Financial Services Agency), also published a research paper regarding the total return of retail investors, showing that 46% of retail investors owning funds have negative performances as of the end of March 2018. If the holding period was long enough, in the market environment of the past few years, most holders should be in positive territory. Such high percentage suggests that they owned the products only for a short period of time, suggesting that some “churning” remains a practice at distributors. Behind these provocative headlines, the key message is that long-term investing, including through regular saving schemes, has a much higher probability of generating positive returns and therefore develop confidence in fund investing.

On a more positive note, 2018 has seen some positive developments in the field of stewardship and corporate governance. The corporate governance code was revised this year (the stewardship code was revised the previous year) and the interest for ESG (Environment, Social and Governance) and SDGs (Sustainable Development Goal) continue to grow.

Europe is well advanced in the ESG field and EBC members can certainly contribute to such developments in Japan.

Key Issues and Recommendations

■ Global competitiveness of Tokyo as an operational platform

Yearly status report: progress. The EBC Asset Management Committee has been active in 2018 on topics related to our past recommendations for the improvement of the operational platform for the asset management industry in Japan.

Several meetings with trust bank representatives were organised to discuss about the limitations of the operational platform and more specifically about the practice in Japan for “dual NAV calculation”.

The EBC Asset Management Committee submitted its comment when JITA called for public comments in June 2018 on this issue and this is available on JITA website.

JITA has published in September 2018 the results of the Governance Working Group on this issue and EBC Asset Management Committee welcomes that fact that a new study working group will be established to review the practical implications with a specific focus on studying European market practices such as in Luxembourg.

Recommendations:

- Continuous encouragement by authorities and industry associations to enable those working groups to generate recommendations to be implemented.
- In addition to the “Dual NAV calculation” topic, Japan should also investigate how to remove hurdles to make fund mergers possible. This would help reducing the number of small funds in a constructive manner, as well as simplifying the offering to retail investors.

■ Encouraging Japanese households to invest for the long-term

Yearly status report: no progress. A key challenge for Japanese society is building financial assets with a long-term perspective, in particular, to prepare for financial needs after retirement. Anecdotal evidence suggests that a major obstacle to household investment in financial products is lack of financial education, resulting in confusion. Independent financial advice provided by qualified professionals with a fiduciary duty would alleviate this issue. However Japanese households have little or no access to such services. While platforms such as NISA (Nippon Individual Savings Account), Junior NISA and DC (Defined Contribution) are proving more popular, all still suffer from low annual ceilings with respect to tax savings. Moreover, a significant part of money allocated in the DC schemes remain in cash or cash equivalent.

Recommendations:

- Increase the maximum yen amounts that can be saved tax free in NISA, Junior NISA and DC platforms, especially if those amounts are funded by conversion of deposits.
- Change the default option for DC schemes to long-term financial investment products
- The Japanese Government should foster and publicize provision of IFA (Independent Financial Adviser) services – with services provided in-person or online – to help boost household investments.

Mr. Christopher Dark

Chair, Banking Committee

(Managing Director, Morgan Stanley Japan Holdings, Co., Ltd.)

c/o Morgan Stanley Japan Holdings, Co., Ltd.

Otemachi Financial City South Tower

1-9-7 Otemachi, Chiyoda-ku, Tokyo 100-8109

Phone 03-6836-5000

BANKING

Introduction

Over the past 12 months, the Nikkei 225 reached its highest level since Japan's 'bubble' years, first-half outbound M&A volume tripled year-on-year for 2018, and Governor Koike released a plan to position Tokyo as a leading Global Financial City. Initiatives to make Japan more attractive for international investors are starting to bear fruit as evidenced by rising ROEs (Return On Equity) for major Japanese corporates. With encouraging economic figures and the upcoming Olympics set to shine a global spotlight on Tokyo, Japan's banking sector is poised to grow stronger. The EBC Banking Committee welcomes the recent regulatory changes and infrastructure enhancements; these represent positive steps to stimulate growth for financial institutions and the overall economy. However, there are still several important areas that make Japan a challenging market (e.g. labour market conditions, the speed of change, and the pace of internationalisation). European and other non-Japanese firms continue to contribute positively to the market, and stand ready to help Japan grow.

Tokyo's standing as a financial hub consistently ranks behind London, New York, Hong Kong, and Singapore in the Z/Yen Group's Global Financial Centres Index. In September, Shanghai overtook Tokyo as Japan's capital fell to 6th globally and 4th in Asia. To reignite the push for Tokyo to be a Global Financial City, the Tokyo Metropolitan Government (TMG) published a set of steps/goals to serve as its vision for structural reforms. This was borne out of an Advisory Panel convened by Governor Koike and comprised of representatives from the financial community – both Japanese and non-Japanese. The EBC strongly supports the goals and mission of the Panel, Governor Koike and the TMG. The EBC encourages the Government to support this initiative with demonstrable and meaningful action.

The EBC is heartened by positive progress to maintain a healthy economy, and make Japan more attractive to investors. The past introduction and subsequent revision of the Stewardship and Corporate Governance codes play an important role in this process. It is clear that the focus on ROE has yielded positive results with significant increases in recent years. Many sectors have also seen ROE growth exceeding global peers. Important steps to open Japan to foreign investors have begun to take shape including a rising number of companies that communicate with shareholders in English, and those with a dedicated Investor Relations department. However, there are still hurdles to overcome.

The EBC welcomes the continued push to reduce cross-shareholdings amongst Japanese corporations and is encouraged by the sustained emphasis on the issue in the TSE's (Tokyo Stock Exchange) revised corporate governance code. The level of cross-shareholdings has often been seen as a key factor contributing to Japanese corporates' weaker ROEs versus those from other major countries, as friendly shareholders have not pressured managements to make necessary changes. Continuing to reduce cross-shareholdings is critical to the continuing development of a strong corporate governance framework.

As the EBC has stated in the past, fair disclosure is key to ensuring fair markets and that company-specific information is properly distributed. In Japan, there has been a history of non-public information being disclosed to certain securities companies, or disseminated through the media before an official public announcement. The EBC welcomes the introduction of the Fair Disclosure Rules this past Spring and urges proper enforcement by the Financial Services Agency (FSA) and the TSE.

The EBC is appreciative of the progress made in liberalising firewall constraints within the same financial group for control and settlements functions in recent years, but there is still a prohibition on information sharing for sales staff. The EBC continues to believe that this is unnecessary and that principle-based conflict management with appropriate inspection/supervision practices should suffice including allowing sales staff to act as a 'first line of defence' and to contribute to positive regulatory outcomes. This may also encourage firms to use Tokyo as its Asia base for specific business lines.

The EBC Banking Committee stands ready to work with the Government, and other foreign industry associations, to ensure a healthy and prosperous international banking market.

Key Issues and Recommendations

■ Tokyo as a financial centre

Yearly status report: progress. The EBC welcomes the renewed push by Governor Koike to make Tokyo a Global Financial City. The transparent Advisory Committee process has resulted in several actionable recommendations, but, as the decline to number 6 in the recent Global Financial Centres Index shows, significant work remains to be done. Japan's deep capital pools, diverse array of industries, and investable assets make it a promising candidate to become Asia's financial hub. However, since the November 2017 report, there have been few announcements in English: this restricts foreign investors' ability to fully comprehend Tokyo's commitment to the initiative. While the EBC appreciates the interest from the TMG it still believes that the lack of "internationalisation"—including English levels trailing major competitors, restrictive labour regulations, and a "savings" as opposed to an "investment and asset building" mind-set - will hold the city back.

To maintain a healthy and competitive banking sector, Japan must be an attractive destination for both employers and employees (e.g. inheritance tax). The current system may disincentivise skilled talent from staying in Japan. Restrictive labour laws can also drive firms to build out overseas offices instead of increasing staff in Japan. A more flexible labour market, including appropriate white collar exemptions, will help grow Japan's banking sector. With the proper reforms, Tokyo's strength as a financial hub will support a healthy Japanese economy.

Recommendations:

- The TMG should execute the steps recommended by the Committee and outlined in the 'Vision' paper. The TMG should also release more English updates. For the initiative to be a success, it is crucial to retain interest/momentum from overseas investors. The Government should support this initiative with demonstrable and meaningful actions and, as Governor Koike said, avoid "No Action Talk Only". The EBC encourages cooperation with the national government, to achieve these goals.
- Introduce further flexibility in the labour market to encourage foreign firms to expand their Tokyo offices. The inability to adjust operations in-line with fast-changing markets can make firms hesitant to hire in Japan.
- To attract global talent, it is advisable that Japan's individual tax schemes align with other financial centres. Without a skilled workforce, Japan will not be able to compete globally.
- Encourage innovation in, and adoption of, technology that aligns with global standards, and allows Tokyo to compete with other global financial centres; this includes attracting global industry events and conferences. The EBC is encouraged by the focus on FinTech by the Advisory Panel, and in the TMG's 'Vision' paper, and welcomes the growth of this sector in Tokyo.

■ Fair disclosure regime

Yearly status report: progress. Fair disclosure ensures that company-specific information is appropriately distributed to all market participants without bias towards one securities company or media source over another. The new "Fair Disclosure Rules" went into effect this spring. These rules are essential to maintaining a free and transparent market. As in the past, the EBC believes that rigorous implementation is needed to stop information being leaked to select parties ahead of its official release.

Recommendation:

- The Japanese authorities should closely monitor progress and effectiveness of these rules. Ensuring proper compliance will give investors confidence in the markets and the effectiveness of the Japanese authorities.

■ Information sharing

Yearly status report: no progress. While the firewall between different entities within the same financial group has been liberalised for control and settlements functions in recent years, there is still a ban on information sharing for sales staff. The EBC believes this is unnecessary and that a principles-based conflict management regime combined with appropriate inspection/supervision practices should suffice. Taking down the firewall will also allow sales staff to act as a 'first line of defence'. This may encourage firms to leverage Tokyo for certain business lines, and thus advance its campaign to become a Global Financial City.

Recommendation:

- Remove the ban on information sharing within a financial group.

Mr. Kazutaka Matsuda

Chair, Insurance Committee

(Executive Officer, General Counsel,

Legal & Compliance, AXA Life Insurance Co., Ltd.)

c/o AXA Life Insurance Co., Ltd.

NBF Platinum Tower, 1-17-3 Shirokane

Minato-ku, Tokyo 108-8020

Phone 03-6737-7734; Fax 03-6737-5874

INSURANCE

Introduction

In recent years, the Japanese authorities have been gradually harmonising laws and regulations relating to the domestic insurance market with global standards. However, foreign insurance company affiliates in Japan still encounter obstacles that limit efficient development of their businesses. Examples include reserving and solvency regulations that are inconsistent with international norms; the improving, but still lengthy product approval process; the Government's continuing majority ownership of Japan Post even beyond its privatisation; and the separate regulatory framework applied to mutual aid cooperatives (*kyosai*). Future growth of the insurance market in Japan will come from the ageing of the population, which will drive a need for products dealing with extended retirement, changes to family structure and rising demand for healthcare. The EBC urges the FSA (Financial Services Agency) to facilitate a truly open and competitive insurance market capable of meeting consumers' needs.

In the development of Insurance Capital Standard (ICS) Version 1.0 for extended field testing and the years of field testing preceding it, the IAIS has had appreciated both commonalities and differences in solvency regimes across the jurisdictions. There are many practical implementation issues to consider for the ICS to be implemented as a Prescribed Capital Requirement (PCR). The International Association of Insurance Supervisors (IAIS) is aware that stakeholders have been calling for greater clarity on what the implementation of the ICS, following the completion of field testing in 2019, will mean in practice.

The IAIS has agreed that implementation of ICS Version 2.0 will be conducted in two phases. The first phase is "monitoring period", during which ICS Version 2.0 will be used for confidential reporting to group-wide supervisors and discussion in supervisory colleges, but not be used as a PCR triggering supervisory action. After five year monitoring period, the second phase will start for "implementation of the ICS as a group-wide PCR". They also propose that national insurance regulatory bodies in each country increase information sharing with other regulators across borders.

In line with the changes of international regulatory environment, the EBC believes that as the regulator of Japan's financial market, the FSA should adopt the appropriate proposed policy measures and additionally shift to a post-funded scheme for protecting policy holders.

While the FSA has made efforts to speed up the approval process through both a more efficient procedure and increased staffing, the EBC still believes that a "file-and-use" system should be introduced for quicker approval of standard products. This would free up resources for the FSA to focus its attention on more advanced products.

In parallel, the EBC believes that the FSA should accelerate de-regulation of distribution practices based on a risk-based approach, to cater to the growing demand from consumers for better access to more convenient distribution channels targeting their individual needs. This would also benefit the domestic financial services industry, Japanese consumers and Japan's ability to retain foreign investment.

As for Japan Post, even with the IPO (Initial Public Offering) implemented, the Government remains the majority shareholder in Japan Post, and so the public continues to believe that it guarantees the various Japan Post entities. The EBC considers this gives Japan Post Insurance (JPI) an unfair competitive advantage, which JPI is exploiting in its intention to expand its product portfolio. The EBC believes the Government ownership in Japan Post has a negative impact on the private sector.

Key Issues and Recommendations

■ Harmonisation with global solvency and other regulatory standards

Yearly status report: some progress. The EBC appreciates the FSA's willingness to take a leadership role among international regulators. However, further alignment of local regulatory requirements with the approach of Solvency II is crucial for European insurers in Japan as it would enable them to use the same methodologies in all territories and better develop group-wide risk management strategies. Such a move would both encourage and reward improved risk management within insurance companies – a goal shared by the FSA and insurers – and hopefully reduce the overall regulatory reporting burden on insurers conducting business in multiple jurisdictions. The EBC is in a position to provide the relevant information to the FSA on these issues.

Recommendations:

- Japan should accelerate reforms to achieve convergence between Japanese and global solvency standards.
- Japan should consider the approval process of an internal model for risk calculation on new solvency regulation to evaluate the risk characteristics of each insurer correctly.
- The market-based Solvency Margin calculation methodology should be further aligned with Solvency II.
- In adopting FSB/IAIS-proposed policy measures for the Japanese market, the Government should consider the burden that risk management reporting and capital adequacy requirements could impose on businesses and minimise any conflicting cross-border jurisdictional requirements.
- Japan should reform the Policyholder Protection Corporation when introducing new solvency regulation.

■ Product approvals

Yearly status report: some progress. The advantages of simplicity in the approval process have been articulated in our previous submissions. Incremental progress has been made however we continue to seek real enhancement in the form of a file and use system. Not only does it enhance efficiency, but it also enables the FSA to allocate resources to complex products that require more attention.

Moreover, real product innovation requires insurers to offer truly new proposition to customers. At this dynamic era where our customers' needs are constantly changing due to lifestyles, ageing and technology, the insurance industry needs to catch up in offering better coverage in new diseases/illnesses as well as play a more active role in improving our customers' health. These initiatives often require global insights without necessarily locally proven experience. The current FSA product approval philosophy is to focus on proven local data and experience, this significantly hampers product innovation progress, this is not in line with practices by overseas regulators, ultimately disadvantaging Japanese consumers. The EBC believes this recommendation to broaden the philosophy does not only benefit foreign insurers, but also Japanese insurers.

Recommendations:

- The FSA should introduce a system allowing insurers to register products, instead of having to obtain pre-approval. The FSA could retain the authority to conduct post-checks and issue withdrawal orders.
- The FSA should relax the requirement for new innovation to include global expertise and experience.

■ Fair competition in providing group insurance program to banks

Yearly status report: some progress. The EBC continues to be concerned by the strong influence of Japanese insurers over Japanese banks as their major shareholders. The EBC appreciates the monitoring actions taken by the FSA on this topic, wishes for the FSA to continue its attention as the concerned influence still exists. The EBC firmly believes that the competition in this area should be based on the quality of products and services rather than on the shareholding relationship which is irrelevant to the interest of Japanese consumers.

Recommendation:

- The FSA should carefully ensure that competition is based on fair comparison of offers, and is not biased by pre-existing shareholding relationships.

■ Liberalisation of sales through bank channel

Yearly status report: some progress. There are continued restrictions on the sale of insurance through bank channel, which should be liberalised in the interest of Japanese consumers. Our concerns include the restriction related to lending relationships as well as the use of personal financial data held by banks.

Recommendations:

- The FSA should allow banks to sell insurance to employees of companies where banks have a lending relationship, as the current restriction deemed excessive and redundant.
- The FSA should allow banks to use certain personal financial information of their existing customers in marketing insurance products, as it could enhance the suitability of offers. The EBC would like to point out that this is already allowed in the asset management sector products.

■ **Digitalisation/Personal data**

Yearly status report: new issue. The rapid advancement of technologies is clearly changing customers' expectations on insurance. Today's customers expect insurance services to be available real-time, on-demand, contextual and personalised. The EBC believes that both customers and the industry would benefit by further digitalisation and the proper use of personal data in rendering our services. Non-financial, e-commerce platform players are gaining significant powers due to their big customer data, and already entering into financial services leveraging such powers. The incumbent industry players should not be put at a structural disadvantage simply because they are under the traditional financial industry regulations.

Recommendations:

- The Government should accelerate the spread and usage of My Number for private sector services.
- The FSA should continue to explore a more transversal regulatory approach to financial services based on the types of transactions and services, and not on the category of providers, in order to make a level playing field for both incumbents and new entrants.

■ **Distribution practices**

Yearly status report: some progress. Insurance sales by an incorporated insurance agency to members of its parent and affiliated companies are restricted to so-called "third sector" products ("koseiin-kisei"). The EBC considers, however, that the current rule could be a barrier for new entrants and may not be beneficial to Japanese consumers, unbalancing with the potential risk of mis-selling. Furthermore, the EBC recognizes the FSA encourages all insurers including insurance agency to conduct the fiduciary duties, which should be the right direction for this element.

Recommendations:

- Taking into account emerging new technology and evolving insurance distribution, the FSA should review the related regulations, and present a roadmap for further deregulation for the benefit of Japanese consumers.
- When looking into distribution practices, the FSA should put more emphasis on enabling the customer to choose from a wider product portfolio.

■ **Japan Post reform**

Yearly status report: some progress. The Government remains the majority shareholder in Japan Post, and so the public continues to believe that it guarantees the various Japan Post entities. The EBC believes the Government ownership in Japan Post has a negative impact on the private sector.

Recommendations:

- Until 100% of Japan Post's shares are held privately, JPI's product portfolio should not expand and its issue limit should be capped at the current level. The Japanese Government should ensure a level playing field.
- The Government should publish a clearer road map on how it intends to sell its shares.
- The Government should adhere to its commitments under the WTO GATS.

■ **Kyosai**

Yearly status report: no progress. Currently *kyosai* are not subject to Japan's Insurance Business Law. Instead, different ministries regulate the various *kyosai* depending on the sector in which the *kyosai* is active.

Recommendations:

- *Kyosai* should be brought under FSA supervision, be covered by the Insurance Business Law, and not be allowed to expand their businesses until such provisions are in place.
- The membership of *kyosai* should be further clarified and restricted, as originally intended, to a well-defined group, such as a certain profession.

Transportation & Communications

**Airlines
Railways
Telecommunications carriers
Telecommunications equipment
Logistics & freight**

Mr. Donald Bunkenburg

Chair, Airlines Committee

(General Manager for Japan, Lufthansa German Airlines)

c/o Lufthansa German Airlines

3-1-13 Shibakoen, Minato-ku, Tokyo 105-0011

Phone 03-5402-5201

Fax 03-5402-5209

AIRLINES

Introduction

The volume of inbound air travel to Japan continued to grow in 2018. Working with airline partners and offices of the Japan National Tourist Organization (JNTO) around the world continue to be successful promoting tourist travel to Japan. In addition, investments continue to be made within Japan to improve infrastructure in order to ease access to regions beyond the large metro areas. The EBC supports these developments and the resulting steady increase in tourist demand from Europe. It also supports the Government's goal of reaching 40 million international inbound travellers by 2020.

Furthermore, demand for outbound travel from Japan to Europe increased in 2018 particularly on the touristic side. Airline seat capacity, continued to expand in 2018. Both European and Japanese airlines added frequencies and deployed larger aircraft types on existing routes to increase capacity. However, if Japan is to achieve its targets, the total number of seats will need to continue to increase. An increase in the number of seats becomes even more important as outbound travel from Japan continues to increase. Capacities will also need to be ramped up for the Olympics in 2020. Business travel also continues to grow, with a forecast for further steady growth, reflecting an increase in overall travel in preparation for the Tokyo 2020 Olympics, and the recent conclusion of the EPA between Japan and the EU.

The EBC urges the Government to continue to support the promotion of outbound travel to Europe and appreciates the initiative to subsidise passport costs for young people, to encourage them to travel. Stronger demand for outbound travel from Japan to Europe will benefit domestic businesses, including travel agencies and tour operators in Japan that earn commission on sales, since their commission for European destinations tends to be higher than for other destinations.

Airport fees, particularly in Tokyo continue to be high in comparison to regional competitors in Asia which is also an issue when airlines evaluate expansion. Higher fees were recently introduced for Haneda Airport (HND). The recent agreement concluded between IATA (International Air Transport Association) and Narita Airport (NRT) is satisfactory in that fees remain status quo, but there continues to be unusual charges such as a parking fee structure which does not conform to international norms. The EBC recommends refraining from any increase in current landing fees, navigation charges, airport terminal rent, airport terminal common usage fees, and parking fees. In addition, the cost of the continued improvement of security needs to continue to be borne by airport operators and government, and not by airlines.

The EBC has continued concerns about the implementation of the Tourism Tax. The collection process burdens airlines. In addition, there is no transparency as to the usage of the resulting funds. EBC advocates the use of the funds to benefit transportation infrastructure. In addition, the current data requirements set up by the Japanese authorities and how to deliver the data are unclear and European airlines may not be in the position to deliver this requested data due to strict EU data protection law. This needs to be urgently reviewed.

The EBC continues to support the further opening of HND, so long as this is based on fair and transparent distribution of additional slots. The EBC also encourages the Japanese Government to expand the infrastructure for catering and cargo facilities at HND. The current lack of proper infrastructure creates logistical impediments, resulting in higher costs for operating airlines. Moreover, the EBC requests the Japanese Government to further clarify the application of the so-called *Shibari* rule (the unofficial requirement for airlines to remain at NRT despite the expansion of flights at HND). This undermines the ability of European airlines to operate efficiently to and from Tokyo

European airlines have taken numerous measures to lessen their impact on the environment, including the purchase of new fuel- and noise-efficient aircraft, more efficient navigation technology, and bio-fuel testing. It follows that the EBC fully supports the opening of new approach and departure patterns at HND in order to reduce fuel consumption and increase cost efficiency. In line with this, the EBC recommends abolishing the early "gear down" policy at NRT, which unnecessarily increases not only fuel usage, but also noise for local residents.

Key Issues and Recommendations

■ Revitalisation of outbound tourism

Yearly status report: good progress. The Government continues to allocate substantial funds to promote Japan as a tourist destination. However, the EBC believes the expected demand for inbound travel, including for the 2020 Tokyo Olympics, cannot be sustainably met if outbound tourism is not also encouraged.

Recommendations:

- The Japanese Government should continue to promote “exploring the world” initiatives with PR campaigns and should work together with tour operators and travel agencies with a focus on Europe, which yields them higher commissions.
- The Government should continue its subsidisation of passport costs for young people in order to encourage travel abroad.

■ High costs at Japanese airports and new Tourism Tax proposal

Yearly status report: some progress. Operating costs at Japanese airports continue to be high in comparison similar airports. While demand for outbound travel to Europe is strong, it is the commercial viability of flights that determines the addition of capacity. Recent negotiations with NRT held the line on prices. Added to such cost issues, the Government continues to require airlines to file published fares and surcharges for approval prior to sale – a time-consuming and costly exercise not required in other major markets.

Recommendations:

- The EBC recommends that all airport fees remain stable. This will encourage airlines to maintain and grow capacity and frequencies, which will enable growth in traffic to and from Japan. Current airport fees are too high, particularly in comparison with other airports in the region
- The decision by the Japanese Government to reduce specific fees at domestic airports in Japan to further encourage travel should be used as a template to lower fees at international airports.
- The EBC urges the Government to reconsider the value to consumers of insisting that airlines file published fares and surcharges for approval prior to sale.
- The EBC was against the implementation of the new Tourism Promotion Tax as it burdens the airlines to collect it and raises costs for the consumers. In the implementation phase, the EBC requests clarification of data requirements which may be in conflict with EU data protection laws and prohibit EU airlines from delivering it. Also needed is a transparency of usage for the collected revenue.

■ Airport infrastructure

Yearly status report: limited progress. The EBC encourages the continued opening up of HND airport slots. In addition, improved “on or near airport” facilities, including for catering and cargo are needed. We welcome the opening of the new air corridor at HND with its positive business and environmental impacts.

Recommendations:

- HND should be fully opened up to all international traffic, including flights to and from Europe, on a non-discriminatory basis.
- More space for catering and cargo suppliers should be allocated at HND, in order to increase efficiency and reduce costs for operators.
- Additional car park facilities should be added at HND to alleviate waiting times for parking spaces. This would improve quick access to the airport.
- Numbers of immigration staff should be increased at all international airports as waiting times are high.
- The “early landing gear down” policy at NRT should be re-evaluated in consultation with local communities, on environmental as well as cost grounds, as it results in higher fuel consumption and increases noise.
- The Government should implement the opening of the new air corridor at HND as announced.

Mr. Shigetoshi Kawahara

Corporate Adviser

c/o European Business Council in Japan

Sanbancho POULA Bldg. 2F.

6-7 Sanbancho, Chiyoda-ku, Tokyo 102-0075

Phone 03-3263-6222

Fax 03-3263-6223

RAILWAYS

Introduction

Japan has long benefitted from an extensive railway network, connecting Kyushu in the south with Hokkaido in the north. The connection between these two islands, separated by the main island of Honshu, was enhanced by the extension of the Tohoku Shinkansen to join the Hokkaido Shinkansen. The Japanese railway sector has always been and continues to be dominated by domestic suppliers. Relatively few foreign players are present, a situation that is at its most extreme in the rolling stock market, in which none of the major foreign players has any significant activities. Nevertheless, Japan represents a large market that would benefit enormously from the technological expertise and international competitiveness that European manufacturers and service providers offer.

The EBC appreciates the work of both the European Commission and Japanese ministries in concluding the EU-Japan EPA, both in terms of the technical work in harmonising standards and test methods, and in recognising the overseas approvals, but also regarding the expansion of local entities that will be covered by the regulations on public procurement. Not to forget is of course also the removal of the Operation Safety Clause (OSC). It is however important to state that the success of the agreement will depend on the actual result of its implementation. So the EBC takes for granted that the OSC will be implemented as stated in EPA within one (1) year after the entry into force of the EPA. Furthermore, the Ministry of Land, Infrastructure, Transport and Tourism shall support and make certain that cities do take the necessary preparations to inform and include European companies in the railway related procurement.

Currently, products that have already been tested and certified according to international standards will not even be considered by Japanese railway operators without further extensive testing. (The only exception to this is products the operators have sourced themselves from specific manufacturers.) The EBC strongly requests the Japanese Government to improve this situation by introducing regulatory reforms that facilitate smoother imports and exports. It is of the utmost importance that when the Japanese and EU authorities consider harmonisation in the railway sector, they ensure the Japanese standards and specifications under discussion are those actually used by the Japanese operators. It is, furthermore, important that standards and specifications are made publically available so that European manufacturers have a genuine opportunity to meet and exceed these requirements. We believe that the technical working group set up in the framework of the EU-Japan EPA negotiations is a good start towards achieving this goal, but more information from the working group needs to be shared with industry, and industry should be more closely involved in this exercise. The EBC furthermore hopes that the committee on technical rules set up during the EPA negotiations will continue its work to further work for harmonisation and mutual recognition of standards and approvals.

On the same note, the EBC believes that the Japanese market would benefit from a national testing scheme which is used by all operators. This would not limit operators to differences in testing related to performance, but rather to testing related to safety which should be the same for all operators in Japan. This would remove the need for testing to be repeated and would be beneficial to all suppliers in Japan, whether they are foreign or domestic. The EBC believes that the MLIT together with Japanese operators should take a greater role to achieve this.

The EBC welcomes the EU-Japan EPA agreement and the progress achieved in regards to railways. We believe that efforts should not stop with the agreement: It will be vital to further harmonise regulations and standards, and to eliminate double testing to make it easier for European companies to do business and invest in Japan. Only then will both economies and passengers alike benefit from the technologies and knowledge that European and Japanese companies can provide.

Key Issues and Recommendations

■ Introduction of open integrated railway systems

Yearly status report: limited progress. Product development in Japan is dominated by operators who appoint manufacturers to develop new products according to pre-set specifications within a closed and vertically integrated system, instead of allowing manufacturers the freedom to find the most appropriate solution. This makes the Japanese market unique in comparison to other markets, where “buying off the shelf” is far more common.

Recommendations:

- The Government of Japan should promote and encourage open integrated railway systems, as a way to boost competition in the domestic market and export prospects for Japanese manufacturers.
- The Japanese Government, research institutes, railway operators and industry should continue their dialogue on this theme.

■ Conformity assessment and mutual recognition of testing and certification

Yearly status report: slight progress. Japan is an active participant in various international standardisation bodies, but there is very little movement towards applying common standards across its domestic railway market. Moreover, Japan lacks a common conformity assessment scheme for this industry. The EBC believes that it will be mutually beneficial for Japanese operators to work together with the EBC Railways Committee to define common requirements. This issue has been discussed in the negotiations towards an EPA and the EBC is looking forward to improvement in this area.

Recommendations:

- Japan should establish a working group to identify minimum common requirements acceptable to all operators.
- The Japanese authorities should take a more active role in setting up a conformity assessment scheme.

■ Operational Safety Clause (OSC) and public procurement

Yearly status report: progress. Japan and the EU are both signatories to the WTO’s Plurilateral Agreement on Government Procurement (GPA). Despite this, Japan has exempted railway procurement from the provisions of the GPA. With the EU-Japan EPA, the OSC will be removed within one year after the entry into force of the agreement. The EBC welcomes this and is also pleased that more cities will open up their procurement market to EU suppliers.

Recommendations:

- Japan should swiftly remove the OSC as agreed in the EU-Japan EPA.
- The Government of Japan should ensure that when planning new railway projects (such as LRT systems), local governments abide by or use the GPA as guidance to set up a proper public procurement scheme, and do not apply the OSC.

■ Tenders

Yearly status report: slight progress. Japan has never had a system of tendering for railway-related projects. The EBC, however, would like to commend JR East for recently issuing calls for tenders for rolling stock. The EBC believes there is a clear business case for tendering and so urges that Japanese operators start to use tendering procedures as the main method for procurement of railway-related products and services. We also hope the voluntary code on publishing procurement plans will result in more transparency and better access to technical specifications, as well as information on how to meet and exceed any set requirements.

Recommendation:

- The Government of Japan should encourage other operators to follow the example of JR East and promote the use of tendering, as this will improve competition in the Japanese market, benefiting both operators and passengers.

Mr. Toshihiko Niizaki

Chair, Telecommunications Carriers Committee

(President, BT Japan Corp.)

c/o BT Japan Corp.

ARK Mori Bldg. 24F., 1-12-32 Akasaka

Minato-Ku, Tokyo 107-6024

Phone 03-5562-6000

Fax 03-5562-0647

TELECOMMUNICATIONS CARRIERS

Introduction

The global economy is increasingly dependent on access to well-functioning networks. Whilst Japan has developed one of the most sophisticated information infrastructures in the world, the EBC believes there are still some areas that can be improved.

The notion of creating an independent electronic communications regulator has been widely discussed in Japan, including in political debates. The EBC regards independence of the regulatory process to be good practice in order to promote decision-making that is objective, transparent and accountable, and to build trust and credibility within the industry in order for different viewpoints and interests, including economic, social, and political objectives to be duly considered. The EBC believes such independence should be reflected in the institutional organisation in Japan and in its system of checks and balances. The resulting regulator should, furthermore, report directly to the Japanese Parliament. Best practice globally has shown that an independent regulator is the preferred model.

Whilst recognising that the Ministry of Internal Affairs and Communications (MIC) has made tremendous progress in advancing the Information and Communication Technology (ICT) industry, the EBC nevertheless believes there is a need for an oversight body with a majority of independent members and due transparency of its proceedings and decisions. This is particularly important in the light of Japan's transition to the model of equivalence, non-discrimination and functional separation. We believe that such a measure could provide more explicit assurances of fair treatment to customers, incumbents and competitors.

The EBC has long argued that ensuring fair competition is essential if Japan is to remain a vibrant telecom market. Creating an independent regulator is crucial, but only one of many elements that need to be put in place. There is also a need for better transparency in the cost mechanism for interconnection charges. Moreover, universal service obligations should reflect actual costs, thus helping to avoid unfair cross-subsidy. Japan has relatively high access prices compared to neighbouring East Asian countries so it is important that a much more holistic approach is taken in order to maximise competition in the market.

As large transfers of personal data between servers are becoming common and involve an increasing number of companies as well as administrations both as users and as providers, authorities are looking into how big data should be regulated. While by no means a new issue, the last couple of years have seen an immense increase in the volume of data. The EBC fully understands the need for regulating this field, emphasising, however, that any regulation should be designed so as to fulfil the security requirements, while avoiding placing companies under an excessive compliance burden. The EBC believes that it is of the utmost importance for there to be flexibility and pragmatism and for new rights and definitions to be clear. The process of formulating the regulations must be transparent and open to comments from outsiders. Special care should be taken regarding the issue of international transfers of information, so that companies can make full use of the advantages of cloud technologies. An appropriate balance should, therefore, be struck between protecting and informing consumers and providing the right environment for companies to conduct business. As such, it is crucial that authorities do not work in isolation, but constantly communicate with each other worldwide to learn from best practices.

The EBC Telecommunications Carriers Committee has high hopes of the benefits that an ambitious EPA between Japan and the EU can bring, and strongly believes that telecom issues should be covered, including detailed commitments and pro-competitive rules for the telecommunications and ICT services sector for business and end users. These commitments should go beyond those made under the WTO Basic Telecoms Agreement of 1998 and its annexed Reference Paper. They should, in particular, cover wholesale access regulation. The negotiations should also explore whether there is a case for enshrining EU-Japan ICT policy and regulatory principles in the Agreement, given the existence of EU-US and US-Japan ICT principles. It may also be instructive to consider if such broad principles can be agreed in future regulatory harmonisation in important hi-tech related areas, such as cloud computing, transborder data flows, data privacy, and cyber-security.

Key Issues and Recommendations

■ Institutional reform

Yearly status report: no progress. The EBC believes that it is inappropriate for the Government of Japan to act as both the regulator and a major shareholder in the Japanese telecommunications sector. Currently, however, MIC continues to enjoy wide-ranging statutory powers of intervention and control. The issue of independence was raised by the previous Government, but so far no discussion has taken place under the current Government. The EBC recommends the creation of an independent government committee as an independent regulatory authority, with a mandate to monitor regulation and business practice within the communications sector from a consumer perspective. The EBC cannot emphasise enough that best practice globally has shown an independent regulator to be the preferred model.

Recommendation:

- An independent, well-resourced and empowered telecommunications regulatory authority should be established with a pro-competitive mandate that measures its success in terms of a market that provides choice and enables the rapid introduction of innovative new services as well as reliable and cost-effective basic telecom/other services. To be independent, members should be selected from outside the Government and the committee should report directly to Parliament, and not to the MIC.

■ Data protection for big data

Yearly status report: new issue. With vast amounts of personal data being sent between servers daily, authorities have realised that there is a need to regulate this area. The EBC is keen to contribute to the policy debate, believing that any changes should be straightforward and practical. Regulation should strike a careful balance between protecting individual privacy and creating an environment that supports innovation of new products and services driving economic growth and employment in Japan.

Recommendations:

- New obligations on data processors should be clear and any definitions must provide clarity.
- The authorities should avoid overly complex regulation that could inadvertently lead to increased cost and so off-set the advantages of offering data processing.
- Any new regulation should also provide a balanced approach to minimise the inherent conflict between privacy for individuals and the need for companies to use information.
- Special focus is needed on international transfers of data to make certain that data flows are not “stopped” at the border, while at the same time introducing best practice to make certain that data are kept safe.

■ Fair competition

Yearly status report: some progress. The EBC believes it is of utmost importance to follow fair competition principles based on global practices. These principles will ensure that future discussions on fair competition rules will be successful.

Recommendations:

- The Japanese Government should ensure the transparency and efficiency of the regulatory process, including providing adequate time for consultation.
- The Japanese Government should introduce open and simple licencing procedures with minimum service and regulatory obligations.
- Incumbent carriers should be obligated not to discriminate on price or other conditions between their own businesses and those of competitors and to provide suitably separated published accounts.
- There should be transparent control by the regulator of access to the radio frequency spectrum, to physical rights of way and to the numbering plan.
- There should be proactive regulatory oversight of the implementation of any schemes for “equal access” and number portability to support newcomers to the market.
- To help avoid unfair cross-subsidisation, operators with significant market power should keep transparent, publicly available, separate accounts.

Mr. Yoshio Honda

Chair, Telecommunications Equipment Committee
(General Manager, Standardization & Regulation,
Technology & Research, Ericsson Japan K.K.)
c/o Ericsson Japan K.K.
MOMENTO SHIODOME, 2-3-17 Higashi-Shimbashi
Minato-ku, Tokyo 105-0021
Phone 03-6721-3300; Fax 03-5408-9744

TELECOMMUNICATIONS EQUIPMENT

Introduction

Structural reforms under the Government of Japan's ICT Strategy have supported the introduction of high-speed, large-capacity ICT infrastructure, the lowering of communications costs, and the development of e-commerce and e-government. Internet access costs have decreased dramatically and access to broadband is now amongst the most developed in the world. With the Tokyo 2020 Olympics approaching, Japan is looking to showcase its latest technology to the world. The Government has already announced its intention to have 5G up and running in time for the Games and is investigating how best to meet the growing need for more bandwidth for cellular applications. This is not limited to more obvious telecommunication areas such as big data and the Internet of Things, but also includes areas such as healthcare and transportation for both ground-based vehicles and drones.

The EBC appreciates the opportunity to contribute to the Ministry of Internal Affairs and Communications' (MIC) policy committees as an official participant and applauds the Government's overall commitment to an industry-led, global approach to standards and platform development. Important steps have already been taken to facilitate the product approval process, firstly by signing an EU-Japan mutual recognition agreement (MRA) for telecommunications terminal equipment in 2001, and secondly by introducing a Supplier's Self Verification of Conformity (SVC) in 2004, similar to the Suppliers' Declaration of Conformity (SDoC) introduced in Europe. Despite these significant achievements, however, implementation to date has been disappointing. The number of accredited testing bodies designated under the MRA remains low and the SVC still applies mainly to wired telecommunications terminals, with limited application to wireless/radio equipment. Although some additional products have been added to the SVC's scope, many products are still not covered.

There are approximately 7.9 billion mobile phone subscriptions globally and 5.4 billion of these are connected to mobile broadband, with overall mobile data traffic doubling each year. In Japan, which is considered a mature market characterised by advanced data services and the introduction of Long-Term Evolution (LTE), smartphone penetration is already at about 70% and is driving mobile broadband growth - traffic usage is projected to rise to 10GB/month per user by 2020. Japan is promoting new wireless technologies for the Internet of Things (IoT), Intelligent Transportation Systems (ITS) and 5G. Advanced wireless technologies can facilitate innovative use of ICT, and contribute to emerging industries and economic growth.

Applications used on smartphones, such as video and social networks, and machine-to-machine communication place different demands on the network. Japan has played an active role in efforts to harmonise the spectrums used for International Mobile Telecommunications (IMT) systems at the global level. It is important that MIC continues to champion this goal at the World Radiocommunication Conference 2019 (WRC-19), especially in relation to the identification of new harmonised spectrums for IMT above 24GHz (Conference agenda item 1.13). This would bring enormous benefits to the IMT industry and its customers by eliminating the need to develop local variations of new telecommunications equipment. The EBC strongly supports this work and hopes that Japan will continue to implement new spectrum bands that are harmonised with other markets.

The telecommunications industry is based on technical standards covered by so-called Standard Essential Patents (SEP), which commit the patent holder to licensing on Fair and Reasonable, And Non-Discriminatory (FRAND) terms. The Japan Patent Office (JPO) introduced in 2018 guidance for SEP licensing negotiations and a process for essentiality evaluation. The impact of these measures should be closely monitored in the coming years.

Key Issues and Recommendations

■ Establishing common technical standards and certification procedures

Yearly status report: some progress. The EU and Japan maintain different technical standards for the same products and, although the differences are not substantial, they lead to double testing and certification for manufacturers. The current EU-Japan MRA provides only for recognised certification organisations to test for both markets. The EBC is disappointed that the SVC system in Japan is limited to wired telecommunications terminals in general and that it has not been expanded to other telecommunications equipment (except for 3G/LTE and WiFi functions in mobile terminals), thus excluding radio base stations for mobile networks.

Recommendations:

- The EU and Japan should mutually accept each other's technical standards and certifications for telecommunications equipment.
- SDoCs issued by European producers should be accepted in Japan without further testing or administrative requirements, not only in respect of wired terminals, but also in respect of specified radio equipment.
- The application of SVC should be expanded to all equipment in the category, "Specified Radio Equipment".

■ Harmonisation of spectrum for IMT (IMT-2000, IMT-Advanced, and IMT-2020/5G)

Yearly status report: some progress. The EBC is pleased that MIC is working to ensure additional spectrum allocation bands to address the increasing demand for mobile broadband and emerging new use cases of the vertical industries. The EBC recognises MIC's plan to allocate spectrum bands for IMT-2020 before March 2019.

Recommendations:

- Japan should continue working for globally or regionally harmonised spectrum allocations for mobile use.
- Japan should engage actively in agenda item 1.13 of WRC-19.
- Japan should accelerate the process for allocating 5G spectrum, to facilitate the development of 5G equipment for its planned commercial service in or before 2020.

■ Future-proof radio regulation for mobile equipment

Yearly status report: some progress. The EBC believes that Japanese radio regulation is not sufficiently flexible and, by stipulating technical requirements based on specific technology on each frequency band, risks delaying the launch of new wireless technologies.

Recommendations:

- Japan should adopt future-proof radio regulation for mobile equipment so that emerging technologies can be swiftly deployed. It is worth studying the technology-neutral approach, especially for unlicensed bands such as 5GHz.
- Japan should review its radio regulation to ensure it avoids imposing undue requirements on radio base stations, especially in respect of AAS (Active Antenna Systems). In particular, the periodical inspection of radio performance at antenna or equivalent monitor ports should be carefully reviewed.

■ IP (Intellectual Property) policy for SEP (Standard Essential Patents)

Yearly status report: progress. Japan Patent Office's "Guide to Licensing Negotiations involving Standard Essential Patents" released in June 2018 has received a positive reception from the industry. The "Essentiality Determination of Standard Essential Patents" process, which received less attention, established in April 2018 by JPO. As it still waits for its first case the effectiveness and fairness cannot be verified. EBC will monitor the impact and fairness of these the newly established principle and processes in regards to the European telecommunication industry.

Recommendation:

- Japan should continue the communication with European Commission, European Patent Office, and other European organisations to harmonise the regulations related to Standard Essential Patent licensing.

Mr. Richard Van Schie

Chair, Logistics & Freight Committee

(General Manager, Schenker-Seino Co., Ltd.)

c/o Schenker-Seino Co. Ltd.

Tennoz Central Tower 15F., 2-2-24 Higashi-Shinagawa

Shinagawa-ku, Tokyo 140-0002

Phone 03-5769-7365

Fax 03-5769-7361

LOGISTICS & FREIGHT

Introduction

European logistics and freight companies offer consumers the benefits of access to their worldwide logistics operations. This has been even more evident in the last couple of years as e-commerce and home deliveries have increased exponentially. Moving forward there are no signs that this trend is receding, and companies in the logistics and freight sector are struggling. This is true both from a regulatory perspective but also due to the labour shortage and the fragmented digitalisation. Moreover, companies struggle with Japan's high cost base, inadequate infrastructure, heavily congested ports, and rigid customs clearance procedures. They also have to deal with outdated restrictions on foreign-owned companies engaging in the domestic freight forwarding business, and unfair competition caused by differences in the rules and regulations applied to carriers providing the same service, resulting in inefficiencies and higher prices for users. The EBC appreciates the Government's efforts as of late, and believes that it is on the right track. However, if the Government truly wants Japan to become a viable logistics hub for regional trade, it must now take account of all stakeholder perspectives and ensure the right regulation and infrastructure are in place.

The current demographic situation in Japan, with an ageing population and shrinking workforce, combined with an expanding e-commerce sector, is placing logistics and freight companies under increasing pressure. As a result, some major domestic companies have already announced drastic changes to their activities. The EBC calls upon the Government to accelerate policy and regulation, both short- and long-term, that will enable companies to meet the challenges. It is indeed positive that the Government is attaching importance to this issue, but unfortunately a sense of urgency is missing as well as a more comprehensive solution.

It is clear that the logistics and freight sector needs to modernise and make further efficiency gains. While part of the solution must lie with companies themselves, the role of Government is also crucial, for example in speeding up and simplifying the process for "open" parcel locker subsidies, changing the legislative framework for autonomous driving, and allowing larger vehicles. The non-proprietary "open" parcel lockers might alleviate some of the problems with failed deliveries and it has been well received by both consumers and business. The EBC believes a new and cross-ministry approach is required, for example, to improve the sustainability and effectiveness of last mile delivery, and it is essential that relevant policies are enacted without delay.

Companies expected the introduction of the Authorised Economic Operator (AEO) concept in Japan to lead to simplification of many of the transport and customs processes they need to undertake. Unfortunately, the new system has missed this target: instead of streamlining these processes, it has burdened companies with an increase in administrative tasks and compliance requirements in order to achieve AEO status. The EBC believes that more simplifications should be introduced, similar to those proposed when the AEO concept was first presented.

Finally, while MLIT has introduced positive reforms aimed at improving Japan's overall business infrastructure there is still some to do to remedy the challenges to shipping services. The Super Core Port initiative, announced by the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) as far back as November 2002, has yet to yield tangible improvements to the high-cost structure of Japan's ports. The development of Japanese container terminals is being initiated by local authorities rather than by central Government, such that anticipated economies of scale and efficiencies will remain difficult to achieve. Data show Japan's decline in port activity: Kobe Port, for instance, dropped in the Asian rankings from fourth place in 1980 to 59th place in 2015. Tokyo and Yokohama ports combined only ranked in 20th place globally in 2015 based on containers moved. Structural improvements are desperately needed if Japan wants to remain a vibrant shipping country.

Key Issues and Recommendations

■ Future delivery modernisation

Yearly status report: new issue. The final mile delivery in Japan can be hugely challenging, with service providers working extended hours and dealing with re-deliveries as a result of the consignee being away from home or unable to receive the delivery, even if the delivery is made within the agreed time window. Against the background of an overall tightening of the labour market and, in particular, a well publicised driver shortage, the EBC believes that a new approach is required to improve the sustainability and effectiveness of final mile deliveries.

Recommendations:

The Government of Japan should:

- Enable use of larger vehicles for inter-city movement to reduce the number of vehicles and drivers required.
- Allow and encourage the use of autonomous vehicles by delivery companies.
- Increase the subsidy for non-proprietary “open” parcel lockers and simplify the application process for such subsidies. In particular switching from the pre-installation to a post-installation application process should accelerate the deployment of parcel lockers.
- Educate the public about socially responsible delivery arrangements by highlighting the social and environmental costs of failed delivery attempts and encouraging the consignee to be home and able to receive the delivery within the requested time window or to choose alternative “delivery options”.

■ Labour shortage

Yearly status report: limited progress Given Japan’s projected population decline and ageing society, it is anticipated that the current shortage of available labour will continue, severely impacting the logistics sector as expansion of e-commerce drives up demand. The logistics sector is especially vulnerable as many of the long-haul drivers it employs have reached or are reaching retirement age. In order to continue meeting the demand for logistics services, it is important that the Government puts in place practical strategies to improve the availability of labour in the short- and medium-term. The EBC appreciates the various initiatives put forward by the Government. However, many of them do not quite hit the target but are held back by limitations either in scope or by administrative restrictions. There is a particular concern around the short-term challenge, since potential solutions such as the use of new technologies, including autonomous driving, and increased use of automation in freight handling will only become available in the long term.

Recommendations:

- Japan should ease its visa requirements to allow foreign temporary labour, particularly during peak periods of demand, such as Golden Week and around the end of the year.
- Japan should make it easier for logistics companies to use the Technical Intern Trainee Program.
- The authorities should support companies in setting up childcare provision, including through access to training and certification for child care workers, to facilitate the employment of women in the sector.
- Japan should promote the importance of the logistics sector to encourage more female participation.

■ Authorised Economic Operator (AEO)

Yearly status report: some progress. The current system of AEO has not led to the anticipated easing of the administrative burden. In many cases, the burden has increased. The EBC seeks a system giving companies a simplified process and extended powers to handle matters without the involvement of the authorities in every single case, provided operators can demonstrate sufficient control over the flow and that traceability is ensured.

Recommendations:

- The AEO concept should focus more on offering simplifications, provided the operator meets the agreed criteria for tracing each product and adhering to the agreed process flow.
- The Government should introduce more benefits for imports handled by AEOs, including but not limited to:
 - ✧ Enabling access to NACCS from servers outside Japan
 - ✧ Allowing quarantine checks at transporters' own bonded warehouses
 - ✧ Reducing the physical examination of shipments
 - ✧ Allowing the use of digital archives

■ Port costs and development

Yearly status report: limited progress. Port costs in Japan continue to be high in comparison to other advanced economies. High port costs also undermine the competitive position of Japanese ports in Asia, for example in the provision of transshipment services, since South Korea and China offer more competitive condition. Foreign shipping lines are still not allowed to transship their own overseas cargo on their own vessels in Japan, thus encouraging them to transship cargo elsewhere, reducing business at Japanese ports. While similar restrictions apply in Europe, it is nevertheless possible for a Japanese carrier to transport its cargo across borders within the EU, for example from Germany to France, thereby meeting business requirements. That said, we have seen positive development on the transportation of empty containers where European shipping lines are now permitted to process/facilitate the movement of empty containers throughout Japan.

Recommendations:

- Japan should continue to address the high cost of the port operations structure within its Asia Gateway Strategy Council.
- Rules and regulations that prevent container lines from offering intermodal-through-transportation in Japan should be reviewed and brought in line with international standards.

■ Digitalisation

Yearly status report: new issue. With ever increased traffic, of not only physical goods, but also of accompanying documents, logistics companies are under increasing strains. While the core of the problem does not lie with a regulation or a standard, but rather with the behaviour of the stakeholders, the Japanese Government should support and promote a digitalisation of the sector. Currently, there are still many situations where orders are made either over fax or over phone or where documents are delivered physically. With an improved digitalisation, not only will logistics cost go down, but times from order to delivery will do the same. Many neighbouring countries are far ahead of Japan in this area. Needless to say digitalisation will also help cope with the labour shortage.

Recommendation:

- The Japanese Government together with the various applicable sector organisations should work to enhance digitalisation within the logistics sector. This would improve the competitive advantage of the Japanese market.

Health Science

IVD (In Vitro Diagnostics)
Medical equipment
Pharmaceuticals
Vaccines
Cosmetics & quasi-drugs

Mr. Shuichi Hayashi

Vice-Chair, Medical Equipment & Diagnostics Committee

(Industry Affairs Advisor, Roche Diagnostics K.K.)

c/o Roche Diagnostics K.K.

Shinagawa Season Terrace, 1-2-70, Konan, Minato-ku,

Tokyo, 108-0075

Phone 03-6634-1111

Fax 03-5479-0532

IVD (IN VITRO DIAGNOSTICS)

Introduction

Healthcare in Japan is suffering as the social security system comes under increasing pressure from the effects of an ageing society, declining birth rate, and rising national healthcare costs. It is clear the Japanese Government needs to reform the way the healthcare system operates while also re-evaluating its purpose. The EBC considers serious discussions on the value and role of clinical examinations (specimen examinations), which already play a significant part in medical practice, are crucial to achieving the Government's objectives of "improvement of the quality of medical care" and "optimisation of medical costs". It is imperative that healthcare in Japan continues not only to benefit from clinical examinations but also to realise their full potential in respect of improved diagnosis, treatment and prevention. This will only be possible through re-evaluation of their value and role by both medical care providers and medical system operators.

The medical reimbursement system for clinical examinations has been under discussion since 2007 between the Japanese Promotion Council for Laboratory Testing (JPCLT), *in vitro* diagnostic (IVD) industry associations, and the Ministry of Health, Labour and Welfare (MHLW). Since then, the results of an investigation into current problems and issues as well as possible future directions have been announced, opinions have been exchanged and proposals and recommendations have been made both at "study sessions on medical diagnostics" and at "periodical meetings on the medical reimbursement system". The EBC applauds the fact that the Government has already recognised what is referred to in periodical medical reimbursement price revisions as the need for "quality enhancement of clinical diagnostics and faster examination" and that this led to a continuous rise in IVD fees between 2008 and 2016. Furthermore, the medical reimbursement revision of 2016 introduced "Global Standard Examination Management Additions". Whether or not a facility qualifies for these additions depends on its ability to demonstrate "approved technological competence based on global standards" and on the quality of its examinations. This too has had a positive effect on the medical diagnostics sector.

Cooperation between the medical diagnostics industry and the pharmaceutical industry, and consultations with the Government are progressing on the increasingly important topics of personalised healthcare and companion diagnostics. The final objective is the introduction of relevant approval processes and the establishment of an insurance reimbursement system linked to drugs. The clinical application of advanced technologies, such as next-generation sequencing, is rapidly advancing. A system to evaluate the accuracy and quality of the tests made available through these technologies is required. Against this background, it is essential that the current medical system is streamlined and reformed so that personalised treatment can be expanded, the quality of medical diagnostics and medical care can be maintained and improved, and clinical diagnostics can continue to play their value-added role. Other major improvements needed to enhance the quality of medicine and deliver the latest medical care to patients include providing prompt access to new IVD tests and setting Health Insurance Points (HIP) based on their latest clinical value.

The EBC Medical Equipment & Diagnostics Committee and its IVD Sub-committee continue to advocate the value of clinical diagnostics in cooperation with the JPCLT and other IVD industry groups. We are also continuously ready to work with the MHLW and the PMDA (Pharmaceuticals and Medical Devices Agency).

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Philips Japan
Radiometer
Roche Diagnostics
Siemens Healthcare
Smith & Nephew
Teijin Pharma
Thermo Fisher Diagnostics
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Key Issues and Recommendations

■ Approval examination and safety measures

Yearly status report: progress. The EBC, jointly with the Japan Association of Clinical Reagents Industries (JACRI) and the IVD Committee of the American Medical Devices and Diagnostics Manufacturers' Association (AMDD), presented the following recommendations in a periodical opinion exchange meeting (6 Aug. 2018) with the MHLW's Pharmaceutical Safety and Environmental Health Bureau and the PMDA, to discuss the approval examination and safety measures.

Recommendations:

- The definition of IVDs needs to be re-defined in order to take in consideration diagnostics pharmaceuticals and Therapeutic Drug Monitoring which are used in the selection of a remedy or in treatment policies such as dose adjustment.
- Request for revision of the qualification requirements of the business condition administrator of IVDs, not to be limited to pharmacists as at present, and to enhance governance, considering the completion of specialized courses or practical experience required to fulfill the responsibilities as administrator.
- Request for revision of the conditions so that QMS (Quality Management System) conformity research may be omitted. There has been discussion overseas regarding the omission of QMS research through the use of the MDSAP (Medical Device Single Audit Program) certificate, so from the same viewpoint, it is also requested that the omission of research on factories through more effective utilisation should be investigated.
- Japan should revise the requirement so to promote greater utilisation of digital media. While is allowed, it is unfortunately burdensome due to the applicable requirements.
- Request for notification of the contents of the agreement and precise implementation in order to accelerate the approval process and improvement of operation.
- MHLW and PMDA should continue its efforts to resolve approval examination and safety measure issues.
- Japan should conform with EU'S In-Vitro Diagnostics Medical Device Regulation (IVDR) and the handling of the MDSAP.

■ Issues and recommendations concerning medical reimbursement of IVDs

Yearly status report: progress. The EBC has set up a joint medical policy committee with JACRI and the IVD Committee of AMDD and discussed methods of medical reimbursement. Furthermore, at the regular meeting (3 Sept. 2018) with the Economic Affairs Division of the Health Insurance Bureau of the MHLW, the EBC made recommendations and presented opinions regarding the following medical reimbursements.

Recommendations:

- Japan should include evaluation results in the deliberations of the insurance medical material special committee, as it is currently not explained how "innovation" of new innovative products is evaluated.
- In some items, IVDs approved as pharmaceuticals and LDT (Laboratory Developed Tests) coexist, so the EBC requests clarification in the future to give priority to IVDs and to sort out corresponding LDT.
- It has become necessary to select application destinations when listing new insurance, and the EBC requested that the selection of application destinations be done following an appropriate point standard, taking into account not only similarities in the measurement principles but also clinical positioning.
- It is necessary to enhance home healthcare and strengthen the function of family doctors in order to construct community-based integrated care, and the EBC requests that a system be created under which this examination that requires labour and high cost would be implemented appropriately when necessary.
- In the 2018 medical reimbursement price revision, an "Antimicrobial Stewardship addition" was established, however, the implementation requirements are not clear, and each facility interprets and implements this in their own way. The EBC requests that the implementation of the examination mentioned in the guidance be added to the requirements.
- Preventive medicine and pre-emptive medicine are in a category outside the medical reimbursement system. However, it is a problem that risk diagnosis using genes is becoming widely used without regulations. The EBC requests that discussions be started on how to promote the usage of specimen examination in this category appropriately.

Mr. Hideaki Mori

Chair, Medical Equipment & Diagnostics Committee

(President & CEO, Siemens Healthcare K.K.)

c/o Siemens Healthcare K.K.

Gate City Osaki West Tower,

1-11-1 Osaki, Shinagawa-ku, Tokyo 141-8644

Phone 03-3493-7500

Fax 03-3493-7654

MEDICAL EQUIPMENT

Introduction

The national cost of medical care for Japan in the 2016/17 fiscal year was 41.3 trillion yen, down 0.4% from the previous year. The slight fall is regarded as temporary and due to a significant decrease in anti-viral drug charges, including for hepatitis C drug treatments. In many other respects, the main challenges remain as before, including changes to the overall disease profile driven by the ageing of the population and a rise in chronic conditions, and the promotion of medical innovation in parallel with controls on medical costs. However, healthcare delivery is becoming extremely complex, because of labour shortages stemming from the decreasing birth rate and ageing population, shortages of specialists in ICU (Intensive Care Unit) pathology, and the decline in business or business failure of a significant number of hospitals and clinics.

In order to improve the situation, it is important to move from a primary focus on the treatment of disease to a more holistic approach aimed at health maintenance and disease prevention; to utilise medical information and improve the efficiency of medical services in parallel, and to promote healthcare reform and technical innovation. Medical costs should be reduced by a combination of detecting abnormalities at an early stage through health monitoring, delivering accurate and specific diagnoses, sharing diagnostic results among healthcare institutions, and realising timely and efficient medical services, as well as by deploying and disseminating these improvements throughout the healthcare system. These actions will, in turn, reduce the burden on patients and increase the health of the general population and labour force, thereby contributing to social and economic growth.

Innovative European medical equipment, materials and services can help Japan to meet its healthcare challenges. In particular, effective accident and emergency care, telemedicine and nursing care using IT medical technology, should be introduced as soon as possible. Furthermore, digitalisation of efficient medical data should be provided using IoT and AI equipped medical devices with appropriate measures for cyber security and GDPR (General Data Protection Regulation) as implemented in Europe. To do this, Japan should align its regulations and processes with international standards, allow use of European approvals and data, and improve the predictability of the reimbursement system. Moreover, information on the Japanese medical care system should be provided internationally in multiple languages to encourage more overseas businesses to participate in the Japanese market. Japan should continue to introduce measures to improve the Foreign Direct Investment (FDI) environment as this has proved to be a real driver for investments in the domestic market.

The EBC Medical Equipment & Diagnostics Committee intends to continue working in cooperation with the Japanese Government, especially the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) and other associated industrial organisations, and will present recommendations in order to help reform the Japanese medical system and industrial structure. The aim will be the deployment in Japan of not only excellent medical equipment but also advanced healthcare models and effective medical systems, where we believe Europe has much to offer.

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Philips Japan
Radiometer
Roche Diagnostics
Siemens Healthcare
Smith & Nephew
Teijin Pharma
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Key Issues and Recommendations

■ Revision of insurance coverage and functional classification of insurance medical material

Yearly status report: slight progress. In the 2018 medical reimbursement price revision, the insurance coverage classification was revised and B3 for re-evaluation of innovation was established. As a result of revision of the functional classification of insurance coverage material, six classifications were added. A regulation for exceptional rules still remains an issue.

Recommendations:

- Japan should appropriately handle the price research associated with the consumption tax hike.
- Appropriate reimbursement for innovative technologies through more detailed functional classifications.
- Improvement of the insurance reimbursement price system based on the product characteristics.

■ Deployment of Japanese-version HTA for medical equipment

Yearly status report: some progress. The cost effectiveness evaluation targeting five equipment items started in April 2016 as a trial. The detailed method of incorporating results is currently under deliberation with the Central Social Insurance Medical Council (CSIMC).

Recommendation:

- HTA should be deployed carefully taking into account the inappropriateness of application of QALY (quality adjusted life year), uncertainty as to the results depending on the skill of examiners or data, and the short improvement cycle of medical equipment.

■ Streamlining the foundation of medical technology using ICT

Yearly status report: ongoing. Laws concerning the use of big data including the next-generation health infrastructure law are being developed and institutionalisation of online diagnosis is also being promoted. On the other hand, migration to the cloud by medical organisations is slow.

Recommendation:

- MHLW should promote and support the use of cloud services by medical organisations.

■ Mutual recognition and global standards for clinical evaluation

Yearly status report: some progress. Japanese authorities encourage the usage of the prior consultation service of the PMDA in order to promote the use of overseas clinical evaluation results when applying for equipment.

Recommendation:

- The EBC request that the Japanese authorities continue the very successful work of promoting the use of overseas data.

■ QMS mutual recognition and global standards

Yearly status report: some progress. Some progress was shown in conformity with the global standards. Formal participation in the MDSAP assists further development of discussions for conformity with the global standards.

Recommendations:

- Japan should dispatch information through a formal QMS ministerial ordinance in English for conformity with the QMS global standards.
- Japan should eliminate the differences in requirements of the OMS ministerial ordinance, and conform with the global standards for the product group classification.

■ Mutual recognition and global standards of medical equipment license

Yearly status report: some progress. The approval examination period of the PMDA was shortened by enforcement of the Japanese PMDA law and performance was improved.

Recommendation:

- Japan should recognise EU approvals for Class 2 products as equivalent to Japanese approval.

PHARMACEUTICALS

Introduction

Although overall healthcare costs in Japan are rising as the population ages, and use of innovative pharmaceuticals is growing significantly, total pharmaceutical spending has been well under control.

Japan's healthcare spending in fiscal year 2017 increased by 2.3% (0.9 trillion yen) to 42.2 trillion yen. The amount spent on dispensing fees also increased by 3.1%. The 10-year market simulation study conducted by EFPIA Japan indicates that the Japanese pharmaceutical market will shrink at an annual rate of 1.5% from 2017. In spite of strong increases in total medical expenditures driven by an ageing population and the progress of medical technology, the current pricing system and measures such as greater generic use are proving sufficient to control the drugs bill.

The Price Maintenance Premium (PMP) system was launched in 2010 to shrink the “drug lag” and to promote the development of new drugs in Japan. Since the launch of the system, the PMP has successfully achieved this. However, this drastic pricing system reform in April 2018 also brought the devaluation for innovation with the narrower scope of PMP products as well as unpredictable PMP company criteria. Any significant reduction in the PMP eligibility would reverse the substantial progress already made.

Drug price revisions should continue to be conducted in two-year cycles, linked to the revision of medical service fees. Even if price revisions in “off” years are to be conducted from 2021, the scope of drugs for the revision should be limited to a small number of products with large discount rates from the list price to minimize disruption to the market. Because the total drug budget is already well controlled under the current drug pricing system excessive cost-containment measures on drug cost will not be sustainable and could lead to sharp negative growth in the pharmaceutical market. This would conflict with Government's policy of pharmaceuticals as a strategic growth industry and reduce the incentive to invest in Japan from overseas.

Price revision will be executed for three consecutive years from 2018 and will result in a negative impact to the industry within a very short timeframe. Additionally, this will cause huge burden to healthcare providers, wholesalers and pharmaceutical companies. EFPIA has strong concerns that discussions will be directed towards a full scale price revision in the “off” years from 2021 onward, based on a 3-year consecutive full scale revision. The price revision in 2019 should be positioned as an exceptional price revision in conjunction with the consumption tax hike.

For the first 12 months after a drug is launched it can only be prescribed for a maximum of 14 days, after which a further prescription is required. As a result, many physicians have limited use of the new products for a year after price listed. Given that Japan has robust safety measures, including the Risk Management Plan (since 2013), this 14-day rule for new drugs is outdated, preventing patients from accessing the treatments they need. The Government's own Council for Regulatory Reform recommended the revision or elimination of this rule, and EFPIA supports their position.

Japan introduced a form of CEA/HTA (Cost-Effectiveness Analysis/Health Technology Assessment) from April 2016 on a trial basis. Full-scale implementation is postponed to April 2019. Unfortunately, the European experience shows that CEA/HTA can become a barrier preventing patient access to medicines and be a major administrative burden for academia, government and industry. Japan has sufficient measures to control drug expenditures, so CEA/HTA should not be allowed to become cost-containment measure. EFPIA believes that Japan should take into account the experience gained in the trial study and Europe when designing and implementing CEA/HTA.

Japanese Good Clinical Practice (GCP) in clinical trials is now steadily aligning with global standards, although action is still needed to reduce differences between Japanese medical institutions in the efficiency of the clinical trials they conduct. Japan introduced expanded clinical trials for compassionate use, the *Sakigake* designation system, and optimal use promotion guidelines, and a conditional early approval system. The impact of these measures on patient access needs to be further reviewed and the initiative may need to be considered. The scope of Mutual Recognition Agreement was extended to include the product such as active pharmaceutical ingredients, sterile formulation, and biological medicines in July 2018. The full implementation should be ensured.

EFPIA Japan Member Companies

Actelion Pharmaceuticals Japan	Janssen Pharmaceutical
AstraZeneca	LEO Pharma
Bayer Yakuhin	Lundbeck Japan
Bracco-Eisai	Merck Serono
Chugai Pharmaceutical	Mylan EPD
CSL Behring	Nihon Servier
Ferring Pharmaceuticals	Nippon Boehringer Ingelheim
Galderma	Novartis Pharma
GE Healthcare Japan	Novo Nordisk Pharma
GlaxoSmithKline	Sanofi
Guerbet Japan	Shire Japan
Ipsen Pharma Japan	UCB Japan

Key Issues and Recommendations

■ Drug pricing system

Yearly status report: negative progress and new issue. The price maintenance premium (PMP) introduced in 2010 was drastically revised with a negative outcome with drug pricing system reform in 2018. The target scope of PMP was substantially narrowed in addition to the introduction of company criteria leading to a broken down the price maintenance schema. In addition, discussion on the “off” years price revision has progressed similar to an annual price revision. The more severe pricing environment for innovative drugs is reducing the attractiveness of the Japanese market.

Recommendations:

- The PMP, which provides appropriate reward for innovative new medicines, should be continued without any reduction in the level of support for innovative products. Innovation should be appropriately rewarded.
- In terms of “off” years price revision, annual price revision based on the survey of actual market prices should not be concluded by the actual situation of three year’s continuous price revision from 2018-2020.
- Generic erosion has been drastically increased and a new target of 80% has been set for the near future. This means that there is huge saving money and these savings should be allocated for the rewarding of innovative drugs.

■ Cost-Effectiveness Analysis / Health Technology Assessment (HTA)

Yearly status report: minimum progress. There is significant room to improve to implement the full-scale implementation of this system.

Recommendations:

- Any approach based largely or entirely on cost per QALY (quality-adjusted life year) thresholds risks inappropriate appraisal of drug value. Thus, additional factors should be adequately incorporated in the appraisal.
- The number of products assessed should be limited as Japan does not yet have a well-established HTA capability and at present is unable to assess a large number of products.
- HTA should not restrict or delay patients’ access to new drugs.

■ International harmonisation (clinical trial environment)

Yearly status report: some progress. There is scope to improve the efficiency of clinical trials in Japan.

Recommendations:

- Japan should carry out specific actions to further enhance efficiency in clinical trials, in accordance with the Government’s initiatives 2011 and 2012 “Report concerning Enhancement of Efficiency in Clinical Trials” and the “Action Plan for the Five-Year Program toward the Revitalization of Clinical Studies and Trials”.
- Japan should enhance efficiency of drug development further with taking advantage of the new guidelines on multi-regional clinical trials (ICH E17, GENERAL PRINCIPLES FOR PLANNING AND DESIGN OF MULTI-REGIONAL CLINICAL TRIALS) reached Step 5 and was published in June.

■ New systems related to new drug review and approval

Yearly status report: some progress and new issues. There are limitations to the improvement in patient access that can be achieved by drugs under development through clinical studies sponsored under GCP.

Recommendations:

- Expanded clinical trials: Alternative compassionate use systems should also be considered.
- “Sakigake” designation system: Japan should make the system permanent and provide adequate resources to relevant organisations beyond the current pilot introduction.
- Optimal use promotion guidelines and conditional early approval system: These should be carefully reviewed and improved in order to enhance patient access to new drugs. To facilitate the success of them, incentives to drug developers need to be considered.
- General principle on planning/designing of ICH-E17: The actual implementation of clinical studies based in the new principle should be facilitated to improve the drug development in Japan.

Dr.Jun Honda

Chair, Vaccine Sub-committee, Biologics Committee, EFPIA Japan

(Senior Expert, GlaxoSmithKline K.K.)

c/o GlaxoSmithKline K.K.

1-8-1 Akasaka, Minato-ku, Tokyo 107-0052

Phone 03-4231-5000

Fax 03-4231-5977

VACCINES

Introduction

Access to vaccines in Japan started to improve rapidly from 2008 onwards, following the sequential introduction of several new vaccines. Before then, Japan had suffered from a significant vaccine gap. By October 2016, many vaccines had been designated an integral part of “routine immunisation”, and they are, therefore, included in the suite of vaccines strongly recommended, as well as funded, by the government. The rotavirus and mumps vaccines are the only remaining WHO (World Health Organization)-recommended vaccines excluded from Japan’s routine immunisation programme. The only other gap remaining derives from shortcomings in the development of combination vaccines, which would alleviate the congested immunisation schedule for infants. For example, the combined MMR vaccine (mumps, measles and rubella), and the 5- or 6-in-1 combination vaccine (where hepatitis B and/or Hib vaccines are added to the 4-in-1 DTaP-IPV-diphtheria, tetanus, pertussis and inactivated polio) are still not available in Japan.

Concerning the inclusion of mumps vaccine into routine immunisation, the Expert Council on Promotion of Vaccination, comprising 17 academic societies, sent a petition to Ministry of Health, Labour and Welfare (MHLW) in May 2018, mentioning that during 2015 and 2016, there were at least 348 patients who suffer from mumps deafness which is one of the complications of mumps infection. Coincidentally, the popular NHK morning drama, which aired in the first half of FY2018, had a main character that suffered from this complication. Furthermore, there was a nationwide outbreak of measles originated from a tourist from Taiwan in March 2018. Considering the recent increase of inbound tourists to Japan, recurrence would be consequential, with mumps having an endemic cycle of 5- to 6-year intervals. Japan would be putting the health of the people, including visitors from abroad, who continues to increase (28.7 million in 2017), at risk if the Tokyo Olympic Games are held without taking any action. Japan experiences vaccine supply issues all the time, due to a mix of sporadic endemics, manufacturing issues and natural disasters. A recent example of this is the supply issue of flu vaccines in the 2017/18 season. As part of crisis management, adding vaccines into routine immunisation and improving vaccine supply issues need to be addressed urgently.

The process for recommending vaccines into the routine immunisation programme is not clear, and the outcome can be difficult to predict, thus increasing the risk for manufacturers considering the development of vaccines in Japan. This has been a problem and was mentioned in this report last year. Uncertainty is further increased by the decision first made in June 2013, and still in force as of September 2018, that active recommendation for human papillomavirus vaccination be suspended, even though a causal relationship between the various symptoms reported and the vaccination has not been medically and scientifically proven. This in addition to reconfirmation by various reports such as Cochrane review on efficacy and safety of these vaccines. Again, we have not seen any changes in this area since last year. If companies are to develop vaccines smoothly in Japan, an infrastructure must be created that will allow the regulatory authorities to make decisions and implement policies based on scientific judgements. Women in Japan should not be deprived of the opportunity to prevent cervical cancer, and the current situation should be promptly rectified.

Another issue is in the regulation (conditions for review and development) upon introduction and development of vaccines, which has always been the case for import vaccines, and prompt improvement is needed. Specifically, the need for compliance with domestic requirements such as Minimum Requirements for Biological Products and Requirements for Biological Ingredients. There are cases where compliance with the same requirements as the domestic vaccines is requested, regardless of its influence on vaccine efficacy or safety. This makes introduction of vaccines impossible despite their needs.

That being said, the perception on these issues by regulatory authorities are changing, and considerations are being made to establish a forum for periodic discussion on these issues with four vaccine related industry groups including EFPIA. EFPIA will continue to make proposals to various stakeholders including the utilisation of this forum in order to promote progress in revision of the vaccination system and vaccine policy in Japan.

Actelion Pharmaceuticals Japan	Janssen Pharmaceutical
AstraZeneca	LEO Pharma
Bayer Yakuhin	Lundbeck Japan
Bracco-Eisai	Merck Serono
Chugai Pharmaceutical	Mylan EPD
CSL Behring	Nihon Servier
Ferring Pharmaceuticals	Nippon Boehringer Ingelheim
Galderma	Novartis Pharma
GE Healthcare Japan	Novo Nordisk Pharma
GlaxoSmithKline	Sanofi
Guerbet Japan	Shire Japan
Ipsen Pharma Japan	UCB Japan

Key Issues and Recommendations

■ Incorporation of WHO-recommended vaccines into routine immunisation and promotion of development of combination vaccines

Yearly status report: no progress. As from October 2016, hepatitis B vaccine is included in Japan's routine immunisation programme, and the Vaccination and Vaccine Subcommittee of the Health Science Council is considering the recommendation that the remaining rotavirus and mumps vaccines be included, but with no progress. They have also proposed that the early development of combination vaccines should be treated as an issue of high priority.

Recommendation:

- The remaining approved and WHO-recommended rotavirus and mumps vaccines should be included in routine immunisation without further delay. In addition, combination vaccines that are not available in Japan should be promptly introduced and/or developed.

■ Securing a stable supply of vaccines

Yearly status report: no progress. Concerns have arisen that Japanese public health could be adversely impacted by issues such as problems with manufacturing processes or the occurrence of natural disasters that lead to an unstable supply of vaccines. In fact, the 2017/18 season saw supply issues in flu vaccines. For important vaccines like those in the routine immunisation programme, diversifying supply sources to multiple manufacturers, both domestic and global, would allow a stable vaccine supply in Japan. Also, long-term supply purchase agreements and stockpiling should be considered.

Recommendations:

- Diversify vaccine suppliers to multiple domestic and global manufacturers, securing stable supply routes.
- Investigate long-term supply purchase agreements and stockpiling by the government.

■ Elimination of the “structural vaccine gap”

Yearly status report: some progress. It is difficult to predict whether the regulatory authorities will recommend that a particular vaccine be part of the routine immunisation programme or not, and companies are hesitant to develop vaccines in Japan because of this uncertainty. As a result, there is a risk that the vaccine gap in the product portfolio may re-emerge. EFPIA invited an expert from the German Standing Committee on Vaccination (STIKO) and provided some insights at MHLW's Health Science Council in May 2017. As a result, it was decided at the Council in June 2018, citing the document EFPIA provided, that “We [the Council] will continue discussions by hearing more from the vaccine industry groups and to take into account the measures taken overseas”.

Recommendation:

- The routine immunisation process should continue to be streamlined and an environment created where clear policy decisions can be made based on sound medical and scientific evidence.

■ Promotion of international harmonisation of regulatory requirements including Mutual Recognition Agreement (MRA) and Minimum Requirements for Biological Products (MRBP)

Yearly status report: progress. The number of EU Member States covered by the EU-Japan MRA on GMP (Good Manufacturing Practise) was expanded in April 2016, and vaccines have come into scope in July 2018, which is considered a major progress. However, a great deal of time and effort is still needed to introduce and supply vaccines due to pharmaceutical regulations such as the lack of clarity in MRBP related to the timing of reviews, revision procedures, and criteria for listing. Also, even if the MRA is fully in effect, national testing remains, thus it can still take more than 6 months before a vaccine is released to the market after importation.

Recommendation:

- The current MRBP should be abolished and its contents consolidated and integrated into the Japanese Pharmacopoeia.

Dr. Nobuyuki Hagiwara

Chair, Cosmetics & Quasi-Drugs Committee
(Head, Regulatory Affairs, Johnson & Johnson K.K.
Consumer Company)
c/o Johnson & Johnson Family of Companies
First Chiyoda Bldg. 15F, 3-5-2 Nishi-Kanda
Chiyoda-ku, Tokyo 101-0065
Phone 03-4411-6118; Fax 03-4411-7149

COSMETICS & QUASI-DRUGS

Introduction

The European Cosmetic and Quasi-Drugs sector works to ensure the quality, efficacy, safety, and environmental sustainability of its products by investing in the research and development of new ingredients, monitoring global developments in science, providing information to consumers, and meeting or exceeding strict post-marketing surveillance and control requirements in accordance with Good Vigilance Practice (GVP) and Good Quality Practice (GQP). The sector produces a wide variety of innovative and safe cosmetic and quasi-drug products that contribute to consumers' quality of life, for example by helping them stay clean and healthy, protecting them against the damaging effects of extreme weather, preventing dental cavities, and enhancing their appearance. These outcomes fit well with the efforts being made by the Japanese Government to promote self-care and, where appropriate, self-medication, so that people in Japan can enjoy the best possible health and avoid placing unnecessary strain on the national healthcare budget. Many cosmetic and quasi-drug products can assist in these efforts.

Shipments of cosmetics in Japan were worth a total of 1,629 billion yen in 2017. In the same year, Japan imported cosmetics valued at about 267 billion yen, of which some 98 billion yen came from Europe, indicating that European cosmetic and quasi-drug products are popular with Japanese consumers as they account for a considerable share of imports. The import process was made easier in 2016, when the Ministry of Health, Labour and Welfare (MHLW) abolished import notifications and eased the rules relating to Partial Change Approval for prescription drugs. It is now possible for the applicant to decide the timing of a product change. The EBC applauds Ministry of Health, Labour and Welfare for these actions.

However, European companies still face challenges in bringing cosmetic and quasi-drug products to Japanese consumers in an efficient manner, due to Japan's lack of regulatory transparency, the low degree of harmonisation between its product standards and those used in other parts of the world, and its unnecessarily complex approval and manufacturing requirements. As a result, the launch of many European cosmetic products in Japan is severely delayed, even when the same products are already in global use and have clinically proven efficacy. Some quasi-drugs even need to be reformulated because their global version uses new active ingredients or excipients for which obtaining approval is too time-consuming or difficult in Japan. European and Japan also maintain different rules governing which ingredients are allowed in cosmetics. Even if an ingredient does not require regulatory approval in Japan when used in a cosmetic, the use of the same active ingredient in a quasi-drug often requires a lengthy approval process. It is therefore considered to be difficult to deploy into the Japanese market promptly. Hence there is no choice but to change the ingredients in some cases. Furthermore, disclosure of information on effective ingredients and additives in quasi-drugs that are already approved in Japan is extremely limited, which is one of the reasons why such quasi-drugs require a long time to be introduced onto the market.

Parallel imports currently account for a substantial portion of the Japanese luxury cosmetics market. Some studies indicate that 11% of the units sold are parallel imports. Most are sold online via e-commerce portals. As these imports were not produced for the Japanese market, there is a risk that they are either not approved for Japan or do not have the proper labelling. There is also a risk that the imports may be expired products or products that have not been transported or stored properly and so could cause harm to consumers. The EBC calls on the Japanese authorities to make certain that all cosmetics sellers are subject to the same high standards when it comes to consumer products, with a particular focus on formula registration, laboratory facilities, and labelling.

The EBC believes that Europe and Japan have an opportunity to lead the way in the global cosmetics and quasi-drugs market, by bilaterally negotiating faster registration of quasi-drugs, expanding efficacy claims, and harmonising ingredients that are allowed for cosmetics and quasi-drugs. In addition, the EBC would welcome greater leadership by European and Japan in the International Cooperation on Cosmetic Regulation, which meets to discuss how to promote multilateral regulatory coordination and harmonisation to minimise barriers to trade, while maintaining the highest level of global consumer protection.

Key Issues and Recommendations

■ Reform of the quasi-drug approval system

Yearly status report: slight progress. The Director of the MHLW's Evaluation and Licensing Division issued a "Notification concerning approval and review of medicated soap" in March 2018 to specify the review guideline for medicated soap. Additionally, the PMDA holds an explanatory meeting every year for staff in charge with regard to points to be noted when creating application forms and the review policy. While such actions will lead to improvement in the quasi-drugs review system, it is not guaranteed that this would shorten the review period. Furthermore, the review is conducted based on material from the explanatory meeting for staff in charge, however, the positioning of such material is not clearly indicated. For instance, a new item is approved because it is identical to an already approved quasi-drug only when the precedent of approval has been presented, however, this is not mentioned at all in the notification, etc. issued by the MHLW.

Recommendations:

- MHLW should shorten the review period for quasi-drugs for which review guidelines have been created and which are believed to be identical to already-approved quasi-drugs.
- When submitting an application related to a quasi-drug that uses ingredients of the same standard as those contained in quasi-drugs already approved, re-examination of the pertinent contents mentioned in the separate sheet standard should be omitted in order to improve efficiency and shorten the review.
- When ideas concerning the review change, this should not only be announced at the explanatory meeting for PMDA staff in charge but also be announced by issuing a notification or clerical communication after gaining understanding from the applicants through the collection of opinions, etc. using public comments in advance.

■ Harmonisation of quasi-drug and cosmetic ingredients

Yearly status report: progress. The EU and Japan maintain different rules governing the type and quantity of ingredients allowed in cosmetics and quasi-drugs. The effectiveness of fluoride in preventing tooth decay has been scientifically verified: it is important for the health of the mouth and the entire body and is therefore key to self-care. Japan used to permit a maximum of 1,000 ppm of fluoride in toothpaste sold as a quasi-drug as an approval standard, while concentrations of fluoride of up to 1,500 ppm are allowed in Europe. In March 2017, MHLW approved the sale of products containing a maximum of 1,500 ppm fluoride, in line with the international standard (ISO) used in other countries.

Mouthwash with fluoride concentrations of 226 ppm is sold at drugstores and supermarkets throughout Europe and the United States. However, Japan approved the use of fluoride in mouthwash for general consumption in 2015 as a drug requiring guidance, and at last it has just been included as a general drug (category-1 OTC drug) this year. The EBC notes that the Japan Society for Oral Health suggested at an academic meeting in February 2017 that the environment should be improved for older people's oral care, including through deregulation, so that drug products containing fluoride can be developed and used more effectively.

Recommendation:

- MHLW should revise the medicated dentifrice approval standard in line with international norms, raising the upper limit of fluoride concentration allowed in medicated toothpaste (a quasi-drug) and allowing the use of fluoride in mouthwash (another quasi-drug) without restrictions.

■ Expansion of advertising representation for cosmetics and quasi-drugs

Yearly status report: no progress. Fifty-five efficacy claims were defined as permissible for cosmetics in Japan in 2000. In 2011, a further efficacy claim of "making fine wrinkles due to dryness less noticeable" was added to the list. Yet the scope of efficacy claims approved in Japan is still narrower than in Europe, which hinders foreign-made cosmetics based on the latest research and technology from entering the Japanese market. Sector associations are currently studying the efficacy claim of "prevention of ultraviolet ray-derived photo-ageing" which may lead to a further expansion. However, current advertising regulations still do not permit claims relating to the significance of daily care using cosmetics or quasi-drugs such as moisturising creams for atopic

skin or sunscreen products to prevent skin cancer, despite the fact that this plays an important role in maintaining health and preventing illness.

Recommendation:

- Advertising claims connected to the maintenance of health and prevention of illness should be deregulated so that the significance of daily care using cosmetics and quasi-drugs can be claimed.

■ Online notifications and applications for approval of cosmetics and quasi-drugs

Yearly status report: no progress. The Government enacted the “Basic Act on the Advancement of Public and Private Sector Data Utilization” in December 2016, which stipulates the use of necessary measures for determining online usage for administrative procedures in principle. However, with regard to cosmetics and quasi-drugs, notification and application should be made using floppy discs or in paper form excluding the export report for which NACCS (Nippon Automated Cargo and Port Consolidated System) can be used, so the procedure remains unchanged compared with other countries. Furthermore, the prefectural authorities, the PMDA and Customs are not linked, so separate procedures are required for notification and application concerning the manufacturing and sales of cosmetics and quasi-drugs, and presentation of the necessary material for import customs clearance. The MHLW included the promotion of online application and notification procedures as a new item in the budget request for 2019, so it is expected that application and notification procedures will become completely online.

Recommendation:

- An online notification and application system should be established for submitting Notifications on the Manufacture and Sale of Cosmetics and Applications for Approval of Quasi-Drugs. This system should be linked to the Customs clearance system to provide a one-stop service for application procedures.

■ Applying the same standards to all market participants

Yearly status report: new issue. Ensuring safety is crucial, both from a legal and, more importantly, from a consumer perspective. Manufacturers and importers of cosmetics and quasi-drugs are therefore required to spend considerable resources implementing post-marketing surveillance and control schemes to monitor safety and quality. However, parallel importers do not always comply with these requirements, sometimes illegally using registered trademarks, importing versions of products that are not approved in Japan, and selling products with damaged or missing labels or that have passed their expiry dates.

Recommendations:

- Japan should ensure that everyone involved in the sale of cosmetics and/or quasi-drugs complies with the same legal requirements related to safety and quality.
- The authorities should support an industry-led campaign to educate consumers so that they have a better understanding of products sold by authorised suppliers and those that are not.

■ Establishment of alternatives to animal testing

Yearly status report: progress. MHLW issued a new guidance in January 2018 concerning the evaluation system in which multiple in vitro alternatives are combined. This opened up the possibility to use an alternative skin sensitisation test without the need for animal testing. However, when submitting an application related to quasi-drugs containing new ingredients in Japan it is required to submit the results of animal testing as a hazard evaluation for ingredients. The ban on animal experiments and shift to alternative testing that started in Europe is spreading throughout the world, and so ideas regarding safety evaluation need to change significantly.

Recommendation:

- Japan should proactively promote the development of alternatives that use no animals so that these alternatives can be used in applications related to quasi-drugs. Japan should also establish a risk evaluation method for the final products without depending on safety data based on animal experiments.

Consumer Goods

Liquor
Food & agriculture

Mr. Bruno Yvon

Chair, Liquor Committee

(President, MHD Moët Hennessy Diageo K.K.)

c/o MHD Moët Hennessy Diageo K.K.

13F Jimbocho Mitsui Bldg.

1-105 Kandajimbocho, Chiyoda-ku, Tokyo101-0051

Phone 03-5217-9723

Fax 03-5217-9751

LIQUOR

Introduction

Europe is the leading exporter of liquor and wine worldwide. The Japanese liquor market is one of the largest in the world with estimated annual sales of 4 trillion yen and growing consumption in several categories. Despite such figures, in terms of value, foreign liquor imports in 2017, at 286.4 billion yen (according to Japan Customs), accounted for a mere 7% of the total Japanese liquor market, including beer and beer-like products.

The EBC welcomes the EU-Japan EPA agreement in principle, and looks forward to its smooth implementation. Of particular interest is the complete removal of tariffs on wine (15% or 125 yen/litre whichever is lower) and sparkling wine (182 yen/litre) at the entry into force of the EPA. While no specific information has been officially released regarding white spirits, the EBC assumes that the tariff on white spirits of EU origin will be permanently removed. The agreed mutual protection of geographical indications (GIs) will ensure the protection of 139 liquor GIs from the EU. Significant additives to wine were approved by both Japan and the EU (25 items by Japan and 28 items by the EU), making it possible for Japan to import wines that use EU-approved additives. Separately, the Ministry of Health, Labor and Welfare (MHLW) surveyed possibly deleting existing additives out of the 365 existing food additives. The EBC liaised with SpiritsEUROPE's and Comité Européen des Entreprises Vins (CEEV) to urge MHLW to accept their requests on keeping the existing additives, and it was successfully achieved.

In Japan, the display of producer lot codes (traceability information) is not compulsory under the Food Sanitation Law, although it is recommended in the administrative guidelines of the Ministry of Health, Labour and Welfare (MHLW). By contrast, the EU makes it obligatory to display lot codes on food and beverage products as such codes fulfil an important role in any effective and efficient product recall or withdrawal process. Despite the fact that most importers of EU liquor products ensure that lot codes are in good order when the products are marketed and put into distribution in Japan, it is common practice for some opportunistic traders, prioritizing business profit over consumer safety, to import products with lot codes that have been erased, tampered with or covered up. The EBC encourages the Japanese Government to take more proactive measures to protect the safety of Japanese consumers since 2010. The EBC appreciates the notice issued by the National Tax Agency (NTA) in September 2014 and the new liquor sales management training textbook/DVD, which was produced by the NTA in April 2017 and includes these concerns. Furthermore, the EBC recognizes the notice issued by the Ministry of Economy, Trade and Industry (METI), MHLW, and the Ministry of Agriculture, Forestry and Fisheries (MAFF) in July 2017, stating their concern regarding the presence of liquor products with erased lot codes in the market. The EBC continues to urge the Japanese Government to take further proactive measures to ensure the display of product lot codes for traceability. Japan Wines and Spirits Importers' Associations (JWSIA) submitted the request letter including legal expert's opinion paper regarding the quality assurance role of production lot codes as an integral element of a brand's trademark on 23rd June 2018. The EBC supports JWSIA's action that the NTA will establish notice under article 86 of the Liquor Trade Association Act and introduce the legal regulations to eradicate the distribution of imported liquor without production lot codes.

A new liquor tax policy was formulated to reduce the tax on beer and to increase the taxes on *happoshu* and "new genre" beverages in three phases (in 2020, 2023, and 2026), ultimately making the tax rate for all these beverages a uniform 157 yen/litre. While this will eliminate the current complex tax system for beer, the EBC continues to urge Japan to work on lowering its high tax rates. The tax on wine will be raised in two phases (in 2020 and 2023), ultimately making it equal to the reduced tax rate for sake. Although taxes on spirits will not be subject to the upcoming tax hikes, they are quite high at 370 yen/litre for products with less than 37% ABV (Alcohol By Volume) plus an additional 10 yen/litre for each additional percentage of ABV. The EBC objects to the increase in the tax on wine and urges Japan to reduce taxes on spirits.

Key Issues and Recommendations

■ Decoded products

Yearly status report: slow progress. Original production lot codes fulfil an important role in any effective and efficient product recall or withdrawal process. However, the official notices 2014/2017 and liquor sales management training from 2017 have no binding force to prohibit the import and sales of any such products with lot codes that have been erased, tampered with or covered up. In June 2018, JWSIA submitted the request letter including Legal expert's opinion paper regarding the quality assurance role of production lot codes as an integral element of a brand's trademark. The EBC liquor committee support JWSIA's action.

Recommendation:

- The Government of Japan should issue legislation, reinforced by penalties, that forbids the wholesale or retail of liquor bottles whose lot codes have been erased, tampered with or covered up.

■ Tariff on wine and white spirits

Yearly status report: good progress. Tariffs on wine will be abolished at the entry into force of the EU-Japan EPA. The temporary zero tariff on white spirits, rum, gin, vodka and liqueurs should be made permanent.

Recommendations:

- The EBC urges Japan to completely remove all tariffs on wine as anticipated.
- The EBC urges Japan to change the tariff lines for white spirits to become permanently zero.

■ Liquor taxes

Yearly status report: no progress. Japan will reduce the tax on beer and increase the taxes on *happoshu* and “new genre” beverages in three phases (2020, 2023, and 2026), ultimately to 157 yen/litre. However, taxes on wine will be raised in two phases (2020 and 2023), making it equal to the reduced tax rate for sake, at 100 yen/litre. Taxes on spirits, not subject to the upcoming tax hikes, are high at 370 yen/litre if less than 37% ABV plus an additional 10 yen/litre for each additional percentage of ABV.

Recommendations:

- Japan should promptly revise its liquor tax system for beer in accordance with the 2017 tax reform.
- The EBC objects to the increase in the tax on wine and urges Japan to reduce taxes on spirits.

■ Additives

Yearly status report: progress. Wine additives were approved in the EPA negotiations, making it possible for Japan to import wines that use EU-approved additives. Separately MHLW surveyed possibly deleting existing additives out of the 365 existing food additives in 2018. However, kaolin, spice extracts, rice bran oil extract, powdered stevia, tannins (extracts), mastic gum, L-lysine and rutin (extract) are in the list.

Recommendations:

- Japan should swiftly approve additives that are in common use among other industrialized countries.
- The EBC urges to remain spittitsEUROPE's and CEEV's requests in the list.

■ Wine and whisky definition

Yearly status report: no progress. A loose wine definition opens the door for different products to be sold as “wine” misleading Japanese consumers and creating unfair competition for European wines, which meet the international accepted definition. The same is also true for whisky.

Recommendations:

- Japan should implement the wine definition in conformity with international specifications as used in the EU and the US and endorsed by the International Federation of Wines and Spirits.
- Japan should implement a stricter definition of “Japanese whisky”.

■ Geographical indications

Yearly status report: good progress. The mutual protection of GIs agreed upon through the EU-Japan EPA will ensure protection of geographical indications for 139 liquor products from the EU.

Recommendation:

- The EBC urges and looks forward to the smooth implementation of the EU-Japan EPA.

Mr. Olivier Convert

Chair, Food & Agriculture Committee
(Managing Director, Roquette Japan K.K.)
c/o Roquette Japan K.K.
2F. KDX Kasuga Bldg., 1-15-15 Nishikata
Bunkyo-ku, Tokyo 113-0024
Phone 03-3830-1510
Fax 03-3830-1525

FOOD & AGRICULTURE

Introduction

Despite their global presence, European food and agricultural products have had difficulty penetrating the Japanese market. Although they can be found in regular supermarkets, the selection available is, with a few exceptions, limited to only a fraction of the potential. The situation is better in upscale and gourmet specialist shops, where price matters less. However, there is no reason why imported European food should be either so expensive or exclusively upscale.

With the implementation and entry into force of the EU-Japan EPA just around the corner, the EBC have high hopes of a much improved market access for EU products. For this to happen though, not only tariffs will be removed or reduced in accordance with the agreement, but also the management regarding the TRQs (Tariff Rate Quota) need to be published so that both exporters and importers can make use of the system from day one. There is currently very little information on the how, the when and the where in this area. We believe that it is of utmost importance that this is done in a timely matter as well as in a transparent way. Only then can the Japanese consumers reap the full benefit of the EPA.

Apart from tariffs, various non-tariff food-related issues also impact the availability of European products in Japan. For example, Japan remains “out of sync” with other countries, in that it has still not approved the majority of food additives and enzymes declared safe by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO). Sanitary and phytosanitary issues are of course included in the EPA. It should, however, be stated that the agreement currently only includes very general wording on what benefits suppliers and importers can foresee. It is therefore important that the two authorities continue to work in this field to improve the current situation, where duplicate testing has to be done for imported goods due to lack of harmonisation or mutual recognition of approvals of test methods.

An example of an area that could benefit from harmonisation is for food contact materials. Japan is currently exploring the possibility of introducing a positive list system similar to what is in use in the EU and the US. This is something that the EBC support. It is furthermore important that Japan is studying the issue of the use of materials that are not in the list. Both the EU and the US have provisions for this.

A further issue is the new Labelling Act requirement for labels specifying the origin of all ingredients. Although this requirement is currently only applicable to domestically produced food, the EBC notes with dismay the imposition of yet another administrative burden as well as the huge cost of compliance, as the same ingredients (for example berries or sugar) can be sourced from multiple countries.

The EBC is very keen to work closely with all relevant parties in the Government of Japan and the European Commission to help bring about effective and positive change to support the goal of providing consumers in Japan with a much wider variety of safe, high-quality food. We very much hope that the EU-Japan EPA will ensure that tariffs are abolished, standards harmonised and the market authorisations of both regions mutually recognised. The EBC Food & Agriculture Committee firmly believes this can be achieved without compromising food safety. Furthermore, it will lead to more choice in supermarkets, stimulating healthy competition in the food and agricultural sectors of both zones, and to European food becoming more accessible, something we know Japanese consumers would appreciate.

Key Issues and Recommendations

■ Tariffs & quotas

Yearly status report: good progress. With the implementation of the EU-Japan EPA, and the removal or reduction of tariffs, EU products will have an improved market access. The EBC has big hopes that this will also translate to more European food products in the shopping bags of Japanese consumers. It is however important that these liberalisations are implemented without the use of stringent safeguard measures. Furthermore, the tariff quota system must be easy to use and information on how to use them must be made public early.

Recommendations:

- Japan should abolish its tariffs in accordance with the EPA without delay and refrain from the use of safeguard measures.
- The information regarding the new quotas for EU products shall be made public immediately so that these can be used when the agreement enters into force.
- It is of utmost importance that the quota management system is transparent, easy to use and that information on how to use it is released as soon as possible.

■ Food additives, enzymes and processing aids

Yearly status report: progress. Differences in the lists of additives and enzymes approved by Japan and other major markets are still common. While the EBC has seen progress in Japan's approval of additives, the approval process still remains an obstacle, and an overall lack of transparency. EU and Japan should use the EPA to further strengthen the work in this field.

Recommendations:

- Japan should harmonise its definition of food additives to exclude processing aids which as per its definition do not remain in the product after it has been produced. MHLW and the FSC should ensure that standards of use in Japan are not in conflict with international standards of use.
- The EU-Japan EPA should guarantee that food enzymes in wide use in the EU and accepted as safe by the FAO/WHO Joint Expert Committee on Food Additives will be approved for immediate use in Japan.
- MHLW should put the same focus on enzymes as it has on food additives and actively approve enzymes that are well established in other major markets.

■ Beef and processed food including beef and by-products (casings, gelatines)

Yearly status report: progress. While for many years the approval process was slow, to the credit of the Japanese authorities, the number of EU Member States approved to export beef to Japan has recently increased. There are however still Member States waiting to gain such approval. The EBC notes that several of these Member States are designated as having "negligible BSE (Bovine Spongiform Encephalopathy) risk" - the same status as Japan.

Recommendations:

- Processed food containing beef, bovine gelatines, or products made with beef casings, should be approved for import to Japan, as they are widely used in the European food industry, which has already established high safety standards.
- The Ministry of Agriculture, Forestry and Fisheries (MAFF) and MHLW should speed up the approval process in respect of the EU Member States that have already submitted data.

■ Malt and quota management system

Yearly status report: progress. Japan has a tariff quota system for brewing-malt to balance the demand from domestic beer manufacturers for cheap malt and the perceived need to protect domestic barley farmers and malt manufacturers. Historically, to make use of the quota, a company must manufacture beer or import malt exclusively for the use of a particular brewery. In addition, a company can only apply for the quota twice a year, meaning that any imports using the quota must be based on forecasts and not on actual short-term demand. With the EPA EU origin malt will have its own tariff quota. This will be a first-come first-serve quota for EU origin malt. The new quota, however, only covers 70% of the current imports from the EU. Furthermore, the allocating mechanism is still unknown at the time of production of this report. It is therefore doubtful whether malt export

from the EU to Japan will increase. Furthermore, due to the lack of information on the management of the EU quota, there are some concerns that the quota will share some of the limitations as the general quota.

Recommendations:

- Japan should abolish the tariff on EU malt so that there is no need for European suppliers to use the quota. This would be beneficial not only to European supplier but also to especially Japanese breweries with smaller production capacities.
- In the meantime, Japan should increase the volume of the quota and at the same time make certain that it does not have the same limitations as the general quota.

■ Origin labelling of ingredients

Yearly status report: no progress. The Government of Japan is planning to introduce a requirement that the origin of all ingredients in food and certain beverages must be listed. This new requirement will apply to domestically produced food. The EBC stresses that it should not be extended to goods produced overseas, where multiple sourcing of ingredients is far more common and the cost implications would be severe and potentially discriminatory.

Recommendation:

- Japan should not include overseas products in the scope of ingredient origin labelling as this would impose a disproportionate administrative burden and additional cost on European suppliers.

■ Food contact

Yearly status report: new issue. Materials that come in contact with food, such as wrapping, packaging, plates, cups etc. have to fulfil the rules set out by the Food Sanitation Act. Japan is currently planning to introduce a positive list of materials that are allowed to be used for the above-mentioned purpose. Several other markets are also using positive lists. The MHLW has for this purpose asked some domestic business organisation for lists of resins currently in use, and has then compiled a list of 32 resins. If there is no harmonisation as well as a procedure of exemptions as is the case in the EU and the US, European suppliers and Japanese buyers run the risk of not being able to import the products to Japan.

Recommendations:

- Japan should allow resins allowed in the EU and the US.
- Japan should also introduce a system where materials can still be used without being on the positive list, similar to the EU and the US.
- Japan should furthermore make use of ISO standards as test methods, as to avoid specific testing for the Japanese market.

■ Testing and approvals

Yearly status report: new issue. Many European products undergo frequent and expensive testing to be approved for either import or for selling on the Japanese market. Examples of these are: cyanide testing, radioactivity testing, microbiological testing etc. The EBC believes that in many cases it should be possible to use approvals and testing carried out in Europe. This is currently not possible in many cases due to non-harmonised test methods and standards.

Recommendations:

- Japan and the EU should use the EPA to streamline test procedures by looking into what tests are necessary to eliminate double testing. The goal should be that products approved for consumption in one market should be allowed for consumption in the other market.
- Japan should furthermore make use of ISO standards as test methods, as to avoid specific testing for the Japanese market.

Industry

Automobiles
Automotive components & aftermarket
Aeronautics
Space
Defence & security
Materials
Energy

Mr. Kintaro Ueno

Chair, Automobile Committee

(President and CEO, Mercedes-Benz Japan Co., Ltd.)

c/o Mercedes-Benz Japan, Co., Ltd.

Shinagawa Seaside Park Tower

4-12-4, Higashi Shinagawa, Shinagawa-ku, Tokyo 140-0002

Phone 03-6369-7200

Fax 03-6369-7126

AUTOMOBILES

Introduction

In the first half of 2018, the sales of passenger cars in Japan were 2,292,025 units. Sales of the foreign-brands, mainly from Europe were up by 0.5 percent from a year earlier to 151,803 units, posting the 3rd highest figure ever for a first half period. Moreover, total imported vehicle sales including the Japanese brands were up by 5.0 percent from a year earlier to 182,519 units. For the second half of this year, the imported vehicle market will likely continue posting positive results. The new models that were launched in the first half will further improve the figures.

The Economic Partnership Agreement (EPA) between the EU and Japan was signed on July 17, 2018. The agreement will create a massive free trade zone accounting for 37 percent of the world's trade by value. The EBC Automobile Committee appreciates the efforts and contribution of all the parties concerned. The EU-Japan EPA agreement is, an important achievement, signalling to the world that both the EU and Japan remain open for international business in a time when protectionism is rising and the risk to multilateral trade is under a growing threat.

Non-tariff measures (NTMs) add to the cost of doing business for European importers of both passenger cars and commercial vehicles. The EBC Automobile Committee has been calling for the harmonisation of Japanese regulations with international norms and therefore welcomes the importance given to the elimination of NTMs in the automobile sector in the EU-Japan EPA agreement.

One of the concrete outcomes of the EPA is the provisional harmonisation on the use of hydrogen container for fuel cell vehicles to the restricted vehicles such as PR demonstration cars or test vehicles. Further efforts/studies are needed to reach the complete international harmonisation as a GTR (Global Technical Regulation).

Although major NTMs are abolished through the EPA agreement, there still remain NTMs in some areas including commercial vehicles. Most of Heavy Duty Vehicle importers in Japan, for example, homologate the vehicles by the Preferential Handling Procedure (PHP). PHP still requires HDV emission Conformity of Production sample test using an engine bench which means dismantling the engine unit from the vehicle. The number of emission test for the homologation of HDVs by Parallel Import (PI) are more than that of passenger cars. There are still some more NTMs on importing HDVs.

Technical harmonisation alone is not sufficient to open up markets. Currently, the unique Japanese system of classifying vehicles shuts European compact cars out of some 37% of the passenger car market. As noted in previous EBC annual reports, Japan's specifications for *kei*-cars reduce the market opportunities for foreign compact cars. Furthermore, *kei*-cars receive preferential tax treatment that undermines the competitiveness of imported cars with similar performance and pre-tax price. The EBC urges the Japanese Government to take further steps, as recommended by the Ministry of Economy, Trade and Industry (METI), to narrow the gap between the level of taxation of *kei*-cars and of compact cars.

The process for reviewing the targets of parties to the Paris climate change agreement for curbing their emission of global warming gases has gotten underway. In 2017, the European Commission proposed a Post 2021 CO₂ regulation for passenger vehicles and vans, and deliberations have been conducted with the stakeholders. At the same time, the Japanese Government started in March 2018 the deliberation of its Post 2020 Fuel Efficiency regulation for passenger vehicles. The EBC Automobile Committee requests that the Japanese Government should take these international developments into consideration when setting up new fuel efficiency standards.

The EBC Automobile Committee continues to support the aim of the EU and Japan of realising a truly fair and open market.

Key Issues and Recommendations

■ Future Implementation of International Whole Vehicle Type Approval (IWVTA)

Yearly status report: some progress. The implementation of a partial IWVTA system in July 2018, marked an important step towards mutual recognition of vehicle certification between Japan and the EU. However, Japan still retains unique national regulations.

Recommendations:

- Japan should abolish its remaining unique regulations.
- Japan should work closely with the European Commission to extend the scope of the IWVTA system so that it covers all the requirements of the Japanese type approval system.

■ Post 2020 Fuel Efficiency regulation

Yearly status report: new issue. The Japanese government has started the deliberation of Post 2020 Fuel Efficiency regulation for passenger vehicles aiming at setting the target in March 2019.

Recommendations:

- Japan should harmonise its regulation with the EU Post 2021 CO₂ regulation.
- Japan should accommodate the deliberation based not only on powertrain developments such as Plug-in-Hybrids and Electric Vehicles but on other technologies as well.

■ Tax reform, including kei cars

Yearly status report: little progress. Compared with other countries, Japan imposes an excessively heavy tax on the purchase and ownership of motor vehicles. There is unfortunately also an artificial differentiation between kei-cars and other registered vehicles, which distorts competition

Recommendations:

- The Government of Japan should reduce the Automobile Tax rate and abolish the Tonnage Tax in order to lower the tax burden on vehicle owners and ensure fair tax treatment of registered vehicles and *kei*-cars. It should furthermore harmonise parking and insurance regulations between the two different vehicle classes.
- The Japanese authorities should simplify the structure of automobile taxation and reduce the overall tax burden on motorists in line with international best practice.
- Japan should adopt and implement, in step with the EU, internationally harmonised standards for measuring fuel efficiency and exhaust emissions as used to assess tax incentives for environmentally friendly vehicles.
- Japan should produce guidelines of tax reduction direction for the next 5-10 years. Two years are too short to adhere to the conditions of the tax reduction for Clean Energy Vehicles.

■ Automated and connected driving

Yearly status report: new issue. SIP-adus, the Japanese Government's Strategic Innovation Program for automated driving technologies, has started the second programme in parallel with its first programme. Japan aims to realise automated driving at SAE Level 3 on highways and SAE Level 4 in restricted areas by 2020, and SAE Level 4 on highways by 2025. For this purpose, the "safety guideline for automated driving vehicle" was published in September 2018.

Recommendation:

- Japan should lead the international harmonisation on standardisation on safety, infrastructures and necessary wireless communication technologies.
- The Government of Japan should share information about the progress of reviewing the related institutional development in a timely manner, for the chance of feedback from overseas to promote policy and regulatory harmonisation. EBC requests that importers have the same opportunities as domestic OEMs.
- Japan should support the promotion of automated driving e.g. by publishing a roadmap of the introduction of OTA (Over-the Air) wireless software update in line with real market needs, even before the international standards are completely formulated.
- Japan should harmonise the requirements with EU's Event Data Recorder (EDR) and DSSAD (Data Storage System for Automated Driving) for automated driving features.

Mr. Joaquin Martori

Chair, Automotive Components & Aftermarket Committee

(Managing Director, Mahle Trading Japan Co. Ltd.)

c/o Mahle Trading Japan Co. Ltd.

3-2-6 Mita

Minato-ku, Tokyo 108-0073

Phone 03-6809-4382

Fax 03-3453-7887

AUTOMOTIVE COMPONENTS & AFTERMARKET

Introduction

The EBC Automotive Components & Aftermarket Committee welcomed the announcement, on 6 July 2017, that the European Union and Japan had reached an agreement in principle on an Economic Partnership Agreement (EPA). Shared values and a firm belief in the advantages of common standards are the foundations of this historic outcome. While work continues to bring the EPA negotiations to a final successful conclusion, the prospect of reduced tariffs and trade barriers between two such important markets is now real and promises to benefit business and consumers alike.

The process of globalisation and intense competitive pressures have together caused the outsourcing of automobile component development and supply to emerge as a clear trend in the European automobile industry, fostering an environment of low risks, reasonable prices and flexibility. In the past, European component manufacturers that had enjoyed success with Japanese transplants in Europe were seldom able to build on this base to become suppliers of the parent company in Japan. However, European firms are finding that, as a result of recent changes in the Japanese automobile manufacturing sector, new opportunities are surfacing. An increasing number of companies are therefore dedicating resources to attracting business in Japan, investing in local infrastructure, and building knowledge of local technical requirements, with the goal of promoting more direct contact and closer relationships with Japanese clients. Against this background, the EBC greatly values the ongoing, regular dialogue between European component manufacturers and Japanese carmakers as a vital mechanism for sharing information and promoting understanding. It is hoped that this will, over time, foster increased opportunities for mutually beneficial business development.

One area where regulatory change would ultimately benefit Japanese and foreign firms is the auto components independent aftermarket (IAM). The EBC supports the position paper issued by the European Association of Automotive Suppliers (CLEPA) earlier this year, calling for a level playing field in Japan's IAM. At present, business is seriously constrained by restrictive practices; for example, when carmakers in Japan enter into supply contracts, they routinely prohibit the suppliers from selling the parts independently, a practice at odds with the situation in Europe and the US. In fact, EU law prohibits carmakers from imposing such restrictions in their parts-supply contracts. The EBC urges Japan to introduce a similar legal framework, allowing healthy competition and fair opportunities for all, so that end customers have a wider choice.

The EBC recognises that the Japanese authorities have been making efforts toward regulatory harmonisation related to tyres. In addition to the implementation of UN/ECE (United Nations Economic Committee for Europe) regulation R117-02 (rolling sound emission, wet traction, and rolling resistance) by the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) in October 2015, 3PMSF (3 Peak Mountain Snow Flake) marked tyres have recently been recognised as Winter tyres by Japan Automotive Tire Manufacturer Association (JATMA)—Tire Industry and Standard Organisation in Japan. 3PMSF marked tyres have been approved in Europe through a regulation test to guarantee the right level of performance under winter condition. This decision also removes the necessity of additional winter testing for imported tyres and is a very fair decision for import tyre distributors.

It should be noted that the tyre market consists of both new vehicle (original equipment) and replacement markets. For the replacement market, the timeline for implementation of the above-mentioned UN/ECE regulation R117-02 remains undecided. There are, furthermore, barriers in the replacement market because of the peculiarities of the Japanese distribution environment, which is fragmented and only partially integrated, making it difficult for foreign companies to access. Distributors in many other countries in Europe, and even in Korea, have opened up their brand policies from mono-brand to multiple-brands in retail in order to offer more choices to consumers.

Accessing consumers via garages, repair shops, and tyre shops is a critical factor for success in the Japanese replacement market. A recent survey by the Japan Fair Trade Commission (JFTC) shows that domestic brands still account for most of the market: around 90% in all tyre segments (truck/bus, light truck and passenger tyres). The EBC would welcome action aimed at limiting exclusive distribution arrangements and facilitating access for all firms, domestic and foreign, to the fragmented distribution market.

Key Issues and Recommendations

■ Aftermarket

Yearly status report: no progress. Currently automotive components companies supplying Japanese vehicle manufacturers are restricted in respect of where they can sell their products on the Japanese aftermarket. As a result, in many cases Japanese consumers can only purchase original high-quality spare parts from dealerships tied to a specific car manufacturer. Strangely, no such restrictions apply to companies that make copies or non-original parts, which leads to the independent aftermarket being characterised by potentially lower quality and less safe products.

Recommendations:

- Japan should set up a legal framework that allows automotive components manufacturers to sell on the aftermarket similar to the EU's Motor Vehicle Block Exemption legislation. This would increase the options for Japanese consumers wishing to source original high-quality vehicle parts.
- Components suppliers should be permitted to apply their own trademarks or logos and their own part numbers to goods supplied to vehicle manufacturers.

■ Tyres

Yearly status report: progress. The EBC appreciated the recent actions taken regarding UN/ECE regulation R117-02 by the MLIT and also the 3PMSF marking for winter tyres by JATMA in Japan. However, the EBC notes that foreign manufacturers still face difficulties in gaining access to replacement market sales channels in this sector.

Recommendations:

- Further accelerate regulatory harmonisation for not only new vehicles but also the replacement market.
- Limit exclusive distribution and facilitate access to the fragmented distribution market.

■ Globalisation of the automobile industry and promoting information exchange

Yearly status report: progress. The EBC welcomes the opportunity that globalisation presents for innovative European firms to strengthen their relationship with Japanese automobile manufacturers in developing new products and sharing technical expertise. Japanese automobile manufacturers are increasingly making use of foreign tie-ups to develop their business and respond to competitive pressures both at home and abroad. Nevertheless, European automotive component and system manufacturers continue to face numerous challenges in promoting European technical expertise to automobile manufacturers in Japan. It is of crucial importance, both for Japanese and foreign firms, that Japan harmonises its regulatory framework to better accommodate the globalisation of the automotive components sector.

Face-to-face meetings between the European Association of Automotive Suppliers and Japanese car manufacturers were established in 1995 to promote information exchange between European and Japanese companies. These meetings have proven to be a highly effective venue for discussing issues of mutual concern relating to products, platforms, global strategies and other important matters affecting the industry. The EBC also sees considerable potential value in the Japan Society of Automotive Engineers' (JSAE) Automotive Engineering Exhibition and the annual congress/paper presentation scheduled for 22 May 2019 in Yokohama.

Recommendations:

- Encourage the Japanese automobile industry, when procuring components and systems, to focus on the technical, commercial and logistics aspects of automobile production and to avoid excessive reliance on affiliated companies. Increased purchasing on a global basis and more emphasis on single platform development would improve the cost-effectiveness of the Japanese industry.
- Recognise foreign test results from accredited European agencies to avoid the necessity of re-testing for the Japanese market.
- Continue face-to-face meetings between leading representatives of European suppliers and the Japanese automobile industry, as these have led to increased understanding. The EBC also recommends that the scope of these meetings is expanded in future to include opportunities to meet at Japanese venues.

Mr. Stephane Ginoux

Chair, Aeronautics, Space, Defence & Security Committee

(President, Airbus Japan KK)

c/o Airbus Japan KK

Roppongi Hills Mori Tower, 19F

6-10-1 Roppongi, Minato-ku, Tokyo 106-6119

Phone 03-5775-3300

Fax 03-5775-0123

AERONAUTICS

Introduction

Politics have long influenced the aeronautical industry in Japan, sometimes favouring the long-term relationship with the US over business realities. The Airbus A350 selection by Japan Airlines (JAL), and selection of the A320 neo and the A380 by All Nippon Airways are signs that traditional Japanese corporations may now be thinking differently. The private sector is expected to make business decisions based on economic grounds rather than politics, creating opportunities for Europe and Japan to develop new commercial and industrial ties. The military sector was thought as increasingly open to consider cooperation with European manufacturers but still needs to be validated in real business opportunities. In addition, the Aeronautics, Space, Defence & Security Committee is looking positively at the new development of cooperation in the UAV / Urban Mobility domain initiated by the Ministry of Economy Trade and Industry. The EBC is actively supporting these developments.

Historically dominated by US manufacturers since the beginning of the 1950s, the Japanese commercial aircraft and helicopter market is among the largest in the world. The EBC welcomes the decision by the two major Japanese airlines to choose European products. This is clear evidence that Europe can lead the way when it comes to high technology, quality, customer services, and cost-effectiveness.

There are several examples of successful cooperation between our industries. Kawasaki Heavy Industries (KHI) and Airbus Helicopters on the BK117 helicopter co-development programme, collaboration between various Japanese industries and Rolls-Royce on the Trent engines, and other cooperations between Safran and Leonardo with their respective Japanese partners, are encouraging examples of successful collaboration between the European and Japanese aeronautics industries. The Government of Japan and European Governments have signed various bilateral agreements that have led to increased engagement and project discussions. The EBC expects positive results deriving from concrete programmes of Europe-Japan co-development.

The EBC strongly believes that shifting from a policy of sole domestic development to one of international co-development will create superiority in the technological field, and expand Japan's market in both volume and range of products. Proactive collaboration with successful European companies would enable Japanese corporations to strengthen their positions in commercial aeronautics. By joining a wider range of projects, Japanese firms would be able to expand their international business opportunities and further develop their technological base. The EBC feels that there are considerable opportunities for large-scale joint development programmes between Japanese and European industries, especially in the field of transport aircraft, and urges Japan's Government and aerospace players to support such initiatives.

As part of the Aviation Strategy adopted on 7 December 2015, the European Commission "recommended that the EU negotiates further bilateral aviation safety agreements with important aeronautical manufacturing nations such as Japan". In March 2016, the 28 EU Member States authorised the European Commission to do so on behalf of the entire European Union. The European Commission is supported by the European Aviation Safety Agency, which is recognised throughout the world as the EU's aviation safety and aircraft certification body, to negotiate with its Japanese counterpart, the Japan Civil Aviation Bureau. The EBC encourages this initiative which will remove the duplication of oversight activities and support mutual safety recognition between the EU and Japan.

Key Issues and Recommendations

■ Promoting partnerships with the EU

Yearly status report: progress. The aeronautics market is becoming more and more global, and Europe has strong technological advantages. For example, European companies have experience in the area of high-end technologies that are environmentally friendly. Procurement decisions should be made taking into consideration both competitive and technological advantages. European manufacturers of commercial aircraft, engines, components, and navigational equipment offer state-of-the-art technology at internationally competitive prices. The EBC consistently requests Japan to modernise its air traffic management system. Some of the European companies are recognised worldwide as setting state-of-the-art standards, yet they face great difficulty in even being considered in the process for new equipment procurement in Japan such as for the air traffic management system. The EBC deplores this situation, which may be keeping Japan from benefiting from the latest advances in safety standards.

Recommendations:

- The EBC encourages Japanese firms to diversify their sources of supply and consider the advantages of European products in the aeronautics field for the benefit of their customers, the general public, and shareholders.
- The EBC urges the Japanese authorities to facilitate greater use of equipment from European manufacturers who can help them address the need for improvements in air transport safety.

■ Supporting BASA negotiation between EU and Japan

Yearly status report: progress. In March 2016, the European Commission was authorised by the 28 member states to open negotiations with a view to concluding a Bilateral Air Safety Agreement (BASA) between the European Aviation Safety Agency and its Japanese counterpart, the Japan Civil Aviation Bureau. Such an agreement will enhance air safety worldwide and enable cooperation in the aviation safety domain, including certification, testing and maintenance of aeronautical components, air operations, flight crew licensing, air traffic management and airports. It will also reduce the transaction cost of exporting aircrafts, while ensuring high levels of safety in partner countries and helping to harmonise product standards worldwide. Despite exchanges between Japan and Europe, slow progress has been made on this topic.

Recommendations:

- The EBC encourages the EU and Japan to conclude negotiations with the goal of finalising a Bilateral Air Safety Agreement as soon as possible in order to develop business opportunities between the EU and Japan by removing administrative hurdles. To support such discussions, the EBC committee has drafted recommendations pertaining to this agreement which reflect the position of the EBC Aeronautics Committee member companies. These recommendations have been communicated to the various competent authorities.
- The committee is looking for the finalisation of this agreement which has been scheduled end 2018.

■ Promoting the use of large aircraft at Haneda Airport

Yearly status report: limited progress. The Tokyo 2020 Olympics now less than two years away, and with the number of foreign visitors to Japan already exceeding 28million in 2017, the new target set by the Japanese Government is up to 40 million visitors in 2020. Accordingly, it is crucial for Haneda Airport, now the preferred airport in Tokyo, to be able to accommodate the increase in traffic. The EBC welcomes the decision to allow Lufthansa to operate the Boeing 747-8i at Haneda, but the airlines should also be allowed to operate the Airbus A380. At least five A380 operators have expressed interest in operating the A380 at Haneda by 2020. In addition, with ANA planning to use the A380 aircraft between Tokyo and Honolulu from 2019, Haneda must be available for such operations. The decision to allow day-time A380 operations at Haneda will increase the number of passengers using Haneda without having to provide additional landing and take-off slots. An added advantage is that the A380 has the lowest noise footprint among the new generation aircraft.

Recommendation:

- The EBC urges the Japanese authorities to engage potential A380 operators in a discussion on the use of Haneda by the A380 aircraft as soon as possible.

Mr. Stephane Ginoux

Chair, Aeronautics, Space, Defence & Security Committee

(President, Airbus Japan KK)

c/o Airbus Japan KK

Roppongi Hills Mori Tower, 19F.

6-10-1 Roppongi, Minato-ku, Tokyo 106-6119

Phone 03-5775-3300

Fax 03-5775-0123

SPACE

Introduction

The Committee on National Space Policy and the National Space Policy Secretariat (NSPS) established in the Cabinet officeset Japan's space policies across all ministries and agencies. Space is treated as an important industrial and commercial sector, and now officially as a national security asset. In an attempt to maintain a healthy domestic space industry, Japan's administration actively seeks growth in export markets, although the industry is still mostly geared towards domestic government contracts. A major evolution of government policy is to emphasise practical downstream applications of existing infrastructure while encouraging private startup-type initiatives in the areas of small satellites and launchers.

The Ministry of Economy, Trade and Industry (METI) actively helps all-Japanese industry consortia to supply satellite systems to emerging countries through Official Development Assistance (ODA) funding. The packages often include satellites, launch services, operations, data analysis, maintenance, training, technology transfers, and other services. Contrary to EU policy, Japan's ODA is tied, which means that contracts must be awarded to its domestic industry, resulting in a distorted market that basically excludes foreign manufacturers and service providers. In August 2015, the Cabinet Office launched a joint government-industry task force on the export of space-related products.

The private satellite market is ostensibly open. Satellites with business and practical applications of former government monopolies have been procured through international tenders since 1990. These now only relate to the Multi-functional Transport Satellite (MTSAT)/ Meteorological satellite series and most of the broadcasting satellite (BSAT) series.

Direct bids in government tenders are generally not possible for foreign companies. No-tender government programmes include the science and technology satellites of the Japan Aerospace Exploration Agency (JAXA), some programmes under METI, and the defence-purpose remote-sensing Information Gathering Satellites (IGS). The NSPS's priority is the Quasi-Zenith Satellite System (QZSS), a Japanese positioning, navigation and timing satellite system. A defence communications satellite programme is also underway; two satellites have already been launched. The next major theme of interest for Japan's space authorities will be debris and space situational awareness. Japan's willingness to cooperate in satellite development programmes, however, still rarely extends to European companies.

Regarding launchers, more mutually beneficial bilateral cooperation is possible. Ariespace and Mitsubishi Heavy Industries already have experience in operation cooperation, including a backup agreement. Currently, Japan is developing the H3 launch vehicle and Europe is developing Ariane 6, both of them due for a first launch in 2020. This coincidence makes it possible to cooperate in developing future improved versions of both launchers and enhance their competitiveness and international contribution. The past talks between the Japanese and European space authorities towards a mutual back-up of government launch missions should also be given a new impetus.

A continuing risk in Public-Private Partnership (PPP) projects is that satellites with both government and commercial payloads could be declared "governmental" as far as building and launching them is concerned. Foreign satellite makers and launchers could thus be excluded from Japan's commercial market in a piecemeal fashion.

Japanese investment in ground equipment has been spurred by its move into security and defence applications. Japan's space activities increasingly require ground equipment for image processing and interpretation, and for applications in agriculture, fisheries and geophysics. In addition, homeland security-type applications enhance defence capability. Protectionist procurement methods are still being used in this area to the disadvantage of foreign suppliers.

While respecting Japan's space policies, the EBC believes that fewer all-Japanese consortia, less tied ODA and more work with Europe would bring gains in terms of budgets, national security, technology, and commercial success.

Key Issues and Recommendations

■ General environment

Yearly status report: protectionist risk. The new approval system for satellite projects and the handling of future PPP projects still hold risks of protectionism. The EBC advocates increasing, not reducing, trade and cooperation. More openness to European industry would benefit Japan. In addition, Europe provides many technologies free from “black-box” technology concealment policies.

Recommendations:

- Satellite projects with both government and commercial aspects should not be declared “governmental” for the purpose of excluding the participation of foreign industry.
- The EBC urges more Japanese cooperation with European space agencies. Space agencies on both sides should compare their projects at an early stage and take greater advantage of cooperation opportunities.
- Japan should also encourage more cooperation between the Japanese and European space industries on satellite platforms and ground systems.
- The EBC recommends Europe-Japan coordination and cooperation in space-related ODA worldwide.

■ Satellites

Yearly status report: no progress. Japan is mostly interested in high technology components (solid state recorders, star trackers etc) for supporting its domestic programmes. The space agencies of both the EU and Japan cooperate and share data in science and research, but have almost no industrially meaningful cooperation. However, the quantity of inquiries and topics under investigation are significantly increasing

Recommendations:

- The EBC advocates closer space agency cooperation in satellite technology development and applications, with pro-active promotion and execution of industrially and commercially meaningful cooperation projects.
- The Government of Japan should increase cooperation with Europe through the procurement of high-quality satellite systems or equipment in fields related to national security. This includes the joint development of high-quality sensors or their production by Japanese industry under licensing arrangements.
- Government procurement methods, terms and conditions should not put European makers at a disadvantage.

■ Launchers

Yearly status report: no progress. Although Europe and Japan are developing their respective next generation launchers almost simultaneously, there is no industrially significant cooperation in that area. A plan for a balanced mutual backup agreement to reduce delays in launching government satellites was evaluated positively by Japan’s space authorities in 2002, but no agreement is in sight due to lack of political leadership.

Recommendations:

- Government satellite programmes increasingly require timely launches. The EBC urges Japan and Europe to bring about an effective, formal back-up cooperation between Japanese and European satellite launchers.
- Europe and Japan should also consider cooperating on the development of the evolutions of their respective new generation launchers. The creation of Ariane Group and a new launcher development organisation in Europe make it easier to realise industry-led cooperation on development.

■ Space debris and situational awareness

Yearly status report: new issue. Near-Earth space is a key resource for society, as crucial as Earth-bound resources. Space debris threaten vital current space systems and the availability of the resource for future projects. New micro-satellite constellations and other projects make a strong “space situational awareness” indispensable.

Recommendation:

- Japan and Europe should dramatically increase the scope of their cooperation in space situational awareness.

Mr. Stephane Ginoux

Chair, Aeronautics, Space, Defence & Security Committee
(President, Airbus Japan KK)
c/o Airbus Japan KK
Roppongi Hills Mori Tower, 19F
6-10-1 Roppongi, Minato-ku, Tokyo 106-6119
Phone 03-5775-3300
Fax 03-5775-0123

DEFENCE & SECURITY

Introduction

In recent years, the security challenges and issues, which Japan has been facing, are becoming extremely complex and diverse. There has been an increasing number of cases of unilateral actions in an attempt to change the status quo by enforcement without respecting the existing international law.

The emergence of state expansionism and increased uncertainty in certain parts of the world including the east Asian region combined with the shift in US foreign policy to focus more on the US mainland have changed the security environment for Japan. The prolonged Syrian civil war cast a light upon the dysfunction of an international order and presented challenges concerning "human security" in the form of a refugee problem throughout the world. Furthermore, the menace of terrorism and asymmetric warfare are growing in gravity, while the importance of the new security domains such as Cyber and Space are rapidly emerging in addition to the traditional domains of Land, Sea and Air. Thus, national security can no longer be addressed and understood only from a traditional geopolitical perspective, and are difficult to be solved by individual countries.

Under the circumstances, while keeping Japan-US alliance as the fundamental and the crucial part of Japanese national security strategy, Japan recognises the increasing need for international cooperation and is trying to position itself within a broader global security relationship with its focus on enhancing the bilateral defence cooperation. Specifically, Japan has recently enhanced bilateral defence relationships from traditional exchanges to deeper cooperation in a phased manner by appropriately combining various means including joint exercises and capacity building assistance, defence equipment and technology cooperation.

Especially in terms of the defence equipment and technology collaboration, Europe has been playing a very important role as Japan's one of the closest and oldest allies that shares universal values and playing a central role in working to address common challenges to global security.

In this regard, the progress has been very remarkable. The Japanese Government made an important commitment to Europe by concluding with the UK its first bilateral agreement on defence equipment collaboration ever after its agreement with the US. After that, similar agreements were concluded with Spain in 2014, France in 2015, and with Germany and Italy in 2017. Further discussions towards bilateral agreements with other European countries such as Sweden are now underway.

The EBC welcomes this trend of enhancing the bilateral defence cooperation and expects the Government of Japan to more actively promote the defence equipment and technology aspect of the collaboration, which would open up a window for European companies to participate in the international co-development programs.

Key Issues and Recommendations

■ Procurement

Yearly status report: some progress. The EBC appreciates the fact that introduction of European products in the land domain has been increasing. To the contrary, the visibility of European products in the sea and air domains is extremely limited. As this trend may be derived from Japanese traditional preference of having US defence equipment, the EBC believes that the transparency of the procurement in those domains shall be improved, and more fair opportunity shall be given to European company.

Recommendation:

- The Government of Japan should regard the use of European defence equipment as a part of fostering the security collaboration with European nations, and should strategically promote it. It would significantly benefit the operation of the Self-Defence Forces in terms of Life Cycle Cost reduction and would benefit both European and Japanese industries throughout the increased international collaboration opportunities.

■ Industrial collaboration

Yearly status report: no progress. The EBC notices that a few Japanese companies are trying to play in a global market. However, strict export control, especially in terms of third country transfer, is discouraging the companies and eventually missing the collaboration opportunity with European companies.

Recommendation:

- The Government of Japan should clarify its political policies regarding transfer to third-party countries and should either operate the three principles of defence equipment transfer in a more flexible way or revise them, to avoid their becoming an obstacle to cooperation between Japanese and European companies.

Mr. Carl-Gustav Eklund

Chair, Materials Committee

(Representative Director, President, Hoganas Japan K.K.)

c/o Hoganas Japan K.K.

Akasaka Shasta East 6F, 4-2-19 Akasaka

Minato-ku, Tokyo 107-0052

Phone 03-3582-8280

Fax 03-3584-9087

MATERIALS

Introduction

Japan has developed vast knowledge and expertise in processing and recycling materials and is at the forefront of many technologies, such as those used to produce rechargeable batteries for hybrid vehicles, nanotechnologies for manufacturing semiconductors, and products related to environmental technology. These advanced technologies depend on key raw materials and Japan's ability to secure a stable, high-quality supply. It is, therefore, of the utmost importance that Japan adopts a strategy based on security of supply at competitive prices, which can only be achieved by allowing overseas suppliers unrestricted access to its domestic market. A shift in strategy among Japanese companies has already taken place to minimise risk and dependency on unstable sources, leading them to diversify purchases despite existing tariffs. Ultimately, however, their competitiveness is compromised and their future threatened because these tariffs have to be passed on to their customers.

It is against this backdrop that the Economic Partnership Agreement will come into play. While this has not been ratified at the time of the production of this report, the two authorities, the European Commission and the Japanese Government have agreed to remove tariffs immediately for products that are of interest to member companies of the EBC. We believe that this will be very beneficial for the Japanese industry who are dependent on the imports of these products. This is especially true for the battery industry and manganous manganic oxide as the domestic production only covers 10% of the demand. The same is true for the Japanese stainless steel industry which needs processed nickel at competitive prices to be able to compete with overseas producers, in particular from South Korea and China. It should be added though that many European companies have a global presence and both complete production and part of the supply chain might be located outside of the EU.

The prospective EU-Japan Economic Partnership Agreement will in general, remove tariffs in the materials sector. This will give European suppliers a competitive edge in the Japanese market. Moreover, it will give a boost to Japanese industries able to source key materials at lower prices. However, not all imports will benefit from tariff removal, since many European companies have a global presence and not all their production is conducted within the EU.

Tariffs are not the only barrier to increasing trade between Europe and Japan. Non-tariff barriers, in the form of administrative burdens, regional differences in registration procedures and inconsistent use of classifications all make doing business in Japan unnecessarily costly and difficult for foreign companies. The benefits of eliminating tariffs and of harmonising and simplifying classifications and procedures would be felt not only by European suppliers, but even more by Japanese industry, making it more competitive.

Chemicals normally fall within the competency of the Ministry of Economy, Trade and Industry (METI), which is involved in the task of harmonising rules regulating chemicals. However, some years ago, the Ministry of Health, Labour and Welfare (MHLW) initiated a discussion on how to label chemical products that could be harmful to people handling them. Unfortunately, MHLW's work seems to have been conducted in isolation and its new system, which entered into force on 1 July 2016, lacks logic. As an example, products that are not registered in Japan, despite having a CAS (Chemical Abstract Service) number, could now be labelled as harmful since MHLW's warning labels are based either on the product's chemical components (rather than on the final substance), or on the most similar substance already registered in Japan. Additionally, it remains unclear whether or not the results of testing conducted in Europe under REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals) can be used.

One example of the issues raised by the MHLW approach relates to a European cement containing aluminium oxide (CAS 1344-28-1). According to the MHLW list, any product containing more than 1% of aluminium oxide must have a label warning how it should be handled. The problem arises from the fact that this particular substance (CAS 1344-28-1) is not regarded or registered as hazardous in Europe. As a result, the same product ends up with a number of non-homogeneous labels, pictograms and safety data sheets that create unnecessary doubts and confusion about its safety.

Key Issues and Recommendations

■ Tariff issues

Yearly status report: progress. Currently, Japan imposes tariffs on some metals. These metals are in many cases essential for Japan's core industries, including the vehicle, battery and more traditional steel industries. Tariffs constrain the competitiveness of Japanese manufacturing, a sector already under pressure from low-cost countries. With the entry into force of the EU-Japan EPA, however, tariffs will be removed on almost all metals with EU origin. This is something that will not only benefit European suppliers of said metals but also the Japan industry that is depended on these products. It should be added though that due to the global nature of the material sector some metals will not be able to benefit from the lower tariff in the EU-Japan EPA. For this to be achieved Japan will have to remove tariffs on a worldwide basis. Moreover, industrial materials imported into Japan are occasionally subjected to arbitrary tariff classifications and revisions. Regional Customs offices do not apply classification rules on a consistent basis and the appeal mechanism is both time-consuming and costly, without any guarantee that the outcome will be in line with international practice. This is a problem not only for products entering the market for the first time, but also for well-established products subject to arbitrary classification reviews.

Recommendations:

- The Government of Japan should remove import tariffs from all industrial raw materials, irrespective of the site of production.
- The Government of Japan should rationalise its tariff classification regime and develop a comprehensive strategy to improve consistency between regional Customs offices in classification rulings and to strengthen and simplify dispute resolution mechanisms.

■ Chemical Substance Control Law

Yearly status report: some progress. With both the EU and Japan now having introduced their own chemical substance registration systems, producers, exporters and importers are faced with re-testing, double submissions and an increased administrative burden to fulfil the respective regulations. On top of this, the EBC is concerned that in some cases, in order for a European product to be tested and approved for sale in Japan, commercially sensitive information has to be handed over to Japanese competitors. This gives the competitors an undeserved advantage and creates unfair competition.

Recommendation:

- Japan and the EU should harmonise their registration systems or mutually recognise test results and supporting documents to avoid unnecessary re-testing and administrative burdens, and also make certain that products are not classified differently in the two jurisdictions.

■ Workers' safety labelling for chemicals

Yearly status report: no progress. When products are not registered in Japan, despite having a CAS number, MHLW does not consider the actual nature of the substance but applies a warning label based either on the individual components or on the most similar substance that is already registered in Japan. This can lead to compounds being unnecessarily labelled as dangerous. There is, furthermore, a lack of information in English on this legislation.

Recommendations:

- MHLW should give due consideration to compounds not currently registered in Japan that nevertheless have an international CAS number.
- MHLW should provide proper information on how importing companies should comply with its regulations, including in English.

Mr. Taku Niioka

Chair, Energy Committee

(Manager, Business Development Dept.

Power Grids Division, ABB K.K.)

c/o ABB K.K.

ThinkPark Tower 22F., 2-1-1 Osaki, Shinagawa-ku, Tokyo 141-6022

Phone 03-4523-6000

Fax 03-4523-6190

ENERGY

Introduction

Japan's electrical utility industry used to be run by ten regional Electrical Power Companies (EPCOs). While liberalisation of the electricity markets was initiated in the 1990s, real change was only triggered through reforms introduced by the Ministry of Economy, Trade and Industry (METI) following the 2011 Great East Japan Earthquake, which revealed weaknesses in the existing system.

As the first step to address those weaknesses, the Organization for Cross-regional Coordination of Transmission Operators (OCCTO) was formed in April 2015 and, subsequently, in September that year, an Electricity Market Surveillance Commission (EMSC) was established under METI to monitor and regulate the market. A second step was taken in April 2016, when full retail liberalisation was introduced as part of the Electricity Market Reform planned by METI's Agency for Natural Resources and Energy (ANRE). The third step, legal unbundling of the transmission and distribution sector from the EPCOs, is scheduled for 2020. The creation of non-fossil value trading in May 2018 and the implicit auctions starting from October the same year are certainly a progress. The ongoing discussion about how to establish capacity, ancillary-service, real-time markets are expected to result in fair and transparent processes enabling healthy competition.

Following the 1970s oil crisis, Japan set out to reduce its dependency on imports of gas, oil and coal through increased use of nuclear energy, such that by 2010, nuclear energy accounted for 26% of the power generation energy mix. However, after May 2012, all Japan's nuclear plants were shut down and a programme of safety reviews and upgrades was initiated, which is still ongoing. Two reactors, Sendai 1 and 2, were the first to be brought back on grid in 2015, followed by Ikata 3 in 2016, Takahama 3 and 4 in 2017, and finally Ohi 3 and 4, and Genkai 3 and 4 in 2018 bringing the number of reactors restarted to nine as of September 2018.

In July 2018, the Japanese Cabinet approved the 5th Strategic Energy Plan which is a policy document formulated by the Government under the Basic Act on Energy Policy from 2002. The plan presents the basic direction of Japan's energy policy, based on fundamental principles, namely, "safety," "energy security," "improvement of economic efficiency," and "environmental suitability", named 3E+S. The 5th Plan consist of:

- Renewable energy: Lay foundations to use as major power source with cost reduction, overcome system constraints and secure flexibility of thermal power
- Nuclear power: Lower dependency on nuclear power generation to the extent possible and restart of nuclear power plants and continuous improvement of safety
- Fossil fuels: Promote independent development of fossil fuels upstream, etc., effective use of high-efficiency thermal power generation and enhance response to disaster risks, etc.
- Energy efficiency: Continued thorough energy efficiency and integrated implementation of regulation of Act on Rationalizing Energy Use and support measures
- Promotion of hydrogen/power storage/distributed energy

The new plan aims for a reduction of greenhouse gas (GHG) of 26% in 2030 (from the base year 2013) and 80% by 2050. The concerns about the investments in new coal-fired power plants were reviewed and some have been cancelled which is in line with the global direction coping with Sustainable Development Goals (SDGs).

The EBC believes that the ties between Europe and Japan in the energy area should be further strengthened to facilitate commercial exchange, achieve consensus on common standards, enable attainment of the CO₂ emissions targets of COP21, and facilitate access to energy at the lowest possible cost based on Cost Benefit Analysis (CBA).

Key Issues and Recommendations

■ Transmission and distribution

Yearly status update: some progress. Japan's transmission network is centred on its production sites, with the main transmission at 500kV. The frequency convertor stations (FC) connecting the 50Hz and 60Hz networks offer only limited additional capacity. Furthermore, the limited interconnections between the individual EPCOs represent a real risk to security of supply. In contrast, European and US grids have extensive plans for use of High Voltage Direct Current (HVDC), which offers more flexibility in energy flows between regions, enables large integration of renewable into the system and also enables long cable connection by subsea or land.

Recommendations:

- As part of the preparations for legal unbundling in 2020, Japan should implement regulations that will ensure security of supply and fair market mechanisms based on wider grid interconnections by especially enhancing further FC capacity and connection to Hokkaido and Kyushu.
- Japan should do more to increase interconnection capacity between Transmission and Distribution System Operators (TDSOs), achieving fair electricity transactions and encouraging mergers between TDSOs.
- The Japanese authorities should ensure that electricity interconnections are developed at national and international levels based on HVDC. Firstly through the “invest and connect” model, then moving onto a “connect and manage” model, which in Europe is based on CBA and not only the initial grid investment cost.

■ Nuclear energy and nuclear safety

Yearly status update: some progress. In its revised Basic Energy Plan (2018), the Japanese Government confirmed that the nuclear closed-fuel cycle policy would continue and that while nuclear power would be reduced as much as possible, a certain amount would be preserved with regards to security of supply and costs. Since nuclear energy will remain a core constituent of the Japanese energy mix, it is essential that its long-term sustainability is based on a reliable and efficient approach to safety concerns, smooth implementation of a back-end policy for recycling spent fuel, and final disposal of radioactive waste. Since it was not mentioned in the revised Basic Energy Plan, it will also be necessary in the near future to address the issue of ageing plants, not only through plant lifetime extensions, but also through replacement of reactors, some set to be 60 years old by the mid-2030s.

Recommendations:

- Japan should increase cooperation and transparent exchange with international organisations such as the International Atomic Energy Agency (IAEA) and World Association of Nuclear Operators (WANO) to improve worldwide nuclear safety levels.
- Japan should develop complete interim and final waste repositories for spent fuel and radioactive waste.
- Japan should address the issue of ageing reactors and develop a long-term plan for their replacement to uphold the latest energy mix target for nuclear power.

■ Wind energy

Yearly status update: some progress. The development of wind energy is essential for Japan to reach its CO₂ emissions targets. Modern and cost-efficient wind turbines now contain sophisticated technology that works well with established power grids of all kinds, ranging from large transmission systems to isolated local grids. Tohoku EPCO's “grid access process”, NEDO's “floating wind farm demonstration” and the “new law for off shore wind farm development” were encouraging.

Recommendations:

- Japan should facilitate the development of on-shore as well as off-shore wind farms by reducing unnecessary regulations that add to their cost and development time, especially in relation to environmental impact assessment requirements.
- Japan should adopt and recognise internationally accepted certification standards and international accreditation for wind turbines and their componentry. This would increase both domestic and foreign direct investment, and support Japanese technology exports.

- Japan should focus on and officially support development in the Hokkaido / Tohoku area to enable investors to build utility-scale wind farms utilising the optimum wind conditions in Japan.
- Since Japan's offshore wind potential is located in deeper waters, Japan should continue to play an active role in supporting the development of the floating offshore wind industry. As this is globally an emerging technology and industry, Japan can still position itself as an industrial hub (supply chain) for this industry. The focus should gradually shift from technology demonstration to cost improvements through changing the support focus to larger scale floating wind farms.

■ Solar energy

Yearly status update: some progress. The principal impediments to sustainable growth of utility and commercial-grade solar energy are: the so far rather discouraging reverse auction system, cumbersome procedure for obtaining special permits for land re-zoning for non-agricultural use, and the prospect of potential curtailment in certain power grids, which affects project financing. Additional challenges that Japanese utility companies may soon encounter are managing cost effective solutions to integrate de-centralised and intermittent renewable generations into the existing power grid.

While Japan has focused extensively on solar power as a renewable energy source, the EBC believes that it must continue to encourage development of this important source of renewable energy. This must be carried out ambitiously with realistic targets, aimed at increasing the safety and reliability of the energy supply.

Recommendations:

- Adopt and recognise internationally accepted certification standards for solar modules, system components and design qualifications, rather than enforcing existing “Japan-only” component and certification standards.
- Adopt an accreditation scheme to support the acceptance of test results, reports and certificates from any accredited certification body, whether domestic or foreign, based on available international standards.
- Incentivise and create standardisation programmes for the EPCOs to use to contract PV project construction to an emerging class of engineering and design companies, with the aim of reducing grid connection costs and lead times.
- Incentivise rooftop PV installation as an alternative to power plants in remote areas requiring substantial land conversion.
- Encourage further grid interconnections, utilise existing pump storage power generation plants, use and improve battery storage, and consider new technologies, such as conversion to hydro for further PV integration.
- Legislative bodies should avoid imposing additional or differing safety requirements on the emerging 1500V technology in order to facilitate plant development applying this latest technology without making changes to the relevant authorisation process.

■ Environmental suitability

Yearly status update: new issue. The development of clean renewable electricity is contributing to energy independence and to a low carbon mix but it needs to be supplemented with other sources of electricity.

Recommendations:

- Japan should through incentive schemes put greater efforts in energy efficiency through smart management of demand, energy storage, low consumption technologies and CO₂ sequestration/capture and storage.
- The Government should use low carbon fossil, mainly natural gas in a context of a growing and mature market with reliable suppliers; new thermal power plants should be with high efficiency and clean gas, and to put target for CO₂/kWh.
- As the development of hydrogen energy is likely to take time before demand and supply volumes will drive competitive cost Japan will have to have clear incentives and compensations will have to be in place to attract sufficient investment from private industries.
- Promote early phase assessments of the use of hydrogen and ammonia in natural gas and coal fired power plants, the use of existing gas transportation and distribution infrastructure for hydrogen distribution, and the use of hydrogen in heavy transport (particularly shipping) through appropriate regulations and support mechanisms.

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EXECUTIVE OPERATING BOARD

EBC Acting Chairman

Michael A. Loefflad

Representative Director & President
DKSH Japan K.K.
DKSH Mita Building
3-4-19 Mita, Minato-ku, Tokyo 108-8360
Tel: 03-5441-4511

EBC First Vice-Chairman

Michael A. Loefflad (Austria)

Representative Director & President
DKSH Japan K.K.
DKSH Mita Building
3-4-19 Mita, Minato-ku, Tokyo 108-8360
Tel: 03-5441-4511

EBC Vice-Chairman

Carl-Gustav Eklund

Representative Director, President
Hoganas Japan K.K.
Akasaka Shasta East 6F
4-2-19 Akasaka Minato-ku,
Tokyo 107-0052
Tel: 03-3582-8280; Fax: 03-3584-9087

EBC Treasurer

Erik Ullner (Finland)

President, EU Japan Consulting &
Associates Co., Ltd.
5-49-12-2F, Matsubara Setagaya-ku,
Tokyo 156-0043
Tel: 03-6379-4931

EOB Members

Gregory Van Bellinghen (Belgium/Luxembourg)

Director
Belgian-Luxembourg Chamber of Commerce in Japan
Dai10 Daitetsu Bldg. 5F.
Arakicho 23, Shinjuku-ku, Tokyo 160-0007
Tel: 03-6457-8662; Fax: 03-6457-8663

Marcus Schuermann (Germany)

Chief Executive Officer / Delegate of German Industry and
Commerce in Japan, German Chamber of Commerce and
Industry in Japan
Sanbancho KS Bldg, 5F
2-4 Sanbancho, Chiyoda-ku, Tokyo 102-0075
Tel: 03-5276-8723; Fax: 03-5276-8736

Florian Kohlbacher (Britain)

Director, Corporate Network, North Asia
The Economist Corporate Network
Yurakucho Denki Bldg. North Tower 15F
1-7-1 Yurakucho, Chiyoda-ku, Tokyo 100-0006
Tel: 03-5224-6113; Fax: 03-5223-8104

Athanasios Fragkis (Greece)

Managing Director
Nostimia Co., Ltd.
1808-5 Godai, Naka-shi, Ibaraki 311-0111
Tel: 029-298-2464; Fax: 029-298-2575

Claus Eilersen (Denmark)

c/o Danish Chamber of Commerce in Japan
c/o Royal Danish Embassy
29-6 Sarugaku-cho
Shibuya-ku, Tokyo 150-0033
Tel: 03-3780-8729; Fax: 03-3476-4234

Lorcan Brophy (Ireland)

c/o Ireland Japan Chamber of Commerce
Ireland House 4F, 2-10-7 Kojimachi,
Chiyoda-ku, Tokyo 102-0083
Tel: 03-3263-8520; Fax: 03-3265-2275

Guy Bonaud (France)

Representative Director, General Delegate Safran Japan
Safran Turbomeca Japan
Loykrathong Toranomon Bldg. 3F
4-1-9 Toranomon, Minato-ku, Tokyo 105-0001
Tel: 03-5408-1083; Fax: 03-5408-1085

Marco Zoli (Italy)

President
MARPOSS K.K.
5-34-1 Minamimagome
Ohta-ku, Tokyo 143-0025
Tel: 03-3772-7011; Fax: 03-3772-7093



EXECUTIVE OPERATING BOARD

Kiminobu Yoshida (Netherlands)

Head of Government and Public Affairs
Philips Japan, Ltd.
Philips Bldg.
2-13-37 Konan, Minato-ku, Tokyo 108-8507
Tel: 03-3740-5850; Fax: 03-3740-5206

Pawel Komender (Poland)

Partner
PJK Strategy and Marketing Specialists LLP
2302 River City 21 East Towers II
2-1-2 Tsukuda, Chuo-ku, Tokyo 104-0051
Tel: 090-6560-0262

Takeshi Fujiwara (Sweden)

President
B. Braun Aesculap Japan Co., Ltd.
JEI Hongo Bldg.
2-38-16 Hongo, Bunkyo-ku, Tokyo 113-0033
Tel: 03-3814-2948

Masao (Mark) Torii (Switzerland)

President & Representative Director
Novartis Holding Japan K.K.
Toranomon Hills Mori Tower
1-23-1 Toranomon, Minato-ku, Tokyo 105-6333
Tel: 03- 6899-8259; Fax: 03- 6257-3603



BOARD of GOVERNORS

EBC Acting Chairman

Michael A. Loefflad

Representative Director & President
DKSH Japan K.K.
DKSH Mita Building
3-4-19 Mita, Minato-ku, Tokyo 108-8360
Tel: 03-5441-4511

EBC First Vice-Chairman

Michael A. Loefflad (Austria)

Representative Director & President
DKSH Japan K.K.
DKSH Mita Building
3-4-19 Mita, Minato-ku,
Tokyo 108-8360
Tel: 03-5441-4511

EBC Vice-Chairman

Carl-Gustav Eklund

Representative Director, President
Hoganas Japan K.K.
Akasaka Shasta East 6F,
4-2-19 Akasaka, Minato-ku,
Tokyo 107-0052
Tel: 03-3582-8280; Fax: 03-3584-9087

EBC Treasurer

Erik Ullner

President, EU Japan Consulting &
Associates Co., Ltd.
5-49-12-2F, Matsubara Setagaya-ku,
Tokyo 156-0043
Tel: 03-6379-4931

Austria (ABC)

President

Peter Aldrian
Managing Director, Head of Business Unit
Semicon
PLANSEE Japan Ltd.
Ark Hills Sengokuyama Mori Tower
1-9-10 Roppongi, Minato-ku, Tokyo 106-0032
Tel: 03-3568-2451; Fax: 03-3568-2450

Representative

Ingomar Lochschmidt
Commercial Counsellor, Head of Commercial
Section, Austrian Embassy
3-13-3 Motoazabu
Minato-ku, Tokyo 106-0046
Tel: 03-3403-1777; Fax: 03-3403-3407

Belgium/ Luxembourg (BLCCJ)

President

Fabrice D. Tilot
President, Triple-A Management, Ltd.
Isobe Bldg. 7F., 13 Samoncho
Shinjuku-ku, Tokyo 160-0017
Tel: 03-3225-8402; Fax: 03-3341-4550

Senior Representative

Sophie Bocklandt
Dai 10 Daitetsu Bldg. 5F
23 Arakicho
Shinjuku-ku, Tokyo 160-0007
Tel: 03-6457-8662; Fax: 03-6457-8663

Britain (BCCJ)

President

David Bickle
Director, Business Tax Services
Deloitte Tohmatsu Tax Co.
Shin Tokyo Bldg. 5F, 3-3-1 Marunouchi
Chiyoda-ku, Tokyo 100-8305
Tel: 03-6213-3743; Fax: 03-3101-8751

Executive Director

Lori Henderson
Ark Hills Front Tower RoP
2-23-1, Akasaka, Minato-ku
Tokyo, Japan 107-0052
Tel: 03-6426-5739; Fax: 03-6426-5749

Czech (CCCIJ)

President

Roman Watanabe
CEO of Japanese Branch, Asia Regional
Manager, Zoner L.L.C.
2-4-21 Kohama
Suminoe-ku, Osaka 559-0001
Tel: 06-4701-7373; Fax: 06-4701-7374

Executive Director

Pavel Zahorsky
c/o Kazelfa Corporation Office
2-24-17, Hiyoshi
Kokubunji, Tokyo 185-0032

Denmark (DCCJ)

President

Stefan Linde Jakobsen
President & Representative Director
Coloplast K.K.
11F., 2-1-30 Kudan Minami
Chiyoda-ku, Tokyo 102-0074
Tel: 03-3514-4141; Fax: 03-3514-4187

Executive Directors

Leon Esben Ota, Nanami Mie Brandt
& Serena Iida
c/o Royal Danish Embassy
29-6 Sarugaku-cho
Shibuya-ku, Tokyo 150-0033
Tel: 03-3780-8729; Fax: 03-3476-4234

BOARD of GOVERNORS

Finland (FCCJ)

President

Masaoki Fujita
President, Coil Center0 Fujita Co., Ltd.
3-22-7, Honjo
Sumida-ku, Tokyo 130-0004
Tel: 03-3625-3346; Fax: 03-3622-7727

Executive Director

Clas G. Bystedt
Forest View Meguro 101
5-11-17, Shimomeguro
Meguro-ku, Tokyo 153-0064
Tel: 03-5725-9596; Fax: 03-5725-9597

France (CCIFJ)

President

Armel Cahierre
CEO, B4F KK
Fonte Nishi Harajuku Bldg. 5F.
1-13-9 Tomigaya,
Shibuya-ku, Tokyo 151-0063
Tel: 03-5738-5350

Director General

Nicolas Bonnardel
Iida Bldg.
5-5 Rokubanchō,
Chiyoda-ku, Tokyo 102-0085
Tel: 03-3288-9622; Fax: 03-3288-9558

Germany (AHK Japan)

President

Donald Bunkenburg
General Manager for Japan
Lufthansa German Airlines
3-1-13 Shibakoen
Minato-ku, Tokyo 105-0011
Tel: 03-5402-5201; Fax: 03-5402-5209

Chief Executive Officer / Delegate of German Industry & Commerce in Japan

Marcus Schürmann
Sanbancho KS Bldg. 5F, 2-4 Sanbancho
Chiyoda-ku, Tokyo 102-0075
Tel: 03-5276-8723; Fax: 03-5276-8736

Greece (GrCCJ)

President

Tony Andriotis
Counsel, Hughes Hubbard & Reed LLP
Kojimachi Place 9F.
2-3 Kojimachi, Chiyoda-ku, Tokyo 102-0083
Tel: 03- 6272-5831

Executive Director

Konstantinos-Makoto Suwamoto
c/o Economic and Commercial Section,
Embassy of Greece
3-16-30 Nishi Azabu, Minato-ku,
Tokyo 106-0031
Tel: 03-3404-5853

Iceland (ISCCJ)

President

Bolli Thoroddsen
Managing Director, Takanawa Partners
c/o Embassy of Iceland, 4-18-26 Takanawa
Minato-ku, Tokyo 108-0074
Tel: 03-3442-1975

Secretariat

Halldor Elis Olafsson
c/o Embassy of of Iceland
4-18-26 Takanawa
Minato-ku, Tokyo 108-0074
Tel: 03-3447-1944; Fax: 03-3447-1945

Ireland (IJCC)

President

Paul Gilsean
Property Leader, Properties, GE Japan
Akasaka Park Bldg., 5-2-20 Akasaka
Minato-ku, Tokyo 107-6115
Tel: 03-5544-3182; Fax: 03-3588-5270

Executive Secretary

Ayumi Miyano
Ireland House 4F.
2-10-7 Kojimachi
Chiyoda-ku, Tokyo 102-0083
Tel: 03-3263-8520; Fax: 03-3265-2275

Italy (ICCJ)

President

Francesco Tiberio
MM Powertrain Japan, Chief Technical
Officer, Magneti Marelli Japan K.K.
Shinyokohama Square Bldg. 13F.
2-3-12 Shinyokohama, Kohoku-ku,
Yokohama 222-0033
Tel: 045-478-0045; Fax: 045-478-0095

Secretary General

Davide Fantoni
FBR Mita Bldg. 9F
4-1-27 Mita
Minato-ku, Tokyo 108-0073
Tel: 03-6809-5802; Fax: 03-6809-5803



BOARD of GOVERNORS

Netherlands (NCCJ)

President

Jorg van Leeuwen
Manager, International Tax Services
PwC Tax Japan
Otemachi Park Bldg., 1-1-1 Otemachi
Chiyoda-ku, Tokyo 100-0004
Tel: 080-4085-1794; Fax: 03-6212-6901

Office Manager

Kaori Kimura
7F-2 Shinjuku Komuro Building
4-1-22 Shinjuku
Shinjuku-ku Tokyo 160-0022
Tel & Fax: 048-952-3250

Poland (PCCIJ)

Chairman

Piotr R. Suszycki
Chairman, Polish Chamber of Commerce &
Industry in Japan
2F, Kobuncho 243 Bldg., 7-2 Nihonbashi
Kobune-cho, Chuo-ku, Tokyo, 103-0024
Tel: 03-3665-1991; Fax: 03-6203-8165

Operation Manager

Taiko Niimi
2F, Kobuncho 243 Bldg.,
7-2 Nihonbashi Kobune-cho,
Chuo-ku, Tokyo, 103-0024
Tel: 03-3665-1991; Fax: 03-6203-8165

Spain (SpCCJ)

President

Guillermo Gutierrez
Member of the Board, Vice President
Chanel K.K.
3-5-3 Ginza, Chuo-ku, Tokyo 104-0061
Tel: 03-5159-5201

Executive Director

Moe Kato
c/o Embassy of Spain 3F.
1-3-29 Roppongi
Minato-ku, Tokyo 106-0032
Tel: 03- 3505-1730

Sweden (SCCJ)

President

Thomas Östergren
Representative Director, General Manager
Holding Japan, Atlas Copco K.K.
Sumitomo Fudosan Shiba Bldg. 4, 11F.
2-13-4 Shiba, Minato-ku, Tokyo 105-0014
Tel: 03- 5765-7806; Fax: 03- 3455-0369

Executive Director

Martin Koos
c/o Embassy of Sweden
1-10-3-403 Roppongi
Minato-ku Tokyo 106-0032
Tel: 03-5562-5140; Fax: 03-5562-5160

Switzerland (SCCIJ)

President

Michael Mroczek
Attorney at law (Switzerland)
Okuno & Partners
Kyobashi TD Bldg. 8F
1-2-5 Kyobashi, Chuo-Ku, Tokyo 104-0031
Tel: 03-3274-3807; Fax: 03-3272-2245

General Manager

Liselotte Schneider
Burex Kojimachi 209
3-5-2 Kojimachi
Chiyoda-ku Tokyo 102-0083
Tel: 03-6256-9012; Fax: 03-6256-9013

Committee Chairmen Representative

Carl-Gustav Eklund

Representative Director, President
Hoganas Japan K.K.
Akasaka Shasta East 6F, 4-2-19 Akasaka
Minato-ku, Tokyo 107-0052
Tel: 03-3582-8280; Fax: 03-3584-9087

Committee Chairmen Representative

Stephane Ginoux

President, Airbus Japan K.K.
Roppongi Hills Mori Tower, 19F.
6-10-1 Roppongi
Minato-ku, Tokyo 106-6119
Tel: 03-5775-3300; Fax: 03-5775-0123

Committee Chairmen Representative

Karl Hahne

President & Representative Director, Hafele
Japan K.K.
14-17 Kami-shinano
Totsuka-ku, Yokohama 244-0806
Tel: 045-828-3117; Fax: 045-828-3119