

FIRST MILESTONE ACHIEVED

*The EBC Report on the
Japanese Business Environment*

2017



EUROPEAN BUSINESS COUNCIL IN JAPAN
THE EUROPEAN (EU) CHAMBER OF COMMERCE IN JAPAN

First Milestone Achieved

**The EBC Report on the Japanese Business Environment
2017**

**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

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The European Business Council (EBC) is the trade policy arm of the 18 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.

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Messages





Message from the Chairman

Welcome to “First Milestone Achieved”, the 2017 Report of the European Business Council in Japan (EBC).

This has been an exciting year for EU-Japan relations. After more than four years of negotiations, the leaders of Japan and the EU were able to announce in July that they had agreed in principle to an Economic Partnership Agreement (EPA). While work was still needed to finalise some chapters, the two sides confirmed the EPA would boost mutual trade by improving market access for goods, services and investment; open up opportunities in public procurement markets; remove non-tariff barriers; and protect Geographical Indicators and Intellectual Property Rights.

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 and medical devices. The result should be more 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. 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 us, this is the most important phase because, in the end, an Agreement is only as good as its results. 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.

Yet much has still to be done before the EPA comes into effect and its benefits can be fully enjoyed by the economy, business and consumers. The EBC will closely follow developments and actively monitor how the Agreement is ultimately implemented on the ground. No doubt this will be a major focus of EBC reports in the years ahead.

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 individual chapters of this Report reflect the Committees’ latest findings and proposals to make Japan a more open and competitive place for all business.

We in the EBC are committed to helping the EU and Japan reach new levels of mutual trade and economic growth. We approach 2018 with new optimism that the authorities on both sides are working for these same goals. Finalising the EPA is the first milestone achieved: we look forward to many more.

Danny Risberg
Chairman, European Business Council in Japan
European (EU) Chamber of Commerce in Japan
(Chairman, Philips Japan, Ltd.)

Message from the Executive Director

The European Business Council in Japan (EBC) is pleased to present “First Milestone Achieved”, our 2017 Report on the Japanese business environment.

This is the first EBC Report since the announcement in July that Japan and the EU had agreed in principle to an Economic Partnership Agreement (EPA). News of this significant milestone in EU-Japan relations was warmly welcomed, especially by the EBC, which has long campaigned for the removal of the many tariff and non-tariff measures undermining mutual trade and investment. Indeed the EBC specifically called on the EU and Japanese authorities to go beyond the boundaries of traditional free trade negotiations, to secure an agreement sufficiently comprehensive to eliminate all major barriers to trade. For more than four years, EBC expert Committees worked hard in support of the negotiations, providing detailed information on each of the issues affecting their sector of business. While the final text is still awaited, the EBC is encouraged to hear that, as soon as it enters into force, the EPA will remove more than 90 per cent of all tariffs applied to EU goods imported into Japan, ease product registration requirements, open up markets previously inaccessible to EU companies and promote fair competition. These are vital steps towards the goal of enabling the EU-Japan economic relationship to achieve its full potential.

Equally, the EBC is clear that the EPA, though ambitious, does not address all the issues holding back EU companies in Japan. Work will therefore continue in the EBC Committees to bring these issues to the attention of the authorities and to work for their solution. The Committee chapters of this Report are filled with examples and recommendations of what needs to be done to make the business environment in Japan fairer, more competitive and more efficient, in the interest not just of companies but, ultimately, of the Japanese consumer.

My thanks are due to each of the EBC’s Committees for their valuable contributions to the overall work of the EBC and to this Report in particular. I should also like to thank the EBC Policy Director, Bjorn Kongstad, for once again coordinating the many contributions and for providing his helpful introduction and overview.

The EBC greatly appreciates the continuing support of its stakeholders, especially the European National Chambers of Commerce and other business organisations represented in Japan. We should also like to thank the Delegation of the European Union to Japan and the European national embassies in Tokyo for their unique insights and guidance. Finally, we 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 applauds the signing of the EU-Japan EPA. It is a first – and major – milestone on the road to realising the full potential of EU-Japan trade and investment relationship. Yet we are acutely aware that many more milestones lie ahead before that goal can be reached. So while we celebrate, the work of the EBC continues unabated. First milestone achieved: on to the next!

Alison Murray
Executive Director
European Business Council in Japan
European (EU) Chamber of Commerce in Japan



Introduction



INTRODUCTION

At last, some good news: after years in the doldrums, EU-Japan trade and investment may be about to take off. An Economic Partnership Agreement (EPA) is finally on the table and, at the same time, Japan is getting to grips with much needed reforms. The business environment is looking up!

It has to be said that, so far, change has been patchy, from significant in some areas, to non-existent in others. If, however, the EPA wins the necessary support and is implemented on time and if Japan's reform plans actually deliver on their promises, then there will be much to celebrate.

The EPA is the first major milestone. It has taken more than four years of negotiations but finally both the EU and Japan seem ready to commit to a new economic relationship, which will promote free and fair trade between two of the most important global economies. Japan is already the EU's sixth most important trading partner worldwide, with the value of exports amounting to 58 billion euros for goods and 28 billion euros for services. While full details have yet to be published, we know the European Commission expects the Agreement to result in an overall increase in EU exports to Japan of between 16 and 24 per cent. Importantly, as soon as it goes into effect, these exports will enter Japan free from most customs duties, which currently increase costs by 1 billion euros every year. Moreover, the deal will improve market access, open up public procurement and remove many of the non-tariff measures that hinder bilateral trade. It will also protect intellectual property rights and the geographical indications that distinguish many European regional food and drink products. European companies will now have the chance to compete on a level playing field in the Japanese market.

The EPA is expected to benefit an array of EU business sectors, from pharmaceuticals and medical devices to food, chemicals and transport equipment. Yet it is not a one-sided deal: it is a key pillar in Japan's growth strategy and both the EU and Japan believe it will enhance their economies and create more jobs. Crucially, consumers will be the first to gain, through faster access to a wider range of goods at competitive prices.

The EBC was, from the start, a strong supporter of the EPA negotiations and many EBC expert committees have worked hard to provide information and ideas to support the process. The individual chapters of this report reflect what they see as priorities for the final agreement, including:

- Mutual recognition of standards, product certifications and marketing authorisations, and /or adoption of international standards;
- Removal of non-tariff measures, such as unnecessary costs and bureaucracy;
- Fair competition and equal treatment of all companies, domestic and foreign;
- Fair and open tenders for public contracts;
- Better conditions for foreign direct investment.

For EU business in Japan, the success of the EPA depends on whether it addresses these priorities and delivers concrete results on the ground. This means it must be consistently and robustly implemented on time and in good faith: there is no point in removing barriers, only to replace them. Consequently, the EBC will be devoting considerable energy to monitoring the progress of the EPA, not only as it works its way through the political process but also, ultimately, as it enters into effect. The achievements of 2017 represent a first, crucial milestone, but there are many still to come.



Meanwhile, it is worth remembering that the EPA, even when implemented, will not address all the issues holding back the business environment in Japan. For many companies and sectors, progress will continue to depend heavily on roll-out of the Government's broader growth strategy, also known as Abenomics. After initially focussing on monetary policy and fiscal stimulus to keep the economy out of recession, the emphasis has at last turned to structural reform and hence the prospect of truly sustainable improvement.

The economy has enjoyed its longest run of continuous growth for more than a decade and unemployment has fallen. On the other hand, there is as yet no sign of inflation rising to the target two per cent, productivity and wages remain stagnant, and companies are reluctant to invest. There is still much to be done!

Healthcare is an example of a sector identified by the Japanese Government as offering excellent prospects for growth and even global leadership. The EBC has welcomed its initiatives to encourage and reward innovation, such as the streamlining of approval processes to give faster access to leading-edge products, and price reimbursements that recognise the cost of bringing such products to market. Yet additional and irregular repricing exercises, and the possible revision of the Price Maintenance Premium originally introduced to promote the development of new drugs, threaten to undermine this progress. Further details of these and many other issues, as well as recommendations for how they can be resolved, can be found in the committee chapters of this report.

Abenomics has also targeted the energy sector, with reforms aiming to ensure stable supply, boost competitiveness and increase environmental sustainability. Full liberalisation of the retail market for electricity was achieved in 2016, and the legal unbundling of the transmission/distribution sector will be complete by 2020. However, the EBC believes the Government is falling behind in respect of its longer-term objectives, especially in the development and use of renewables such as wind and solar energy, which will be essential for Japan to reach its emissions targets.

Increased tourism is another aim of the Government's growth strategy and significant sums are being invested to promote Japan and extend tourist itineraries beyond the major hubs. The EBC supports these efforts but believes it will not be possible to meet the expected demand for inbound travel, including for the 2020 Tokyo Olympics, if outbound tourism is not also encouraged. Action is urgently needed to address problems at Japan's main international airports, such as high fees and inadequate infrastructure, which undermine the development of profitable routes.

More broadly, Abenomics has led to a number of welcome measures aimed at improving the general business environment and encouraging Foreign Direct Investment (FDI). Among those highlighted in this report are:

- New Corporate Governance and Stewardship Codes, as well as Board of Director guidelines, which have increased transparency and investor confidence in many Japanese listed companies.
- A reduction in the overall effective rate of corporation tax from 35.6% to 31% for large companies in metropolitan areas and to 35% for SMEs.
- Promotion of Tokyo as a global financial centre.

Nevertheless, none of these measures has been enough to raise FDI to the levels achieved by other advanced economies, and Japan is still a long way off its target to double its FDI stock by 2020. This report identifies numerous reasons why potential overseas investors are deterred from committing to Japan, among them the fact that much business regulation remains overly complex; important rules and guidelines are available only in Japanese; transparency still trails behind other developed markets; and M&As are still difficult to achieve.

Similarly, Government efforts to boost productivity have met with mixed success. By 2016 there were on average 1.9 million more people employed in the workforce than in 2012, and of these, 1.5 million were women – a vital improvement in a country faced with a shrinking and ageing population. However, the EBC believes that the country's tax system continues to discourage dual income families, and childcare provision remains inadequate. Moreover, despite a helpful new visa and residence permit system, attracting and retaining overseas staff is still a challenge, not least because work permits often depend on unnecessarily high levels of qualifications and experience and financially punitive inheritance tax laws have been extended to apply to longer-term resident foreigners.

The EBC recognises the success of Abenomics in overcoming deflation and promoting sustained (if still modest) economic growth. These are important steps in setting Japan on course for longer-term prosperity. Yet further and more robust implementation of structural and regulatory reforms is needed if such prosperity is to be maintained. The EU-Japan EPA could and should make a significant contribution to this effort – again, if it is robustly implemented – but on its own, it is not enough. So while a first and important milestone has been achieved, the EBC urges the Prime Minister and his Government to continue work on all fronts to transform Japan's economic prospects for decades to come.

The EBC trusts that the ideas and recommendations in this report will prove a positive contribution to the thinking of the Government of Japan, the 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, 27 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.

Business

Fundamentals

Financial reporting
Intellectual property
Legal services
Retail & wholesale
Tax

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FINANCIAL REPORTING

Introduction

Japanese listed companies continued to make progress towards voluntary adoption of International Financial Reporting Standards (IFRS) in 2017, albeit at a slower rate than before. In its recent analysis, the Tokyo Stock Exchange referenced 154 companies, representing more than 30% of total market capitalisation, that have either already adopted or have decided to or are considering adopting IFRS. This represents only a small increase over the previous year, yet with an additional 233 Japanese listed companies still considering IFRS adoption, it is likely that this temporary slowdown is a result of re-prioritisation in 2017 towards implementation of new Board of Directors guidelines. These guidelines are intended to strengthen listed entities' corporate governance. In general, Japanese listed companies are moving closer to a more transparent corporate governance system, which is seen as a positive step by the wider analyst and stakeholder groups. However, Japan still has some way to go relative to the level of transparency observed in other developed markets.

The EBC welcomes the efforts of the Accounting Standards Board of Japan (ASBJ) to enhance the use of IFRS in Japan and we understand the creation of Japan's Modified International Standards (JMIS) was intended to support such efforts. However, in practice, use of JMIS among major Japanese companies has been limited. This is most likely due to the fact that JMIS requires very specific adjustments to IFRS, mainly with respect to the accounting treatment of goodwill impairment and Other Comprehensive Income, while the vast majority of IFRS accounting standards still need to be applied in full. Therefore, the benefits of applying JMIS might be viewed by potential users of the framework as being rather limited, with the result that introduction of JMIS has fallen short of its intended goal of encouraging broader use of IFRS.

In the meantime, challenges remain for multinational companies headquartered in Europe that have significant subsidiaries domiciled in Japan, because these subsidiaries will likely continue to report under local Japanese Generally Accepted Accounting Principles (J-GAAP), as published by the ASBJ for statutory reporting purposes, while having to reconcile to IFRS for reporting to their parent for group reporting purposes. Any move to reduce the administrative burden of reconciling between the two accounting standards through further application of IFRS would also improve the quality and transparency of the financial reporting process. Therefore, the EBC recommends that efforts be strengthened to encourage greater acceptance and application of IFRS and thereby improve the quality of reporting while also reducing the volume and complexity of reconciliations currently required between the two standards.

There is a range of options available to achieve this objective, from full application of IFRS or JMIS in the separate financial statements of foreign parent's subsidiaries, to further convergence between J-GAAP and IFRS. The EBC acknowledges that any effort in this direction would need to carefully consider Japanese corporate and tax laws since Japanese subsidiaries of European multinationals are required to adhere to local tax reporting rules and regulations, thereby necessitating adjustments in any event. Such subsidiaries often try to minimise these adjustments within the bounds of optimising their tax position, limiting resource commitments, and enhancing transparency. 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) when converging J-GAAP with IFRS and consider adjusting corporate and tax laws to facilitate financial reporting convergence, especially where close ties exist among the reporting regimes.

Following the issuance of IFRS 15 Revenue from Contracts with Customers and IFRS 16 Leases, and the introduction in May of IFRS 17 Insurance Contracts, the IASB's work plans indicate that it does not expect to issue any new standards for the next two years. The IASB's future work will most likely shift focus towards eliminating inconsistencies in existing standards, observing the practical application of IFRS and issuing adjustments to existing standards as necessary. This should give other accounting standard-setters the time and opportunity to re-assess their convergence projects, to come up with consistent interpretations of IFRS standards for local application, and to close gaps between local GAAP and IFRS where possible. The objective of the EBC remains to promote the convergence of financial reporting towards internationally accepted standards and to help clarify compatibility between different accounting frameworks.

Key Issues and Recommendations

■ Revenue Recognition

Yearly status report: some progress. In August 2017, the ASBJ issued an Exposure Draft on Revenue Recognition under J-GAAP, which in general closely follows the 5-step approach in IFRS 15. However, critically, the Exposure Draft includes a number of permissible alternatives that allow companies, for example, to adopt the currently wide-spread practice of recognising revenue at shipment date, for shipments within Japan. The EBC acknowledges the effort by the ASBJ to present a new and consistent revenue recognition model through release of this Exposure Draft and we understand that, by including the permissible alternatives mentioned above, the ASBJ's intention is to minimise any perceived negative impact on users in Japan resulting from introduction of the new Accounting Standard. However, there is a risk that, by allowing significant deviations from the IFRS 15 model, any practical application of the new standard in Japan will provide little benefit with respect to comparability and consistency, which are essential qualities of improved financial reporting.

Recommendation:

- The ASBJ should carefully evaluate the effects of the new revenue standard. If possible, all deviations from IFRS 15 should be eliminated to ensure consistent applicability and comparability in the EU and Japan. This should be possible given the delayed implementation date (proposed for annual reporting periods beginning from April 1, 2021) under J-GAAP, allowing time for Japanese companies to apply a standard that is aligned to IFRS 15 (scheduled to apply for annual reporting periods beginning on or after January 1, 2018).

■ Financial instruments

Yearly status report: no progress. While the EBC notes many similarities between the accounting standards of financial instruments under IFRS and J-GAAP, there is one key area where further alignment is recommended. Under J-GAAP, certain securities such as unlisted equity securities are generally recognised at historical cost. The EBC recommends that all investments in equity securities be measured at fair value, as is the case with IFRS. Changes in fair value would be recognised in Other Comprehensive Income for investments not held for trading, similar to the treatment of debt securities under J-GAAP and the available-for-sale category under IFRS. A comprehensive analysis should also consider new accounting guidance under IFRS 9. The EBC believes that the valuation of all securities at fair value improves the relevance and transparency of financial statements, providing stakeholders with a useful assessment that facilitates decision making with respect to deployment of balance sheet items. The EBC expects that aligning the accounting treatment under J-GAAP with IFRS will yield efficiency gains for issuers who need to prepare financial statements under both regimes. The EBC notes that JMIS does not include an exemption for the measurement of unlisted investments in equity instruments.

Recommendation:

- Japan should align J-GAAP with IFRS to require all equity investments to be accounted for at fair value.

■ Property, Plant & Equipment (PPE)

Yearly status report: no progress. Many companies use tax regulation to determine residual value and useful life of PPE for J-GAAP reporting. Depreciation methods must be reasonable and applied systematically every year. In practice, a significant number of J-GAAP filers use the double-declining method, which avoids reconciling differences between financial and tax reporting and generally achieves greater tax deductions in earlier years. However, it creates differences with IFRS, which generally prohibits using this method as default and uses residual life and useful life assumptions that reflect usage patterns, rather than tax tables. The EBC recommends the IFRS approach, to provide readers of financial statements with a more accurate reflection of usage patterns and related costs, and to enable companies to maintain existing tax advantages, even if this results in a new reconciling item with tax reporting.

Recommendation:

- Japan should align accounting for PPE under J-GAAP with IFRS, while considering implications for taxation.

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INTELLECTUAL PROPERTY

Introduction

In Japan, luxury brand products reach consumers via one of two sales channels: either regular distributors or dealers in parallel imports. (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 products makes them reluctant to engage in e-commerce using any other distributors. Nevertheless, online marketing and sales of their products in the form of allegedly authentic “parallel imports”, mingled with counterfeits of both their brands and also top brand electric appliances, are growing. As in many other countries, the top producer and exporter of counterfeit goods distributed in Japan is China, accounting for 91.9% of all fake goods flowing into the country.

In 2016, more than 400,000 fake items were stopped at the border by Japan Customs. Given that it is impossible for Customs to examine all imported goods, this number is probably only a fraction of the total volume of fakes. As the purchase of counterfeits for “personal use” is not forbidden in Japan, some fake items cannot be stopped even if detected.

Until recently, many Japanese consumers purchased fake items knowingly. However, the main issue today is how to help them avoid fraudulent websites (most of them managed overseas), which deceive them either into buying counterfeits despite their wish to purchase the genuine brand, or into buying products that will never be delivered after payment. The Government is now studying the feasibility of blocking access to websites fraudulently selling counterfeits.

Relevant ministries and agencies are making considerable efforts to protect Intellectual Property Rights (IPR). The Consumer Affairs Agency has set up a Cross-Border Consumer Center to help those who have unwittingly purchased counterfeits. 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 counterfeits. Yahoo!, for example, is endeavouring to clean up its websites by regularly exchanging information with brands, via intellectual property rights-holders’ associations, on counterfeits and criminal dealers. Rakuten is also actively cleaning up its shopping website. When a product posted on Rakuten is suspected of being a counterfeit because, for instance, of a particularly low price or information received from a consumer, the operator makes a test purchase of the item to verify its authenticity with the cooperation of the relevant brand. If the item turns out to be counterfeit, the posting dealer is banned from the website with immediate effect.

As for the fast-growing flea market internet sites, some have focused on eradication of counterfeit goods and have obtained results that are comparable to those of existing auction services. On the other hand, others have fallen behind and still allow the distribution of large quantities of counterfeit goods. In view of this, the EBC welcomes the decision taken by the Ministry of Economy, Trade and Industry to establish a forum enabling Consumer-to-Consumer and Business-to-Consumer sites to exchange information and best practices on successful countermeasures against counterfeit goods. It is important that new flea market sites also join this forum.

Finally, concerted efforts are being made by different sectors in Japan to set up a framework to eliminate counterfeits. Some of their approaches are more advanced than those applied in Europe or the USA. However, problems still remain. Specifically, partnerships with internet service providers (ISPs) need to be developed to build a proper system to protect consumers and control the sale of counterfeit items “for personal use”. The definition of “for personal use” needs to be tightened and made legally binding. This should solve the issue of increasing sales 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: some progress. While major internet shopping portals have succeeded in reducing the proportion of counterfeit products on their sites to less than 1%, some shopping websites have only recently decided to take the necessary measures and so the share of counterfeits of certain brands on their sites still remains relatively high. The delay in taking action by shopping websites can be explained partly by the fact that most uploaded image data are not adequate for determining whether the items for sale are counterfeit or not, and it is often necessary to make test purchases to verify authenticity. Additionally, countermeasures against counterfeit products are not yet effective in respect of flea markets sites, where counterfeits may sometimes account for as much as 99% of the total merchandise being sold. Moreover, in general, initiatives against websites selling counterfeits, fraudulent websites and spoof websites are progressing far too slowly. Measures already put in place by the relevant Japanese ministries and agencies include 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, but these have not yielded fundamental results. Given that consumer interest in and public awareness of the need to protect IPR 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 branded goods sold on the internet, with a view to eliminating counterfeit goods from shopping websites. In addition, the Government should encourage ISPs, 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 websites selling counterfeits, fraudulent websites, and spoof websites hosted by foreign servers, for example: blocking access to them or removing them from search engines.
- The Government should continue to encourage all ISP companies to join the fora where ISP companies and right holders discuss measures against counterfeit products. This is imperative to achieve the objective of further combatting counterfeit goods.

■ Tighter definition of “for personal use”

Yearly status report: no 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 waste manpower and time detecting counterfeits only to find they have no choice but to grant import permits. If this loophole cannot be closed, at the very least the definition of “personal use” should be tightened. 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) and the maximum number of items that may be presumed to be “for personal use”. Given that the resale and transfer of counterfeits remain lawful if they are for “personal use”, relevant laws and regulations must be improved to prevent such dealers from being able to claim that the goods are for their personal use.

Recommendations:

- The importation and purchase of counterfeits, even for “personal use”, should be controlled under the law.
- If the importation and purchase of counterfeits “for personal use” cannot be prohibited by law, the definition of such use should be tightened to address the current situation where importation of unlimited numbers of fake products is permitted so long as they are declared to be “for personal use”.

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LEGAL SERVICES

Introduction

The EBC's recommendations in respect of legal services in Japan remain the same as last year, because no concrete changes have been made to date.

Further to the Regulatory Reform Plan issued by the Prime Minister's Cabinet and approved on 24 June 2014, the following deliberations took place in respect of regulations applicable to *gaiben* (foreign-qualified lawyers):

1. A study group was set up under the auspices of the Ministry of Justice to discuss the *gaiben* system. With the increase in demand for international legal services, in 2015 this Study Group devoted six months each to (1) reviewing the requirement for foreign-qualified lawyers to have specific work experience in order to register as a *gaiben*, (2) reviewing the current limitation on *gaiben* and *bengoshi* (Japanese lawyers) establishing a *hojin* (corporation) together.

The EBC, together with the American Chamber of Commerce in Japan and the Gaiben Association, was invited to present its views on 1(1) and 1(2) mentioned above in May 2015 (the third Group session) and September 2015 (the sixth Group session), respectively. In July 2016, the Study Group, together with the *Nichibenren* (Japan Federation of Bar Associations), issued its report, which makes the following recommendations.

- The current three-year work experience requirement (two years of which must be experience gained outside Japan) should be changed to either (i) three years (one year of which must be experience gained outside Japan) or (ii) two years (one year of which must be experience gained outside Japan).
 - It should be permissible in law for *gaiben* and *bengoshi* to establish a *hojin* (corporation) together.
2. Transparency of the *gaiben* registration system: The Ministry of Justice began to consider this topic in 2015. A forum has been set up for discussions between the Ministry of Justice and the *Nichibenren*, taking into account opinions from registrants as necessary, with a view to making the registration process and timing more transparent and to improving user-friendliness for registrants.
 3. Making the *gaiben* registration process simpler: A separate forum has been set up for discussions between the Ministry of Justice and the *Nichibenren*, taking into account opinions from registrants as necessary, with a view to making the registration process simpler and faster.

The EBC welcomes the recommendations made by the study group in July 2016 and eagerly awaits changes to the law to reflect them. 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 also take a close interest in the roll-out of the recommendations, not least because the study group's credibility and 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 July 2016 Study Group recommendations. 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 25 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 July 2016 Study Group recommendations. 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 new legislation does 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.

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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.

The EBC believes that, once implemented, the EU-Japan EPA will further improve Japanese consumers' access to European offerings in the retail and wholesale sectors. It is, however, of the utmost importance that the agreement is implemented as mutually agreed by the Japanese and EU authorities. Excessive or inappropriate regulation risks making products more expensive and can severely limit their access to the market. In particular, harmonisation is the key to a continued prosperous retail and wholesale market.

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 EBC hopes that the HACCP (Hazard Analysis and Critical Control Point) system, which the Japanese Government has finally decided to roll out in Japan, will be duly and transparently implemented, without introducing requirements unique to Japan.

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 therefore welcomes the implementation of a positive list system for utensils, containers and packaging (UCP) and the opportunity this offers to increase consumer choice in at least this area.

Recommendations:

- MHLW is working on details of the positive list system for implementation. The EBC expects Japan to study the UCP import process in the EU, where the positive list system is already implemented, in order to establish a flexible framework that minimises the heavy burden that importers currently bear.
- 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 Household Goods Quality Labelling Act was finally revised in March 2017, but its 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, which is not transparent and lacks both a legal basis and bright-line rules, should be abolished.

■ Unclear implementation of HACCP (Hazard Analysis and Critical Control Point)

Yearly status report: no progress. HACCP has been implemented in many countries, including the EU Member States. It is now a Japanese policy target but the timeline is unclear, creating uncertainty in the retail and wholesale industry.

Recommendation:

- Japan should clearly state the scope, timeline and steps that will be taken toward complete implementation.

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TAX

Introduction

The EBC welcomes the Japanese Government's continued efforts to stimulate the economy and 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. However, in contrast to this, the Government has again postponed (this time to October 2019) its plans to help restore the country's finances through an increase in the consumption tax rate from 8% to 10%. As a result, 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 Abenomics 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. While the EBC welcomes the 2017 tax reform, which exempts short- and medium-term residents (those who have been resident in Japan fewer than ten out of the last 15 years) from Gift and Inheritance Tax, the treatment of long-term residents has worsened significantly. Foreigners who have spent more than ten of the past 15 years in Japan will now continue to be subject to Japanese Gift and Inheritance Tax on all their assets, regardless of location, for up to five years after they depart Japan. It is questionable whether the extraterritorial application of the Gift and Inheritance Tax to foreign nationals no longer residing in Japan is permissible under international law. In any case, because of this, 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 (including the Czech Republic, Finland, Hungary, Ireland, Italy, Luxembourg, Poland, Portugal, Spain and Sweden) 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. Bilateral trade and investment would further benefit if the EU-Japan EPA were to enable employers' and employees' contributions to social security systems within the EU and Japan to be treated as tax deductible on a mutual basis.

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

■ Research and Development (R&D) tax incentives

Yearly status report: little progress. Innovation-intensive industries are a key driver of growth and employment. R&D 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 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. 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 loss-making, and so is of little benefit to many 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 start-up companies).

■ Corporate restructuring

Yearly status report: no progress. The current tax treatment of cross border and triangular mergers is, in practical terms, a barrier to those market entrants who have no established business in Japan but aim to use their own shares to acquire a Japanese company. For example, the current rules do not permit tax deferral in respect of stock swaps between foreign and domestic companies, even if the transaction is carried out using a Japanese special purpose company, and this has a stifling effect on inward investment. In addition, triangular merger taxation rules make reference to so-called "paper companies", although a definition of a paper company has not yet been released. The same lack of a definition is also a concern for multinational groups with overseas affiliates and therefore subject to anti-tax haven rules, as those rules also mention but do not define a paper company.

Recommendations:

- Tax deferral should be permitted in respect of share-for-share exchanges, including those involving foreign companies with no previous operations in Japan.
- Rules and regulations underpinning corporate restructuring laws should be further simplified and clarified to reduce costs and limit the tax authorities' discretion to interpret undefined key concepts.
- A definition of a paper company should be provided.

■ 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 to file tax returns no later than two to three months after the end of the calendar or fiscal year. This deadline causes very high compliance and overtime costs and puts unreasonable pressure on companies, staff and associated service providers. In Europe and elsewhere, an average period of nine months is allowed, and sometimes up to one 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 but these have proven impractical and have yet to be adopted by many Japanese taxpayers.

Recommendation:

- Tax filing periods should be extended to one year without a formal application process, to reduce the current unduly high cost of tax compliance. Any negative impact on public finances could be avoided as long as the tax rules continue to allow prepayments and impose interest if insufficient prepayments are made.

■ 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 subject to Gift and Inheritance Tax, and continues to be so for up to a five-year period after their departure from Japan. Only one other nation imposes such extraterritorial taxation upon foreigners and it has a wider inheritance tax treaty network than Japan, which provides relief for many expatriates. 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.

Recommendations:

- 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.
- Repeal the extraterritorial taxation of former long-term residents.

■ 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.

■ Tax treaties

Yearly status report: progress. Japan recently concluded and ratified a new tax treaty with Germany, as well as reaching an agreement with Austria and an agreement in principle with Denmark. However, its treaties with 19 other EU Member States still need to be renegotiated. The EBC welcomes treaties that include the exemption of withholding tax on royalties and qualified dividends and interest.

Recommendations:

- The Government should review all current tax treaties with EU Member States.
- 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.
- The EU-Japan EPA should include an arbitration clause to ensure that double taxation is effectively eliminated where the multilateral instrument does not apply and the applicable tax treaty does not resolve double taxation.

Financial Services

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ASSET MANAGEMENT

Introduction

On August 18, 2017, the Bank of Japan published its “Flows of Funds” report comparing the structure of household financial assets in Japan, the US and the Euro area.

The report illustrates again that in Japan, more than 50% of household financial assets are held in cash and deposits: 51.5% as of March 2017. The corresponding figure for the US is 13.4% and for the Euro area 33.2%. The level of cash at banks continues to grow significantly in Japan, and a shift to financial products is not yet visible.

Moreover, funds represent only 5% of financial assets held by households in Japan, compared with 11% in the US and 9.2% in the Euro area. In spite of all the incentives and new schemes (for instance the Nippon Individual Savings Account - or NISA- and *iDeCo*) put in place by the Japanese authorities to promote the shift “from savings to financial asset building ” (recently renamed as “realisation of stable financial asset building” for households), the retail fund market has suffered sharp drops in gross sales for the past two years, and has shown few signs of recovery in 2017.

It is however expected that asset management solutions will gain momentum in the retail space, and this will be in the best interest of Japanese households. In particular, the industry, together with distributors, needs to find the key to attracting first time investors to fund investing. The EBC proposes two initiatives to help with this in the recommendations on the next page.

The Japan Stewardship Code was revised in June 2017, three years after its launch, and its impact is becoming more visible to institutional investors, but not to retail investors, who remain net sellers of stock. Best practices from Europe could be useful guides to achieving further progress, both in terms of stewardship activities and product development for retail investors.

The EBC has been advocating for the past two years that the current operational platform is a handicap for the competitiveness of Tokyo as a global financial centre, particularly:

- when managing global portfolios from on-shore vehicles (retail funds or institutional mandates), and
- when trying to participate fully in future in cross-border schemes such as the Asian Regional Fund Passport.

The EBC therefore welcomes the initiatives of the Tokyo Metropolitan Government (TMG) to position Tokyo as a “Global Financial City”, as per its interim Report “Policy for Global Financial City Tokyo”, published in June 2017. The report highlights ambitions to facilitate developments in areas such as Green Finance and Fintech. The report also points out Tokyo’s competitive weaknesses such as the limited talent pool and high taxation.

Key Issues and Recommendations

■ Encouraging Japanese households to invest for the long-term

Yearly status report: 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, but households have little or no access to such services. Moreover, while platforms such as NISA, Junior NISA and DC (Defined Contribution) are proving popular, all suffer from low annual ceilings with respect to tax savings.

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.
- The Japanese Government should foster and publicise provision of IFA (Independent Financial Adviser) services – with services provided in-person or online – to help boost household investments.

■ Impact of global regulations for companies in Japan

Yearly status report: new issue. Global regulations, including the European Market Infrastructure Regulation (EMIR) and Markets in Financial Instruments Directive (MIFID II), have had a stronger impact than expected on the asset management industry in Japan. The EBC urges the authorities and financial industry associations to provide guidance to the domestic industry on how to adapt to these types of development and other global trends.

Recommendation:

- The Japanese authorities and/or relevant associations should provide guidance to Japan’s asset management industry on how to adapt to global regulations and trends.

■ Global competitiveness of Tokyo as an operational platform

Yearly status report: new issue. The asset management industry is global by nature: the client base and the investment arena are global, and the impact of global regulations is more and more pronounced. The industry in Japan is suffering from the limited pool of financial professionals able to perform their duties in fluent English. TMG’s initiatives to nurture highly skilled financial professionals should facilitate development of the additional resources in Tokyo needed for the development of global activities. The EBC therefore welcomes TMG initiatives to position Tokyo as a “Global Financial City”, as per its interim Report published in June 2017, but would like to see more attention given to the competitiveness of operational platforms. The Report highlights ambitions to facilitate developments in areas such as Green Finance and Fintech. The Report also identifies Tokyo’s competitive weaknesses, such as the limited talent pool and high taxation.

Recommendation:

- Pay more attention to improving the competitiveness of Tokyo’s operational platforms, including such matters as taxation levels and the relatively limited “global-minded” talent pool.

BANKING

Introduction

Japan's relative prosperity has decreased considerably in recent years and, although Japanese consumers have continued to save, their return on capital has been the lowest in the industrial world. On the other hand, Japan has weathered the various financial crises that have occurred during this period much better than many other countries; Japanese capital markets were strong enough to raise substantial funds even during 2009 and 2010. Japan thus remains one of the largest financial markets in the world with high savings rates. European banks have much to offer this market, bringing not only global networks but also valuable expertise in cross-border M&As.

After some years of waning attractiveness as a financial centre, Tokyo has started to bounce back. It is well known for the strength of its capital pool and for three years running has been ranked fifth in The Economist newspaper's Global Financial Centre Index (GFCI). Both the Central Government and the Tokyo Metropolitan Government are now promoting Tokyo as a financial centre and the EBC strongly supports this ambition. However, there is little doubt that much of Tokyo's newfound success is due to "Abenomics", which has had its biggest impact on the stock market, with the Nikkei 225 index rising dramatically since the programme started in early 2013. If Tokyo is to continue to thrive, it is crucial to convert this short-term gain into sustainable growth by introducing meaningful structural reform.

So far Prime Minister Abe's reform plan for the financial sector has not impressed. While the banking sector has seen more movement in capital, especially in the area of securities, lending and projects are still underperforming and the pace of financial innovation remains slow. The current absence of inflation, or at most very low inflation, has created a low-interest market and the economy as a whole is suffering from low levels of Foreign Direct Investment. The EBC therefore believes a more radical approach is needed to build on Japan's existing strengths and realise its true economic potential. To achieve this, Japan cannot rely on monetary policies alone. The banking sector in particular needs to be able to keep pace with changes in the global industry and recruit talented personnel, including from overseas, which current rigid immigration and labour laws make difficult to achieve.

The EBC welcomes amendments to the mandate of the Government Pension Investment Fund (GPIF) and the shift from almost exclusively low-yield investments to more advanced products with chances of a higher return. Furthermore, the introduction of a new corporate governance code and the stewardship code should make Japan more attractive to investors. Early signs indicate that Japanese corporations are now thinking more about return on equity and that consequently, yields have improved. However, it is of the utmost importance that planned reforms are robustly implemented to ensure that external directors are truly independent, and the appointment process is transparent.

Another pressing issue is fair disclosure. Fair disclosure lays the foundation for a market place where company-specific information is properly distributed at the same time to all categories of investors, thereby protecting consumer interests and helping to avoid insider trading. Unfortunately, in Japan, disclosure of such information often occurs through media channels some days before any official public announcement, even though such practices are not officially sanctioned. The EBC, therefore, believes more effort is needed to clarify the responsibilities of all parties involved, which would be in line with the Japanese Government's policy on improving corporate governance.

While the firewall between different financial activities within the same financial group has been liberalised (for example, enabling increased double-hatting) there is still a ban on information sharing. The EBC believes this is unnecessary and a conflict management regime combined with appropriate inspection/supervision practices should suffice. This would be in alignment with other principle-based regulations, which the Financial Services Agency (FSA) has introduced for other regulatory frameworks.

Key Issues and Recommendations

■ Tokyo as a financial centre

Yearly status report: slight progress. The introduction of Abenomics and the policies of current and former Tokyo Governors have moved Tokyo closer to becoming a global financial centre. However, although Tokyo has some of the necessary traits, such as a vast capital pool and a certain regional pull for financial services, there are still many obstacles to achieving this goal. While the EBC appreciates the changes in the mandate to the GPIF and the improved governance guidelines, it believes Tokyo is still held back by its lack of “internationalisation”, small asset management sector and relatively high taxes. It is important that a holistic approach is taken and that central and regional governments work together for Tokyo to be successful, in the interest not only of the city itself but also of the country as a whole.

Recommendations:

- The EBC believes that there is a need for better cooperation between the central Government and Tokyo Metropolitan Government to realise the goal of Tokyo becoming a global financial centre.
- Japan should do more to incentivise talented people to come to Japan.
- Japan should introduce more flexible labour legislation.

■ Fair disclosure regime

Yearly status report: progress. The Government of Japan has introduced a legislative framework for fair disclosure of company-specific information, but this has yet to be implemented. The EBC believes that rigorous implementation is urgently needed to stop information being leaked to select parties ahead of its official release.

Recommendations:

- The Japanese authorities should implement the legislation on fair disclosure.
- The authorities should at the same time ensure that a robust sanction system is in place to discourage the circulation of preview reports.

■ Banking agency system

Yearly status report: good progress. The banking agency system used to require Japanese branches of European banks to apply for a special business licence each time they introduced new banking services provided by another banking entity, even if that entity was a branch of the same financial group located outside Japan. This had a negative impact on cross-border services, in which the Japanese arm of a global financial group supports its Japanese private or corporate clients in opening accounts abroad and introduces its Japanese clients to global cash management. While the EBC appreciates the positive results achieved by the FSA, which have made the system more workable by introducing group approvals, more information is needed on the administrative procedures required to obtain these approvals. It is of the utmost importance that these procedures are easy to use and that the administrative burden imposed on the applicant does not outweigh the actual benefits.

Recommendations:

- The FSA should further clarify and streamline the application process for banking agency licences.
- The FSA should make certain that the group approval system is easy to use and does not impose a heavy administrative burden on the applicant.

■ Information sharing

Yearly status report: no progress. While the firewall between different financial activities within the same financial group has been liberalised (for example, enabling increased double-hatting) there is still a ban on information sharing. The EBC believes this is unnecessary and that a conflict management regime combined with appropriate inspection/supervision practices should suffice.

Recommendation:

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

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INSURANCE

Introduction

In recent years, the Japanese authorities have been gradually harmonising laws and regulations relating to the domestic insurance market with global standards. For example, the amended Act on the Protection of Personal Information (2015) significantly reduced the differences between EU and Japanese privacy law, and Japan's Financial Services Agency (FSA) has introduced a concept of fiduciary duty similar to the concept of customer best interest and consumer protection in other countries. 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 to facilitate a truly open and competitive insurance market capable of meeting consumers' needs.

The EBC has, in previous reports, repeatedly drawn attention to issues concerning Japan Post. Japan Post Insurance (JPI) is currently conducting its life insurance business as part of Japan Post Holdings where, despite an Initial Public Offering (IPO), the Japanese Government continues to hold a majority stake. Unless this changes, Japan Post will continue to enjoy unfair advantages in the market and competition will remain distorted. It is therefore vital for the Government to comply with its obligations under the WTO General Agreement on Trade in Services (GATS) and sell its shareholding without further delay.

In response to the global financial crisis, the International Association of Insurance Supervisors (IAIS) was tasked by the G20 and the Financial Stability Board (FSB) to designate nine insurers as global systemically important insurers (G-SIIs). The FSB/IAIS advocate that such insurance companies maintain certain minimum capital requirements, adopt a market-based solvency measurement methodology such as Solvency II, implement certain risk management strategies, and develop substantial resolution plans. They also propose that national insurance regulatory bodies in each country increase information sharing with other regulators across borders. 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.

Overall, appropriate handling of issues such as the way Japan Post is privatised, bringing mutual aid cooperatives (*kyosai*) into the insurance framework under the FSA, streamlining the product approval process, and applying clear and consistent rules and regulations, would assist Japan's economic growth. This would also benefit the domestic financial services industry, Japanese consumers and Japan's ability to retain foreign investment.

Key Issues and Recommendations

■ Harmonisation with global solvency and other regulatory standards

Yearly status report: progress. The EBC appreciates the FSA's willingness to take a leadership role among international regulators and its work in the solvency area. 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 aimed at attaining convergence between Japanese and global solvency standards by establishing a roadmap, including timelines, for convergence with Solvency II. This is of the utmost importance so that all parties concerned, including private insurers, can prepare for the new framework.
- The market-based Solvency Margin calculation methodology should be further aligned with Solvency II.
- Japan should continue to fully participate in the development by the FSB/IAIS of enhanced regulatory measures for systemically important insurers and internationally active insurance groups.
- 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.
- The Government should consider reforming the Policyholder Protection Corporation when introducing Japanese Solvency II.

■ Product approvals

Yearly status report: some progress. The EBC appreciates the FSA's initiatives to improve the product approval process, and the setting up of a regular dialogue between regulators and insurance companies. The EBC also appreciates the information disclosed by the FSA on the key points in its approval process, which helps insurance companies to prepare for product examination. However, the product approval process is still sometimes lengthy in comparison with foreign markets, causing product development delays and making effective business strategy planning difficult. The EBC believes that faster product approval would be beneficial to not only insurers but also consumers, and would therefore further the FSA's aim of promoting the customer's best interest. Furthermore, while ensuring customer protection, the EBC encourages the FSA to introduce a "file-and-use" system and to present a plan for its implementation.

Recommendations:

- The FSA should look into how product approvals are conducted overseas. The EBC would be pleased to contribute expertise in order to make the research effort more efficient and effective.
- 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 work together with financial institutions and other private players on improving consumer literacy in respect of financial products.

■ Fair competition in bank distribution

Yearly status report: limited progress. As the importance of bancassurance increases in providing benefits to Japanese consumers, the EBC is concerned about the strong influence that Japanese insurance companies have over Japanese banks as their major shareholders. For example, in recent years, European insurance companies have brought a series of innovations to the Japanese market in the area of group credit life insurance and related products, providing valuable protection in case of critical illness and disability to Japanese mortgage borrowers. This business is now being copied by Japanese insurers and, while the EBC welcomes healthy competition in the marketplace to further benefit Japanese consumers, we believe there is a potential conflict of interest when

insurers sell these products to customers of the very banks they own. The EBC believes that it is part of each company's fiduciary duty to carefully monitor the situation to ensure that competition is based on the quality of products and services and capacity to innovate rather than on the shareholding relationship between insurers and banks, which is irrelevant to the Japanese consumer.

Recommendations:

- The FSA should further liberalise bancassurance with appropriate supervision over the level of sales commissions.
- As a first step, the FSA should allow banks to sell insurance to any company employee, regardless of the relationship between the bank and the company, and to use bank data.
- The FSA should carefully ensure that competition is based on fair comparison of offers, and is not biased by pre-existing shareholding relationships.

■ **Japan Post reform**

Yearly status report: some progress. Even with the IPO 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 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.

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 ensure that good corporate governance is in place for Japan Post Holdings, Japan Post Insurance and Japan Post Banks.
- 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.

■ **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 (Insurance Business Law Enforcement article 234, 1998 MoF Notification No. 238). The EBC fully acknowledges the reasons for this restriction as discussed at the Administrative Reform Committee (1997) and the Insurance Council (1992). The EBC considers, however, that the current rule could be a barrier for new entrants and may not be beneficial to Japanese consumers. Furthermore, the EBC believes there should be a public consultation on the possible regulation on commission disclosure, taking careful account of the impact on the social economy and consumers. The EBC hopes that the discussion on how to identify the right level of commission will be accelerated.

Recommendations:

- Taking into account emerging new technology and evolving insurance distribution, the FSA should review the Notification detailed above and 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.

■ **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. (For example, JA *Kyosai* is regulated by the Ministry of Agriculture, Forestry and Fisheries.)

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.
- Until this is achieved, *kyosai* and their respective competent authorities should apply the same standards and regulations as the FSA.
- 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**

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AIRLINES

Introduction

The volume of inbound air travel to Japan continued to grow in 2017. Working with airline partners, offices of the Japan National Tourist Organization (JNTO) around the world were successful at promoting tourist travel to Japan. In addition, efforts were made within Japan to improve infrastructure in order to ease access to regions beyond the large metropolitan areas. The EBC welcomes these developments and the resulting steady increase in tourist demand from Europe, and supports the Japanese Government's stated goal of reaching 40 million international inbound travellers by 2020.

Furthermore, demand for outbound travel from Japan to Europe increased in 2017, particularly on the touristic side. This reflects a return to "normal" tourist travel patterns and, in particular, recovery in demand for travel to France, after the dramatic downturn that followed the terrorist attacks of 2015 and 2016. Airline seat capacity, which was reduced between Japan and Europe in 2016 and into 2017, due to a downturn in overall demand, started to recover as of summer 2017. A further recovery in seat capacity is evident in the additional frequencies and deployment of larger aircraft types in the winter 2017/2018 and summer 2018 schedules of both European and Japanese airlines. 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 have to be ramped up for the Olympics. Business travel also continues to grow, with a forecast for further steady growth over the next few years, reflecting an increase in overall travel activity in preparation for the Tokyo 2020 Olympics, and the 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.

While European and Japanese airlines have added seats recently to accommodate increased passenger demand, each airline must evaluate the commercial value of flights and routes. Increased airport fees threaten to make operations unprofitable and could dampen airline willingness to add extra capacity, even if there is demand. Higher fees were recently introduced for Haneda Airport (HND). Fees for Narita Airport (NRT) are currently being negotiated via IATA (the International Air Transport Association). The EBC is concerned that further increases at NRT will damage the airport's commercial viability in the future, and the same could happen at HND. The EBC recommends re-evaluating and reducing the current high landing fees, navigation charges, airport terminal rent, airport terminal common usage fees, and parking fees. This could help to ensure further airline capacity expansion, which would in turn contribute to the ambitious goals for inbound tourism. Other regional airport hubs have reduced such fees to ensure that airlines do not decrease or eliminate flights in the short term.

The EBC continues to support the further opening of HND, so long as this is based on fair distribution of additional slots so that airlines can add new flights. 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. It may even prevent the expansion of seat capacity and flights overall.

Finally, 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 addition, 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: no progress. Operating costs at Japanese airports continue to be high, with no real relief in sight. While demand for outbound travel to Europe has recovered, it is the commercial viability of flights that determines the addition of capacity. The situation may worsen if the yen rises against the euro and travel costs in Japan (including for hotel accommodation) increase, causing a negative impact on inbound numbers. The risk is that airlines may temper growth at a time when it will be needed in the build up to the 2020 Olympics. 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 be lowered. 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, which have in some cases lowered fees to ensure that airlines retain capacity even in an uncertain market environment.
- 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 is against the implementation of the proposed new Tourism Promotion Tax as it burdens the airlines to collect it and raises costs for the consumers.

■ 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. The new air corridor at HND will enable a reduction in fuel consumption through a more direct approach, which will have a positive impact on the environment.

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 continue to be excessively 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.

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 the negotiations towards an EU-Japan EPA. A limited amount of information on the prospective agreement has been made public and, while no legal text is yet available, the EBC is cautiously positive. It is however important to state that the success of the agreement will depend on the actual result of its implementation. Removal of the Operational Safety Clause (OSC) and an increase in the number of cities required to use public tenders in railway-related procurement would be welcome steps. However, these steps must translate into real business opportunities for European companies. In the same spirit, all the work on harmonisation and recognition of European safety test results needs to be accepted by the Japanese railway operators - merely having the agreement of the Japanese Government is ineffective if the results are not recognised by the industry.

More than five years have passed since the Tohoku Earthquake, yet many railways remain damaged. Some communities are planning their provisional replacement with Bus Rapid Transit (BRT) systems, while others are still undecided about how to proceed. The EBC Railways Committee, with its particular expertise in urban planning and rail technology, believes that a Light Rail Transit (LRT) system should be introduced instead of BRT. The development of an LRT system would contribute to the well-being of people in an ageing and depopulated society. It would also revitalise commerce in the region.

Products that have already been tested and certified according to international standards will not even be considered by Japanese railway operators without further extensive, yet unnecessary, testing. (The only exception to this is products the operators have sourced themselves from specific manufacturers.) The EBC strongly requests the Japanese Government to combat this waste of time and resources 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 welcomes the EU-Japan EPA agreement in principle and the progress achieved to date 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 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 with the participation of the Japan Railway (JR) companies and other major Japanese operators 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 exempts railway procurement from the provisions of the GPA. The EBC understands that the EU-Japan EPA will open up railway related procurement to EU manufacturers no more than one year after the agreement enters into force. 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, issued by the three major JR companies, will result in more transparency and better access to technical specifications, as well as information on how to meet and exceed any set requirements. The strict adherence of the three JR companies to their voluntary codes of conduct remains a critical issue for EU suppliers and the Government needs to ensure full compliance with these codes.

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.

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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.

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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 7.6 billion mobile phone subscriptions globally and 4.6 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) is planning to introduce policy measures for handling SEP disputes, including the establishment of an administrative adjudication system with power to determine royalty rates. In the European industry's experience, FRAND licensing works and provides the necessary incentives for companies to continue investing in standards development, but it is important to understand that by definition, FRAND should be based on global portfolio valuations rather than country-by-country and patent-by-patent valuations. It is simply not feasible, or indeed sensible, for individual governments to develop policies determining royalties that are only applicable in their own country. In a global business environment, maintaining the global FRAND rate is crucial.

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 allocation of the 1,700MHz, 2,300MHz, 2,600MHz and 3,400MHz bands to address the increasing demand for mobile broadband. 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 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, regular radio performance checks at antenna or equivalent monitor ports, and the definition of unwanted emissions according to TRP (Total Radiated Power) should be carefully reviewed.

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

Yearly status report: new issue. Japan's SEP policy measures are of great interest and concern to the EBC because these could be used to disadvantage the European telecommunication industry, which is the major patent holder of the targeted SEPs. Moreover, any arbitrary decision by the JPO relating to SEPs and the royalty level in Japan could disrupt global FRAND licensing practices. It is noteworthy that the European Parliament reached an important decision on European standardisation on July 4, 2017, emphasising the balanced approach with transparent and efficient licensing practices.

Recommendation:

- The Government of Japan should consider the approach taken by Europe and, where possible, coordinate future activities. Japanese industry should follow similar practices to those introduced globally, rather than develop Japan-only solutions.

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LOGISTICS & FREIGHT

Introduction

European forwarding and express companies offer consumers the benefits of access to their worldwide logistics operations, but still face serious and significant regulatory challenges in Japan. Moreover, they struggle with Japan's high cost base, inadequate infrastructure, restricted aircraft operation time windows, 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 believes that, 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 work force, 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. A good example is promotion of non-proprietary "open" parcel lockers that minimise the number of failed deliveries, which has been positively received by both consumers and business.

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 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.

A further concern is the continuing plans of Japan Post to aggressively expand its activities, such as the e-Packet Lite service, while still enjoying preferential regulatory treatment. The EBC recognises the need for a universal service obligation to meet certain socio-economic goals. However Japan Post is benefitting from unfair competitive advantages in the express delivery market, where its Express Mail Service (EMS), a special value-added international express package, already accounts for 18% of the market. EMS is not subject to the strict regulations applied to private sector express services (as detailed on the following page), hence its expansion threatens further to distort competition and will negatively affect not only foreign private operators but also Japanese companies and individuals. It is important to note that EMS is not deemed part of the universal service in Europe or the US. In Europe it is explicitly referred to as different from the universal postal service, while in the US it belongs to the category of "Competitive Services". The EBC believes that there are no obstacles to moving EMS outside the scope of universal service in Japan, similar to the removal of *yu-pak*.

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, reforms aimed at improving Japan's overall business infrastructure have not done much 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”.

■ Level playing field with Japan Post’s EMS

Yearly status report: no progress. Currently, Japan Post is only required to declare EMS packages to customs through the Nippon Automated Cargo and Port Consolidated System (NACCS) system when the goods they contain exceed 201,000 yen in value, while private sector operators are required to declare all packages through NACCS (as de minimis up to 10,000 yen and Low Value Dutiable up to 200,999 yen). Additionally, although the National Police Agency has declared that EMS is subject to the Parking Law, in practice the Law is not applied to EMS-carrying vehicles. EMS shipments containing materials such as quarantine-related goods, which are subject to control by various regulations (*tahourei*) other than the Customs Law, may be checked in postal facilities, whereas such packages transported by private sector operators must be inspected at the first port of entry (usually an airport).

Recommendations:

- The Government of Japan should ensure a level playing field by (1) applying the same NACCS declaration method to both EMS and private express deliveries, (2) applying the Parking Law equally to all parties, and (3) ensuring equal rules for submitting advance cargo information.
- The Government of Japan should allow private express delivery companies to transport all shipments directly to their off-airport bonded warehouses in the first instance, and ideally allow inspections of quarantine-related goods in those facilities.

■ Labour shortage

Yearly status report: new issue. 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 even as expansion of e-commerce drives up demand. 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. There is 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, particular during peak periods of demand, such as Golden Week and around the end of the year.
- The authorities should support companies in setting up child care 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 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 are exceptionally high in comparison to other advanced economies. High costs not only hinder European companies from operating to their maximum potential in Japan, but also drive many Japanese companies to switch production to overseas and ship lower volumes through Japanese ports. High port costs also undermine the competitive position of Japanese ports in Asia, for example in the provision of trans-shipping services, since South Korea and China offer far more competitive services. Furthermore foreign shipping lines are still not allowed to trans-ship their own overseas cargo on their own vessels in Japan, thus encouraging them to trans-ship such 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.

Recommendations:

- Japan should 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. The same applies to coastal transportation of empty containers where, currently, special permits are required unless the country in which the pertinent vessel is registered has a bilateral agreement with Japan.
- The current system of fixed operating hours, which today limits port efficiency, should be removed and replaced with a more effective system.
- The Government should act to relieve traffic congestion in and around the port of Oi. Without prompt action, the 2020 Olympics will probably make the situation even worse.

■ **Promote competition in port operations and stevedore services**

Yearly status report: limited progress. The Japan Harbour Transportation Association (JHTA) still wields enormous discretionary power on the waterfront and changes to operations require prior approval from JHTA. The process lacks transparency and effectively prevents shipping lines from seeking alternative, competitive services. If shipping lines want to operate a terminal independently, they may apply for a licence. Whilst the MLIT has committed to process applications within two months of receipt, requirements such as minimum employment levels still prevent firms from developing true competition for port services in Japan. It is not yet possible for a foreign company to set up its own terminal handling operations in Japan.

Recommendations:

- Japan should promote competition by establishing a system allowing shipping companies to change their operations without seeking prior approval from the JHTA, especially for routine business matters.
- The Government of Japan should allow foreign shipping companies to own their own handling facilities or, at the very least, be allowed to run port operations in a competitive manner.
- Competitive bidding for stevedore services through open tenders should be promoted and regulated.
- The prevailing "Grandfather Principle" that effectively prevents shipping lines from changing container terminal service providers should be eliminated.

Health Science

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

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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.

Air Liquide
B. Braun Aesculap Japan
Biotronik Japan
Coloplast
Dornier MedTech Japan
Draeger Medical Japan
Edaptechnomed
Elekta
Hollister
Integral
Intuitive Surgical
Japan Lifeline

Japan MDC
JIMRO
Laerdal Medical Japan
Lima Japan
LivaNova Japan
Medical U&A
Medis Medical Imaging Systems
Medtronic Japan
Molnlycke Health Care
Nippon Becton Dickinson
Nippon BXI
Nobel Biocare Japan

Novocure
Otto Bock Japan
PENTAS
Philips Japan
Radiometer
Roche Diagnostics
Siemens Healthcare
Smith & Nephew
Sysmex bioMerieux
Teijin Pharma
Thermo Fisher Diagnostics
TKB

Key Issues and Recommendations

■ Periodical meeting with MHLW on approval examinations and safety measures

Yearly status report: progress. At a meeting in August 2017 with MHLW’s Pharmaceutical Safety and Environmental Health Bureau and PMDA, held to discuss approval examination and safety measures, the EBC Medical Equipment & Diagnostics Committee/IVD Sub-committee, 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:

Recommendations:

- The PDMA has increased its staff to speed up IVD approval times. In order to accelerate this process, all stakeholders should be given an opportunity to discuss and contribute to the creation of a new framework, and efforts and progress should be monitored.
- The following five items should be implemented quickly: addition to the approval/recognition standards; streamlining of approval examination requirements; revision of the pre-approval test system; releasing of clinical performance test guidelines at an early stage; revision of unique Japanese approval requirements.
- Labels and attached documents should be simplified.
- The Government should introduce changes in the product changeover time-frame.
- MHLW together with relevant stakeholders should create an action plan to deal with changes in the environment surrounding clinical diagnostics/IVD. Special care should be taken over how to handle innovative diagnostics using advanced technologies, including next-generation sequencing and mass spectrometers, as well as how to promote genetic testing in genome medicine and diagnostics using AI.
- As a basic agreement has already been reached, discussions should be held on what measures are necessary to implement actual usage of the bio bank.

■ In Vitro Diagnostics (IVD) drug medical reimbursement

Yearly status report: progress. Since April 2016, the EBC has been given the opportunity to participate in and express its opinion at meetings of the Central Social Insurance Medical Council (*Chuikyo*) on insurance coverage for IVDs (E2 and E3). The EBC Medical Equipment & IVD Committee/IVD Sub-committee, together with JACRI and the IVD Committee of AMDD, have set up a “Joint Task Force to Negotiate with Chuikyo” and held discussions on the state of IVD medical reimbursement. The Task Force made the following recommendations to MHLW’s Health Policy Bureau Economic Affairs Division and Health Insurance Bureau Medical Economic Division at their meeting in July 2017 on medical reimbursement:

Recommendations:

- “Medical usefulness and “innovativeness” should be taken into consideration when determining HIP. (It is currently not clear how the level of innovation of new products is evaluated.)
- Although the Japanese Government has been promoting home medical care, the cost to patients of conducting home testing is currently high. Home testing as well as management of home specimen examinations should be added to the HIP system.
- The Japanese Government should introduce additional HIP in respect of cases where urgent testing for heart disease or infection is required and so an immediate diagnosis is performed at a primary care doctor’s clinic.
- Infection prevention measures should only be introduced on condition that usage standards for microbial testing are included.
- The *Chuikyo* should consider the role for diagnostics in pre-emptive medicine where onset pre-intervention is carried out.

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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 health care 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. 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.

Air Liquide	Japan MDC	Novocure
B. Braun Aesculap Japan	JIMRO	Otto Bock Japan
Biotronik Japan	Laerdal Medical Japan	PENTAS
Coloplast	Lima Japan	Philips Japan
Dornier MedTech Japan	LivaNova Japan	Radiometer
Draeger Medical Japan	Medical U&A	Roche Diagnostics
Edaptechnomed	Medis Medical Imaging Systems	Siemens Healthcare
Elekta	Medtronic Japan	Smith & Nephew
Hollister	Molnlycke Health Care	Sysmex bioMerieux
Integral	Nippon Becton Dickinson	Teijin Pharma
Intuitive Surgical	Nippon BXI	Thermo Fisher Diagnostics
Japan Lifeline	Nobel Biocare Japan	TKB

Key Issues and Recommendations

■ Revision of the functional classification of materials covered by insurance

Yearly status report: slight progress. In the 2016 medical reimbursement price revision, the functional classifications of medical materials covered by insurance were revised and eight classifications were added as a result. The regulations associated with exceptional rules still remain an issue.

Recommendations:

- The Government of Japan should introduce appropriate reimbursement for innovative technologies through further subdivision of the functional classifications.
- Japan should improve the insurance reimbursement price system based on product characteristics.

■ Deployment of HTA (Health Technology Assessment) for medical equipment

Yearly status report: some progress. A trial to evaluate cost effectiveness started in April 2016 targeting five pieces of equipment. Details of how to utilise the results are under discussion with *Chuikyo* (the Central Social Insurance Medical Council).

Recommendation:

- Japan should introduce HTA carefully, taking into account the unsuitability of applying QALY (Quality-Adjusted Life Years), the unreliability of the results depending on the level of skill of the testers and the techniques applied, and the short improvement cycle for medical equipment.

■ Mutual recognition of clinical evaluation and international alignment

Yearly status report: some progress. The Government encourages companies applying for equipment approval to use the PMDA's prior consultation service to promote utilisation of clinical evaluation results obtained overseas.

Recommendations:

- Both the EU and Japan should work on promoting mutual recognition of clinical trial results by increasing the number of overseas clinical evaluation results utilised in their approval processes as well as ensuring that those carrying out clinical trials are aware of and understand the guidelines.
- Japanese Good Clinical Practice (GCP) is consistent with ISO14155. However, Japan should improve the actual operation of GCP by accepting clinical trial results from Europe that comply with ISO14155. Where a decision is made not to accept clinical trial results from Europe, the scientific grounds for this decision should be made clear.
- MHLW should issue "early disclosure of clinical trial guidance".

■ Mutual recognition of Quality Management System and international alignment

Yearly status report: some progress. Some progress has been made in aligning Japan's Quality Management System (QMS) with international standards. Furthermore, Japan has formally agreed to participate in the MDSAP (Medical Device Single Audit Program) and moved forward with international alignment in this area.

Recommendations:

- Japan should remove the remaining differences in application formats and standards.
- Japan and the EU should promote mutual recognition of medical equipment in low-risk classifications at an early stage.
- Japan should synchronise its timetable for introducing new ISO standards with other countries in order to avoid variations among countries.
- The authorities should make an effort to provide information on QMS ministerial ordinances in English with a view to participation in the MDSAP.

■ Mutual recognition of medical equipment licences and international alignment

Yearly status report: some progress. Japan has decided to accept examination results from other countries that comply with ISO13485. The examination period for PMDA approval has been shortened and performance has improved. However, issues still remain with the recognition of equipment licences.

Recommendation:

- The PMDA and MHLW should work with the EU authorities to mutually recognise each other's medical equipment licences, with PMDA giving priority to low-risk class 2 products.

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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 is well under control. This is because increased use of generics is creating the financial headroom to continue to fund the pro-innovation parts of the system.

Drug market: Japan's healthcare spending in the FY2016/17 decreased by 0.4% on the previous year to 41.3 trillion yen. The amount spent on dispensing fees also decreased, by 4.8%. Looking forward, a 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 other words, even in an environment of strong increases in total medical expenditures driven by an ageing population and the progress of medical technology, the current pricing system for pharmaceuticals and measures such as the encouragement of greater generic prescribing are together proving sufficient to control the drugs bill.

Price Maintenance Premium (PMP): The PMP, known officially as the "premium to promote the development of new drugs and eliminate off-label use", was launched in 2010 to shrink the "drug lag" (the average delay in filing an application in Japan following the earliest equivalent filing in the US or EU) and to promote the development of new drugs in Japan. Regrettably, the possibility of revising or eliminating this premium system has been raised. Yet there is clear evidence that, since the launch of the PMP, the drug lag has shrunk from 41.5 to 5.0 months and the number of development projects in Japan has increased 11.1% each year (versus 2.1% before 2010). In other words, the PMP has achieved precisely the desired results. Any significant reduction in the PMP's support for innovation would risk reversing the substantial progress already made.

More frequent repricing: In general, drug price revisions should continue to be conducted in two-year cycles, linked to the revision of medical service fees. If price revisions are to be conducted in "off" years, the scope of drugs subject to revision should be limited to a small number of products with large discount rates from the list price, in order to minimise disruption to the market. In addition, any immediate price revisions for drugs gaining an additional indication should be limited to exceptional cases (i.e. products with already strong sales set to increase significantly as a result of the additional indication). Because the drug budget is already well controlled, over-zealous use of further cost-containment measures could lead to sharp negative growth in the overall pharmaceutical market. This would conflict with the Government's designation of pharmaceuticals as a strategic growth industry and reduce the incentive to invest in Japan from overseas.

14-day rule: 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 will not prescribe a drug until the product has been on the market for at least a year. Given that Japan has robust safety measures, including the Drug Risk Management Plan introduced in 2013, this 14-day rule for new drugs is outdated and acts only as a barrier, preventing patients from accessing the treatments they need. The Government's own Council for Regulatory Reform has recommended revision or elimination of this rule, and EFPIA supports that position.

Cost-Effectiveness Analysis/Health Technology Assessment (CEA/HTA): The Government introduced a form of CEA/HTA in Japan from April 2016 on a trial basis. Full-scale implementation is planned for April 2018. Unfortunately, the European experience shows that CEA/HTA can become yet another barrier preventing patient access to medicines and can create a major administrative burden for academia, government and industry. Japan already has sufficient measures to control drug expenditures, so CEA/HTA should not be allowed to become another cost-containment measure. EFPIA believes that the Government should implement the new system based on the results of the trial study and the European experience.

Regulatory harmonisation: 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 has recently introduced expanded clinical trials for compassionate use, the *Sakigake* designation system, and optimal use promotion guidelines on a pilot basis. There are plans to introduce a conditional early approval system, and to launch an initiative to facilitate paediatric indication development. The impact of these measures on patient access needs to be further reviewed, and improvement of the systems and initiative may need to be considered.

Key Issues and Recommendations

■ Pricing system

Yearly status report: negative progress and new issue. The price maintenance premium (PMP) introduced in 2010 is officially being discussed on a “zero basis”, and the direction seems to be towards limiting the scope of eligible drugs. In addition, there are new measures to reduce drug expenditures, like annual repricing. This 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.
- Care should be taken when considering annual repricing based on the survey of actual market prices, and immediate price revision following an additional indication, to ensure that the incentive for innovation, including incremental innovation, is not lost.
- The 14-day rule should be abolished or revised. The safety environment has changed substantially since its introduction many years ago, and it serves now only as a barrier, preventing patient access to drugs.

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

Yearly status report: minimal progress. Health Technology Assessment (HTA) using cost effectiveness analysis was introduced in Japan from April 2016 on a trial basis. There are now discussions about the full-scale implementation of this system.

Recommendations:

- A multi-criteria assessment approach should be adopted. Any approach based largely or entirely on cost per QALY (quality-adjusted life year) thresholds risks becoming a major barrier to access.
- The number of products assessed should be limited as Japan does not yet have a well-established HTA infrastructure and at present is unable to assess a large number of products.
- HTA should not 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.

Recommendation:

- Japan should carry out specific actions to further enhance efficiency in clinical trials, in accordance with the Government’s own “Report concerning Enhancement of Efficiency in Clinical Trials (2011)” and the “2012 Action Plan for the Five-Year Program toward the Revitalization of Clinical Studies and Trials (2012)”. Actions already taken should be reviewed and further actions implemented, as necessary.

■ 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 Good Clinical Practice.

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, conditional early approval system, and promotion of development for paediatric indication: These systems and initiatives should be carefully designed, reviewed and improved in order to improve patient access to new drugs. To facilitate the success of these systems, incentives to drug developers need to be considered.

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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-recommended (World Health Organization) 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.

At the end of 2015, Japan experienced vaccine supply issues, due to a mix of Good Manufacturing Practice (GMP) violations and natural disasters, and these had a major impact on both the medical front and on the manufacturers concerned. Vaccines with limited supply sources were the most affected, serving as a reminder that vaccine supply is an important topic on the risk management agenda. It should be noted that regulatory requirements in Japan create a bottleneck in the secure supply of vaccines: for example, it takes more than 6 months for vaccines to reach the market after importation, which in effect cuts down their shelf life.

A further challenge is that in recent years there have been procedural issues with the introduction and development of vaccines. The process for recommending inclusion of vaccines in 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. Uncertainty is further increased by the decision first made in June 2013, and still in force as of September 2017, 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. If companies are to develop vaccines smoothly in Japan, an infrastructure must be created that will allow the regulatory authorities to make decisions based on scientific judgements. More specifically and importantly, women in Japan should not be deprived of the opportunity to prevent cervical cancer, and so the current situation should be promptly rectified.

As the situation has seen no changes as of September 2017 the version of this report and the recommendations remain the same as in 2016. EFPIA continues to make proposals to Ministry of Health, Labour and Welfare, and had its say as a participant at the Health and Science Council hearing in May, 2017. We will continue to make proposals to various stakeholders in order to see progress in revision of the vaccination system and policy in 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, 2017 saw shortages of the Japanese encephalitis vaccine, and in July the Japan Pediatric Society made a request to the healthcare centres to partially suspend vaccinations. 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: no progress. As effective vaccines from overseas are being introduced and the number of vaccines in routine immunisation increases, the relative inadequacy of Japan’s vaccine policies is increasingly apparent and leading to the emergence of a new “structural vaccine gap”. An infrastructure should be established to enable the regulatory authorities to evaluate and recommend vaccination from a safety perspective based on scientific judgments, so that people will not be left unprotected from preventable infectious diseases. Also, it is difficult to predict whether the regulatory authorities will recommend that a particular vaccine should become 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.

Recommendation:

- The routine immunisation process should 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: some progress. The number of EU Member States covered by the EU-Japan MRA on GMP was expanded in April 2016, and vaccines may come into scope in 2018. A great deal of time and effort is still needed to introduce and supply vaccines due to excessive pharmaceutical regulations. For example, because of the procedures for conducting national testing, or the lack of clarity in MRBP related to the timing of reviews, revision procedures, and criteria for listing, it can 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 Pharmacopeia.

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COSMETICS & QUASI-DRUGS

Introduction

The EU 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 1,524 billion yen in 2016. In the same year, Japan imported cosmetics valued at about 244 billion yen, of which some 86 billion yen came from the EU, 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 MHLW 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. Moreover, there is very limited information on which active and inactive ingredients and excipients have already been approved. The EU 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.

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 authorities should also make certain that quasi-drugs are not sold as cosmetics. There is, moreover, a need to make it easier for the consumer to differentiate between products that are supplied by authorised sellers and those supplied by parallel importers, as cosmetic brand consumer surveys indicate that up to 40% of consumers buying products imported in parallel are under the impression that they are buying from official retailers.

The EBC believes that the EU 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. The EU-Japan EPA is an important vehicle for this process. In addition, the EBC would welcome greater leadership by the EU 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. In October 2016 and September 2017, MHLW's Evaluation and Licensing Division issued a notification concerning a "Partial Amendment of the List of Excipients for Quasi-drugs", and added maximum thresholds for the listed ingredients. In addition, a study of real examples of product approval processes was started in order to develop guidelines for examining medicated cosmetics related to medicated soap. However, to-date the guidelines have not been developed.

In order to accelerate the speed of examination, the Pharmaceuticals and Medical Devices Agency (PMDA) created a checklist, planning to request submission of the checklist's cover sheet with any application made from April 2016 onwards. The burden on applicants was, however, a concern, and use of this list was revised in February 2017 and submission of the list is no longer required.

In 2014, the PMDA began collecting information from businesses on the raw material specifications of excipients that had already been approved, and published this information as "Standards of Excipients for Quasi-drugs" (2014). The exercise was repeated in 2015 and again in 2016. However, almost no information was provided by businesses due to concerns about protection of their intellectual property and consequently the publication still covers only 27 ingredients. Although the quasi-drug review system has been improved, there is unfortunately no commitment in the above-mentioned notification to shorten the review period.

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.
- A code should be assigned to standards for ingredients used in already-approved quasi-drugs, and this code should then be used in applications for approval of other quasi-drugs that share the same ingredients, to obviate the need for repeatedly reviewing the standards for those same ingredients. This would enhance efficiency and shorten the review period.

■ 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. However, mouthwash with fluoride concentrations of 226 ppm is sold at drugstores and supermarkets throughout Europe and the United States, and while Japan approved the use of fluoride in mouthwash for general consumption in 2015, its use is limited to products sold as a drug requiring guidance.

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 other countries, 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 introduced a “Basic Act on the Advancement of Utilising Public and Private Sector Data” in December 2016, to regulate online administrative procedures. Since August 2016, applications for approval of prescription drugs, along with supporting clinical investigation reports and other materials have all been accepted in electronic form via the Internet. However, for cosmetics and quasi-drugs, notifications and applications must still be submitted on a floppy disc or in paper form, which are outdated methods compared to those used by many other countries. Moreover, the systems used by prefectural authorities, the PMDA, and Customs are not linked, and separate procedures are required for notifications and applications for the manufacture and sale of cosmetics and quasi-drugs, notifications of export goods, and presentation of materials for import customs clearance.

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: no progress. Animal testing for the purpose of studying the safety and efficacy of cosmetics is completely banned in the EU and the trend towards a ban is spreading to other countries and areas. However, in Japan, safety data based on animal testing must be submitted when applying for approval of quasi-drugs using new raw materials. A notification issued by MHLW in 2011 supports the active use of alternative methods replacing animal testing, but at present there are only a few available that do not use animals.

Recommendation:

- Japan should proactively promote the development of alternative methods that do not use animals and MHLW should issue guidelines to enable their use in applications for quasi-drugs as soon as possible.

Consumer Goods

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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 2016, at 266.4 billion yen (according to Japan Customs), accounted for a mere 6% 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. 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. The agreed mutual protection of geographical indications (GIs) will ensure the protection of GIs for 139 liquor products from the EU.

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, prioritising 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. 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 recognises 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. However, despite this progress, the EBC continues to urge the Japanese Government to take further proactive measures to ensure the display of product lot codes for traceability.

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

■ Traceability

Yearly status report: minimal progress. Lot codes (traceability information) fulfil an important role in any effective and efficient product recall or withdrawal process. In the case of a serious health threat, delays to such processes could endanger consumers: a rapid, targeted and efficient response is vital in order to protect them and preserve their confidence in the supply chain. In September 2014, the National Tax Agency (NTA) issued a notice to eight liquor industry organisations emphasising the importance of lot codes. In addition, the NTA included these concerns in its liquor sales management training material in April 2017, and in July 2017, METI, MHLW, and MAFF issued a similar notice to 28 organisations that engage in sales and distribution of liquor. However, whilst these steps are significant, the notices and training 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.

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: partial progress. Under the 2017 tax reform, Japan will reduce the tax on beer and increase the taxes on *happoshu* and “new genre” beverages in three phases (in 2020, 2023, and 2026), ultimately to 157 yen/litre. However, taxes on wine will be raised in two phases (in 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: good progress. Wine additives were approved in the EPA negotiations (25 items by Japan and 28 items by the EU), making it possible for Japan to import wines that use EU-approved additives.

Recommendation:

- Japan should swiftly approve additives that are in common use among other industrialised countries.

■ Wine definition

Yearly status report: progress. A labeling standard for Japanese wine was established in October 2015. Improvements have been made to the definition of wine. 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.

Recommendation:

- 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.

■ 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.

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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.

At the time of writing, the EU and Japan have reached an EPA agreement in principle but only limited information concerning tariffs applicable to food items has been made public. While more details are needed to make a definitive statement, the EBC very much welcomes the agreement and believes that it will improve the Japanese food market for European companies, and more importantly, for Japanese consumers. With lower tariffs on some key European products, such as cheese, consumers will not only pay less for familiar items but hopefully also enjoy a wider choice, as products that were previously prohibitively expensive now enter the market. At the same time, the EBC notes that a number of tariff lines will be dismantled over a number of years rather than immediately the agreement comes into force. Therefore, it is of the utmost importance that quotas, where applicable, are managed in a fair and transparent way, which has not necessarily happened in the past.

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). While this issue was raised in the context of the EPA agreement in principle, the EBC is as yet unaware of any legally binding commitment in the agreement and so repeats its long-standing message that Japan needs to approve more additives and enzymes to meet the ever-increasing demand from Japanese consumers for high-quality European food and agriculture products. In particular, the EBC asks that Japan sets specific timelines or deadlines for approving food additives and streamlines its approval process so that more overseas data can be used.

Another key barrier to the import of European food and agricultural products is the approach to Maximum Residue Levels (MRLs), which have not been harmonised between the EU and Japan. Moreover, Japan uses a positive list of products and levels, and any product not on the list must have a residue level of no more than 0.01 ppm, even if the base input material has a higher level. The need to set such a low level has never been substantiated.

A further issue is the new 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.

ARYZTA Food Solutions Japan	Nestle Japan
Corbion Japan	Perfetti Van Melle Japan Services
Danisco Japan	Pick
Danone Japan	PinguinLutosa Japan
DSM Japan	Puratos Japan
IKEA Japan	Roquette Japan
Japan Europe Trading	SAVENCIA FROMAGE & DAIRY JAPON
Lactalis Japon	SKW East Asia
MIE PROJECT	Valrhona Japon

Key Issues and Recommendations

■ Tariffs & quotas

Yearly status report: good progress. Japan currently imposes high import duty rates on many foods and food ingredients. The entry into force of the EU-Japan EPA should change this situation for the better. However, the benefits could yet be undermined by long dismantling periods or the mismanagement of tariff quotas. It is, furthermore, crucial that safeguard measures are not abused as a way to offset the tariff reductions.

Recommendations:

- Japan should abolish its tariffs in accordance with the EPA without delay and refrain from the use of safeguard measures.
- The quota management system should be simplified.

■ Food additives and enzymes

Yearly status report: slow 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, with long application periods lacking any deadlines, difficulties in determining exactly what supporting documents are required, and an overall lack of transparency. Both foreign and domestic companies would benefit from a system where each step of the approval process has clear deadlines set out in legislation to be followed by the authorities.

Recommendations:

- The Ministry of Health, Labour and Welfare (MHLW) together with the Food Safety Commission (FSC) should introduce legally binding deadlines for each part of the approval process. Furthermore, repeated requests for additional information should be avoided.
- 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.

■ Maximum Residue Levels

Yearly status report: no progress. While a large number of agro-chemicals approved and in common use in Europe are approved in Japan, Japanese regulation on MRLs is far stricter and involves use of a positive list. However, the main difference between the EU and Japan can be found in how they treat pesticide MRLs in processed products that are not explicitly listed. The EU approach is that, when a derived product is not explicitly listed, the pesticide MRL for the input (raw) material is used (for instance, the EU MRL for deltamethrine in maize is 2ppm, hence the MRL in maize starch-derived products is also 2ppm). In Japan, however, derived products that are not on the positive list have a default MRL of 0.01ppm, even if the original product has a higher MRL. (So, for instance, the Japanese MRL for deltamethrine in maize is 1.0ppm, but in a maize starch-derived product not listed, it is 0.01ppm).

Recommendations:

- The EU and Japan should work together to harmonise MRL levels and, in cases where there is no specific regulation, follow the CODEX levels.
- Japan should introduce the concept of using the level set for the base product for derived products that are not on its positive list.
- The EU and Japan should harmonise their respective lists of approved agro-chemicals.

■ 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 EU Member States that have already submitted data.

■ Malt and quota management system

Yearly status report: no 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. 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.

Recommendations:

- Japan should, as part of the EPA, abolish the tariff on malt so that there is no need for European suppliers to use the quota.
- In the meantime, Japan should allow importers to use the system throughout the year and store malt without the requirement for use at a specified brewery.

■ Origin labelling of ingredients

Yearly status report: new issue. 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.

Industry

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

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AUTOMOBILES

Introduction

In the first half of 2017, total sales of passenger cars in Japan were up 10% from a year earlier to 2,346,634 units. Sales of foreign brands, mainly from Europe, were up 3.8% from a year earlier to 150,476 units and the European share of the domestic vehicle market was 6.1%. Sales of foreign brands' vehicles increased for fifteen consecutive months between April 2016 and July 2017.

For the second half of 2017, the market was expected to grow further, as European brands launched attractive new models and upgraded leading-edge features of their next-generation vehicles. A series of motor shows held in various parts of Japan from Autumn 2017 to the beginning of 2018, in addition to local imported car fairs throughout the country, are expected to help stimulate the market.

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 called 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 negotiations.

The EU and Japan reached an agreement in principle on the EPA in July 2017. The EBC Automobile Committee appreciates the efforts and contribution of all the parties concerned. Although the EU and Japan share an understanding of the need to work together on strengthening their joint commitment to international standards and of the importance of free trade, the full outcome of the negotiations on NTMs has not yet been made public. The EBC understands that there are issues still to be addressed and hopes these will be positively resolved in the final agreement.

In that regard, further efforts are needed so that hydrogen tanks for fuel-cell electric vehicles certified in the EU can be introduced in Japan without additional certification procedures, as a temporary measure until an internationally agreed regulation is created.

Furthermore, the inclusion of a robust and comprehensive Automotive Annex in the EPA is crucial not only to encourage regulatory collaboration, but also to avoid the introduction of new NTMs in future. The Automotive Annex should oblige both parties to consult each other prior to the introduction of any new regulation that has the potential to become a barrier for trade – thereby benefitting EU and Japanese manufacturers alike.

An example of a potential future NTM is the Real Driving Emissions (RDE) test for diesel vehicles, which is planned from 2022. The introduction by Japan of such a test without harmonisation with the existing EU test or without recognising EU test results would lead to double testing. In reality it would be impossible for importers to conduct such a test in Japan and it is, therefore, of the utmost importance that the Japanese Government accepts RDE test results from the EU.

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 35% 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 and other regulatory privileges that undermine 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.

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 Japan, scheduled for 2019, will mark 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.

■ Tax reform

Yearly status report: little progress. Compared with other countries, Japan imposes an excessively heavy tax on the purchase and ownership of motor vehicles.

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.
- 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.

■ Kei-cars

Yearly status report: little progress. The continued existence of regulatory and fiscal privileges for *kei*-cars distorts competition with compact cars.

Recommendation:

- Japan should put *kei*-cars and other motor vehicles on the same regulatory and fiscal footing.

■ Automated and connected driving

Yearly status report: new issue. SIP-adus, the Japanese Government's Strategic Innovation Program for automated driving technologies, plans to start a large-scale Field Operation Test (FOT) from September 2017. The aim of the FOT is to promote global standardisation and R&D in respect of automated and connected driving technologies. The Government is also considering revising and establishing regulations and standards in response to the deployment of these technologies.

Recommendation:

- Japan should promote international harmonisation of regulations and standards for automated and connected driving.

■ Safety Support Cars (S)

Yearly status report: new issue. Japan has issued a report on its plan to promote "Safety Support Cars (S)" to reduce the increasing number of accidents by senior drivers. This plan focuses on an Autonomous Emergency Braking System and a "System to prevent sudden acceleration caused by pedal misapplication", which is being developed uniquely in Japan. Test procedures and evaluation criteria for both systems are still being studied.

Recommendations:

- Japan should promote vehicles equipped with wide-ranging advanced safety technologies and not focus on a Japan-unique system to prevent sudden acceleration caused by pedal misapplication.
- Japan should establish test procedures and evaluation criteria to prevent sudden acceleration caused by pedal misapplication that ensure fair and reasonable assessment of all vehicles, regardless of origin.
- Japan should accept test results obtained at overseas technical services and from the overseas New Car Assessment Programme (NCAP) in evaluating the performance of an Autonomous Emergency Braking System.

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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. One example was the decision taken by the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) in October 2015 to implement UN/ECE (United Nations Economic Committee for Europe) regulation R117-02 (rolling sound emission, wet traction, and rolling resistance) in respect of the Japanese new vehicle market. This regulation will enter into force for passenger tyres in 2018, light truck tyres in 2019 and truck/bus tyres in 2023. The EBC welcomes this decision.

However, 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.

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: new issue. 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 action taken by MLIT to implement fully UN/ECE regulation R117-02 in Japan in respect of new vehicle applications (original equipment) by 2023. 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 May 2018 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.

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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 ANA 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 also seems increasingly open to consider cooperation with European manufacturers. The EBC is actively supporting this evolution.

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 deplors 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, no substantial progress has been made on this topic.

Recommendation:

- 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.

■ Promoting the use of large aircraft at Haneda Airport

Yearly status report: limited progress. The Tokyo 2020 Olympics is less than three years away, and with the number of foreign visitors to Japan already exceeding 24 million in 2016, 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.

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SPACE

Introduction

The Committee on National Space Policy and the National Space Policy Secretariat (NSPS) established in the Cabinet office set Japan's space policies across all ministries and agencies. The latest "Basic Plan on Space Policy" was adopted in January 2015. Space is treated as an important industrial and commercial sector, and now officially as a national security asset. Japan's high sovereign debt contributes to making an effective unification of space policies a necessity. 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. In May, 2017 the Committee on National Space Policy issued its "2030 Vision" for Japan's space industry that set a goal of doubling its space market to about 2.4 trillion yen

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 (roughly one large commercial satellite per year) 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. Japan's willingness to cooperate in satellite development programmes still rarely extends to European companies.

Ariane launchers are successful in Japan and can play a broader role in cooperation. Arianespace and Mitsubishi Heavy Industries have made it possible for commercial customers to shift satellites from Ariane 5 to H-IIA and vice-versa to avoid launch delays due to possible technical mishaps. However, talks between the Japanese and European space authorities towards a mutual back-up of government launch missions have been stalled for more than a decade.

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 mostly ignores Europe’s satellite technology. The space agencies of both sides cooperate and share data in science and research, but have almost no industrially meaningful cooperation.

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 non-critical components for their respective new generation launchers. The creation of ArianeGroup and a new launcher development organisation in Europe make it easier to realise industry-led cooperation on development.

■ Ground equipment

Yearly status report: no progress. As Japan's international procurement activities in this area generally exclude entire systems and remain limited to subsystems and components, European suppliers are placed at a disadvantage.

Recommendation:

- Japan's international procurement of ground equipment should include whole systems. The procurement process for standard ground processing products should not place European suppliers at a disadvantage.

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DEFENCE & SECURITY

Introduction

Over the past few years, the security environment in which Japan finds itself has deteriorated. China continues to expand its military force in a manner which lacks transparency, while the speed of its maritime advancement has accelerated. North Korea has further developed its nuclear weapon and ballistic missile technology: on 29 August 2017, it fired a ballistic missile that passed over Japanese territory and, only five days later, conducted a nuclear test. Japan's territorial disputes with South Korea and Russia have yet to be resolved, thus perpetuating a state of political tension. For Japan to deal successfully with these challenges, it needs to raise more awareness and support among the international community. As a result, in recent years it has been rapidly extending security collaboration, not only with its traditionally closest ally, the US, but also with Europe.

Japan shares basic values with Europe and is recognised by NATO (the North Atlantic Treaty Organization) as a global partner. Prime Minister Abe himself visited NATO Secretary General Jens Stoltenberg, in July 2017 during a visit to Europe, and expressed his wish to consolidate the network of allies between Japan, the US and Europe and promote cooperation between Japan and NATO as a reliable partner.

The 3rd Japan-France Foreign and Defence Ministers' Meeting, held in January 2017, confirmed that Japan and France share an understanding of global, international and regional issues, and wish to promote bilateral collaboration in the security and defence fields. The UK Prime Minister, on a visit to Japan in September 2017, indicated that the UK also aimed to take security collaboration with Japan to the next level and work on shared global concerns, in the Indo-Pacific region in particular. Together, Prime Minister Abe and the UK Prime Minister announced a "Japan-UK Joint Declaration on Security Cooperation". A joint meeting of the UK and Japanese Defence and Foreign Ministers is planned before the end of 2017.

Security collaboration and defence equipment/technological collaboration are two sides of the same coin. Defence equipment/technological collaboration is crucial to the progress of security collaboration. In this regard, the Japanese Government made an important commitment to Europe by concluding with the UK its first bilateral agreement on defence equipment collaboration after its agreement with the US. After that, Japan concluded an agreement with France in March 2015 and with Germany and also Italy in 2017. Further discussions towards bilateral agreements with other European countries are now underway. The EBC welcomes this development and expects the Government of Japan to put these agreements into effect without delay, opening up opportunities for European companies to participate in the Japanese market so that it can benefit from the equipment/technological collaboration on offer.

Key Issues and Recommendations

■ Procurement

Yearly status report: some progress. The EBC appreciates the Japanese Government's desire to move towards collaborative defence programmes with European governments and, in particular, commends progress in signing bilateral agreements with individual European nations. Fairness and transparency will be vital to ensuring that these collaborative relationships fulfil their promise to provide business opportunities for European companies.

Recommendations:

- Japan's Ministry of Defence (JMoD) should place more emphasis on life-cycle costs, which would significantly benefit the operation of the Self-Defence Forces. It would also provide more opportunities for European companies to participate in the Japanese defence market.
- The MoD should use NATO standards in research and development in order to promote competition and to provide valuable equipment to the Self-Defence Forces.

■ Industrial partnerships

Yearly status report: some progress. Japan's ATLA (Acquisition, Technology and Logistics Agency), METI (the Ministry of Economy, Trade and Industry) and Japan-Europe industrial organisations have worked together to encourage closer dialogue between the Japanese and European defence industries. The revitalisation of Japan's defence industry may depend on the success of its collaboration with European companies. As a result of the Japanese Government's decision to support business-to-business collaboration and Japan's more flexible export control policy, the European defence and aerospace industry can now offer new opportunities to Japanese companies. Further cooperation between European companies and the Japanese Government and domestic companies will be crucial if this is to continue. The EBC therefore hopes that enhanced cooperation will be included in Japan's National Defence Programme Guidelines and the next Medium Term Defence Programme.

Recommendations:

- The Japanese Ministry of Defence and each European national defence authority that has concluded an equipment/technological collaborative agreement with Japan should be mindful that the agreement is the cornerstone of present and future collaboration and integral to security collaboration, and its success is dependent on the creation of effective collaborative business.
- In March 2017, ATLA and the UK Ministry of Defence announced the implementation of a "Japan-UK collaborative study regarding the possibility of cooperation with the UK for fighter aircraft in the future". It is vital that associated business opportunities are opened up to UK and other European companies in a fair and transparent way, to avoid this study remaining merely theoretical.

■ Defence exports

Yearly status report: some progress. The European defence industry accounts for a large share of the global defence market through direct/indirect sales and cooperation with foreign governments and industries. European defence-related companies are eager to work with the Japanese defence industry to develop new technologies, including dual use, and to cultivate new markets. The EBC notes, however, the possibility that any resulting business may be carried out not only in European countries but also in third-party countries, and hence measures to facilitate this must be established.

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.

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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.

Tariffs have consistently been the major issue for domestic industries dependent on imported raw materials and for European suppliers. Tariffs on processed nickel significantly increase local procurement costs, at a time when companies in sectors such as stainless steel production are facing stiff challenges from overseas competitors, particularly in South Korea and China. The same situation applies to fused aluminium oxide (artificial corundum) and to silicon carbide, both of which are widely used in the refractory and abrasive industries and in electric components. Imported fused aluminium oxide and silicon carbide are both subject to a 3.3% tariff, even though domestic production can only fulfil, at best, 10% of annual demand. The same is true for manganous manganic oxide, essential for the battery industry, as Japan's level of production is below 10% of demand.

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. Removal of import tariffs is, therefore, imperative for Japan to retain its competitive edge. For the stainless steel industry, where the cost of nickel accounts for 40% of total production costs, the tariff plays a major role in determining competitiveness. The same can be said for the battery and photovoltaic sectors, where it makes little sense to penalise companies with an additional cost added through a tariff, and for silicon carbide and manganous manganic oxide, where domestic production accounts for only 10% of demand. 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, including:
 - ◇ nickel products and aluminium, such as semi-fabricated and flat-rolled aluminium,
 - ◇ fused aluminium oxide, silicon carbide, and manganous manganic oxide, and
 - ◇ non-organic chemicals and polymers.
- 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.

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ENERGY

Introduction

Japan's utilities 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 ongoing discussion about how to establish capacity, ancillary-service, real-time and other markets is 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 August and October 2015, followed by Ikata 3 in August 2016 and Takahama 3 and 4 in May and June 2017. Four additional reactors are expected to restart in the first half of 2018: Ohi 3 and 4, and Genkai 3 and 4, which would bring the number of restarted reactors to nine by mid-2018.

Japan's Basic Act on Energy Policy sets the following goals:

- Securing of a stable energy supply;
- Environmental sustainability;
- Use of market mechanisms, which should, however, remain consistent with the first two basic goals.

In April 2014, the Government completed a review of the energy mix and adopted a new Basic Energy Plan, confirming:

- Nuclear power is an important source of base load electricity, "which will be reduced as much as possible" but "a certain amount will be preserved with regards to security of supply, and costs".
- The target for renewables is "to go beyond previous targets set in past plans".
- The nuclear closed-fuel cycle policy will continue.

The new energy mix target approved by the Japanese Government in 2015 for 2030 was designed to meet goals in terms of safety, energy security, economic efficiency and the environment. The target mix consists of 20-22% nuclear, 27% liquid natural gas, 26% coal, 8.8-9.2% hydro and 13.4-14.4% other renewables. METI has started work on a revision of the Basic Energy Plan and the EBC recommends looking at case studies and the experience of other countries, especially in Europe, which includes examples of countries with a low self-sufficiency ratio in relation to their primary energy supply, some that have undertaken to enhance their transmission grid and others that have shifted to alternative major generation sources. The Japanese Government's energy mix target for 2030 will be reviewed to check if the reduction target in greenhouse gas (GHG) of 26% in 2030, from the base year 2013, is feasible. There is concern that the current plan to invest in new coal-fired power plants might lead to stranded assets.

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.

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 from one region to another and easier integration of non-conventional energy sources into the overall energy supply.

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.
- 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 on to a “connect and manage” model, such as that used in Europe.

■ Nuclear energy and nuclear safety

Yearly status update: some progress. In its latest Basic Energy Plan (2014), the Japanese Government confirmed that the nuclear closed-fuel cycle policy would continue and that nuclear power would remain an important source of base load electricity for Japan. At the same time the Government also stated that nuclear power would be reduced as much as possible, although 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. It will also be necessary in the near future to address the issue of increasingly ageing plants, not only through plant lifetime extensions, but also through replacement of reactors, set to be some 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.
- The Japanese authorities 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: no progress. The development of wind energy will be 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. Currently the deployment of wind farms is too slow.

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.

■ Solar energy

Yearly status update: some progress. The principal impediments to sustainable growth of utility and commercial-grade solar energy are: the cumbersome procedure for obtaining special permits for land re-zoning for non-agricultural use, and the difficulties in obtaining reasonable interconnection commitments from regional electric utilities and project financing for utility-scale photovoltaic (PV) projects. Potential curtailment remains an issue in relation to these points. 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:

- Japan should 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.
- Japan should 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.
- The Japanese Government should 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.
- Japan should 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.
- The Japanese Government 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.

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