

EU AND JAPAN: AVENUES FOR COOPERATION

The EBC Report on the
Japanese Business Environment

PUBLISHED: October 28, 2022

Travel restrictions

STATUS: **RESOLVED**

The EBC fully understands and supports the Japanese government's efforts to try to stem the spread of Covid-19 among the residents of Japan. However, it cannot be emphasised enough that European firms, as well as Japanese and other non-Japanese firms, have been suffering for months because they have not been able to bring in essential personnel from overseas. This is true both for specialists – such as engineers, researchers, and medical personnel – and for those in top management positions.

Resolved

- The immediate easing of restrictions on entry into Japan of people who have been vaccinated or have proof of a negative PCR test
- An end to mandatory quarantine for vaccinated people who have vaccination passports or certificates that are similar to Japan's vaccination certificate
- The Japanese government to make it easier for non-vaccinated non-residents to enter Japan

PUBLISHED: December 1, 2022

Diversity, equality and inclusion

STATUS: **NEW**

Japan, known to have the world's highest rate of seniority, also has one of the fastest population declining paces in the world. Its economy is bound to drastically change in the following decades due to a decrease in population of 30 million by 2050. To offset its shrinking labour force, Japan needs to bring more women into the workforce by supporting working mothers, reducing its gender pay gap (second largest among OECD countries) and giving them access to more stable jobs.

Recommendations

- The Human Resource Committee, together with The Sustainability & Social Responsibility committee of the EBC, support Prime Minister Kishida's "New Capitalism" encouraging investment in human capital as one of the main pillars of his growth strategy. We expect that this initiative will result into a more inclusive Japanese economy.
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Labour market regulations, flexibility & digitalisation

STATUS: **SOME PROGRESS**

The future prosperity of Japan in an increasingly globalised world hinges on ensuring a highly skilled, diverse and competitive workforce that can support its ageing population and drive its economy. Key to this are ongoing policies, now and in a post-COVID-19 world, that allow more flexible approaches to working, greater female participation in the workforce, new ways of sourcing foreign labour and use of automated processes and artificial intelligence where meaningful and appropriate. The EBC strongly urges the Japanese Government to place focus on achieving greater productivity in the workplace and flexibility for both employees and employers.

Recommendations

- Encourage companies to create ongoing lasting policies, during and well after COVID-19, to allow greater numbers of employees to continue to take advantage of flexible ways of working, including remote working from home, by providing government guidelines to support this. Overcoming workplace cultures that place value on physical presence over outcomes gains is a key focus area.
 - Introduce employment legislation that encourages the creation of a competitive workforce based on merit and performance. Adequate protection of employees is required, but employers also need a legal framework within which to remove under-performing workers, and whose skills may be transferable. The same shall apply for corporate re-structuring with clear rules on how to compensate affected workers.
 - Introduce legislation to speed up court procedures in labour disputes. Long court procedures lead to legal uncertainty and slows down corporate investments. The efforts of the Japanese government to digitalize court procedures to accelerate decisions are much welcomed by the EBC.
 - Continue to actively promote the uptake of technology that contributes to boosting productivity in the workplace, including incorporating digitalisation and artificial intelligence into daily operations, while considering the interests and well-being of the human workforce.
 - Increase and improve the infrastructure necessary to support greater work-life balance, by ensuring sufficient child-care facilities to support female participation in the workforce and male participation in the home. Further promotion of part-time jobs for working parents.
 - Encourage companies to set up child-care facilities by offering them identical or similar financial contributions to those given to public day-care centres.
 - Remove the spouse special income tax credit (*haigusha-tokubetsu-kojo*).
 - The Japanese Government and universities in Japan should promote the set-up of internship and vocational programmes for university students in incorporating work experience, reflecting the changing needs of businesses. The EBC is willing to support government initiatives by sharing experiences in Europe, for example best practices from the German dual education Vocational Education Training 'VET' programs.
 - Amend the employment legislation to expand the "highly skilled system" to include employees who earn less than the current system regulating highly skilled professionals, while keeping adequate protections of employees. People with high skills and high motivation want to work based on output instead of work hours.
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Pensions

STATUS: SOME PROGRESS

The Defined Contribution (DC) Pension Law of 2001 has introduced a series of revisions to enable employers to offer more flexible and attractive pension schemes to employees. Further incentives are necessary though to encourage individuals to prepare financially for their own retirement. This should be equally applicable for employed, self-employed or part-time workers. Meanwhile, social security agreements have been concluded or are being negotiated with several European countries, to the benefit of their citizens, whose mandatory contributions to Japanese pension plans can now be refunded in full. This is important not only with European countries but also with neighbouring countries.

Recommendations

- Raise the DC plan contribution level limits to allow for further adoption of the corporate plans.
- Make similar amendments to iDeCo (individual Defined Contribution pension) limits.
- Extend the payback period and expand pay-back to include the company contributions for leaving expats.

PUBLISHED: December 1, 2022

Border control, Immigration legislation and policies

STATUS: SOME PROGRESS

The EBC welcomes the relaxation of COVID-19-related Border Measures in fall 2022. European companies are now once again able to bring personnel vital for the company, be it top management or specialists. The Government needs to also continue to take an increasingly proactive approach to immigration policies and deregulation. Several sectors are currently restrained by the shortage of available labour. This holds true for both skilled labour and unskilled labour in the major urban centres and regional Japan.

Recommendations

- Provide a greater level of immigration policy transparency for businesses and permanent residents.
- Extend the scope of on-line visa applications and visa extensions. This would be in-line with continued digitalisation of the Japanese administration and would support remote working.
- Lower the requirement for industry experience from ten to five years for those without a university degree.
- Formalise visa procedures for partners that are not married or are in same-sex partnerships.
- Continue to review concrete measures to increase the uptake of the 'specified skills visas' to non-high skilled workers, and their integration in the workplace and society.

PUBLISHED: December 8, 2023

Authorization for the importation of “products with removed trademarks”

STATUS: NO PROGRESS

There have been cases in the past where customs authorities allowed the importation of counterfeit products when the trademark has been removed.

Recommendations

- Referring to the report of the special panel on the case against China (DS362), as indicated in Article 46 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), except in exceptional cases, we hope that the customs authorities share awareness so that they do not allow the counterfeit products to enter the distribution channel mere removal of unlawfully attached trademarks.

PUBLISHED: December 8, 2023

“Law on the Protection of Consumer Interests Using Digital Trading Platforms”

STATUS: NO PROGRESS

In May 2022, the “Law on the Protection of Consumer Interests Using Digital Commerce Platforms” came into effect. It appears that the enactment and enforcement of this law have provided a positive impetus to Japanese B2C online sales platforms, since they have all started to review their intellectual property protection systems. However, it does not seem to have had a significant impact on B2C online sales platforms owned by foreign companies. Therefore, the law should be revisited with the aim of strengthening its implementation and impact on foreign-owned online sales platforms.

Recommendations

- We are aware that the seller's identity verification, as stipulated in the “Act on the Protection of the Interests of Consumers Who Use Transaction Digital Platforms,” has not been reinforced, and notations in accordance with the Special Commercial Code have not been adequately executed. Therefore, the law should be strengthened through the use of the review provisions of the law.

PUBLISHED: December 8, 2023

Legislation prohibiting the importation of counterfeit products “for personal use”

STATUS: GOOD PROGRESS PROGRESS

The revised Trademark Law came into effect on October 1, 2022. The importation of counterfeit products “for personal use” sold by foreign platforms and operators has been regulated, and very positive results have been observed since then.

Recommendations

- Foreign importers claiming that their products are not counterfeit and wanting to sell in Japan must provide Japanese customs authorities with documentation proving the authenticity of the products in question. We hope this implementation of law will continue.

Strengthening and continuation of measures aimed at eliminating counterfeit products from Japanese and foreign B2C and C2C online sales platforms

STATUS: NO PROGRESS

Foreign-owned B2C online sales platforms and some Japanese-owned C2C online sales platforms are making efforts to detect and remove counterfeit products by analyzing image information using computer systems and AI, and by maintaining a human control system based on cooperation with rights holders. However, counterfeit products and the ways they are sold are constantly evolving, and rights holders and consumers are able to detect them more quickly than the online platform operators. Furthermore, it is difficult to assert that AI or computerized systems for detecting and removing counterfeit products will work effectively. In particular, when it comes to "AI," it seems that its capabilities remain limited for now, and therefore the extent of cooperation with rights holders and other measures such as strengthening identity verification, collecting complaints from purchasers, utilizing infringement information obtained from removal requests from right holders, and blacklisting malicious users, as mentioned above must be reevaluated.

Recommendations

- To establish relationships between the right holders and online platform operators, the government regularly calls on operators who have not yet participated in forums for dialogue where online platform operators and rights holders discuss measures to eradicate counterfeit products. This measure should be continued by the government in the future, especially with foreign-owned operators. Exchange of opinions should thus be conducted regarding the measures to be taken, particularly in relation to the elimination of commercial practices on each online selling platforms and the pursuit of an understanding of rights holders.

PUBLISHED: October 20, 2022

Temporary in-activation of gaiben licence

STATUS: **NEW**

With the increased use of secondments within the legal services field, it is not uncommon that registered *gaiben* temporarily leave Japan and then come back to again practise foreign law in Japan. For a domestic lawyer it is possible to either (1) continue paying their bar membership fees while remaining on the bar tills with their original registration number or (2) stop paying fees whilst temporarily suspending their license only to re-activate it when returning to Japan through a simple application process. This is not possible for a *gaiben*. The only thing possible for a *gaiben* is to re-apply from scratch. The EBC sees no reason for this blatant discrimination of foreign lawyers.

Recommendations

- Japan should immediately extend the same possibilities given to domestic lawyers to foreign lawyers in this regard.

PUBLISHED: November 29, 2021

Recognition and approval as a foreign lawyer in Japan

STATUS: **SOME PROGRESS**

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 shortened the process, but the requirement for approvals from both the Ministry of Justice and committees at the *Nichibenren* and local bar associations inevitably gives rise to delays. After over 30 years of operation, the *gaiben* system needs 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.
 - 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.
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Branches

STATUS: **GOOD PROGRESS**

Legislation was finally passed in 2014, permitting a gaiben law firm to incorporate itself as a hojin, and thereby become eligible to open more than one branch. However, the 2014 legislation did not permit gaiben and bengoshi together to establish a hojin. The effect is to severely limit the usefulness of the 2014 legislation. We understand that the changes in the Act to permit gaiben and bengoshi to establish a hojin together have been enacted and we await confirmation that the changes have been implemented by no later than September 2020.

Recommendations

- Implement the changes to 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.

PUBLISHED: November 29, 2021

Scope of International Arbitration Cases which gaiben can be involved in

STATUS: **GOOD PROGRESS**

We await confirmation that changes in the Act have been implemented by no later than September 2020. We understand that changes have been enacted to clarify the scope of “international arbitration cases” under the Act so that gaiben will be able to be involved in such cases.

Recommendations

- Japan shall pass and implement the changes to the Act so that gaiben can take a more active role in international arbitration cases in Japan.

PUBLISHED: November 29, 2021

Limited liability

STATUS: **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.

Recommendations

- 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.

PUBLISHED: October 19, 2022

Denan Act or PSE requirements

STATUS: **NEW**

Most electrical appliances on the Japanese market need to be labelled with a PSE symbol: either a so called *maru-PSE* or a *hishigata-PSE*. For this to be possible the products need to undergo the applicable testing and certification, and also be reported to the Japanese authorities as a “Notification of business,” or Import Business Report, with information such as type classification, *katashiki*, and manufacture information. While some of these requirements are mirrored in other jurisdictions, Japan stands out in some respect. Every single product needs to be checked beforehand either at production site or a warehouse, and a report of this inspection needs to be kept for 3 years by importers. Furthermore, tests and approvals from Europe can only be partially used or not used at all as the Japanese standards are still not harmonized with international standards in the latter case.

Recommendations

- The EU and Japan should work together to achieve better harmonisation between the two regions with the aim of avoiding re-testing when marketing the products on either market.
- Japan should remove the need to inspect every product at the production site to align with IEC, international standards.
- Japan should better clarify the scope to make it easier to understand which products, or products categories, are covered by the legislation. At the same time also provide written answers to questions related to this.
- Remove requirement for companies to keep certificates in paper form.
- Remove the need for an “Import Business Report”, or at least only request it if needed.

PUBLISHED: October 19, 2022

Labelling

STATUS: **SOME PROGRESS**

The revised Household Goods Quality Labelling Act introduced some improvements, however requirements remain too detailed and long. This often means that labels are too complex for consumers.

Recommendations

- The Labelling Act should be reformed to aid the consumer in understanding the product and to introduce flexibility for the retailer.
 - Introduce the possibility of referring to websites for more information by using for instance QR-codes instead of having the information on a label affixed to the product.
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PUBLISHED: October 19, 2022

Regulatory cooperation

STATUS: **NEW**

The EPA provides for regulatory cooperation between the EU and Japan. The EBC has long called for the two economies to work together to make certain that double testing is eliminated or that products do not have to be developed specifically due to differences in regulations or standards in the two markets. This is also something that is recommended by the EU-Japan Business Round Table.

Recommendations

- The EU and Japan should work together to achieve better harmonisation between the two regions with the aim of avoiding re-testing when marketing the products on either market.

PUBLISHED: October 19, 2022

Prohibitive import, testing and certification procedures

STATUS: **SOME PROGRESS**

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

Recommendations

- MHLW should make certain that the current draft positive list for food contact products is harmonised with other countries. It is furthermore of important that the list is also offered in English.
- Japan should accept inclusion of common non-SI units on measuring devices when SI units are also used.

PUBLISHED: November 29, 2021

Shoe quotas

STATUS: **RESOLVED**

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.

Resolved

- Now that the EPA has entered into force, METI monitors the system, rejects applications from entities not trading shoes, releases their quotas, and implements stricter penalties for infringements.
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PUBLISHED: November 29, 2021

Competition law/Anti-trust legislation

STATUS: NO PROGRESS

Japanese Competition Law includes recognition of “market power” with minor shares in vertical restraint, and “superior bargaining power” irrespective of dependence, which differs from global practice. The Subcontractor Law lacks bright-line rules, and “yellow card” infringement notices lack explanation.

Recommendations

- Japanese Competition Law/Subcontractor Law should be harmonised with global practices.
 - The “yellow card” system, not transparent and lacks both a legal basis and bright-line rules, should be abolished.
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PUBLISHED: November 26, 2021

Limitations on selling liquor via telecommunication channels

STATUS: NOT PRIORITISED

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.

PUBLISHED: March 1, 2024

Sustainability in Supply Chains

STATUS: SOME PROGRESS

In its current regulatory landscape, Japan addresses human rights in supply chains but lacks regulations addressing critical environmental challenges such as GHG emissions, biodiversity impact, and deforestation.

Recommendations

- Japan should expedite the formulation and enforcement of guidelines and regulations addressing the environmental impacts of Japanese companies' supply chains. Drawing inspiration from advanced frameworks like the EU's CSDDD and CSRD, which define robust business disclosures and due diligence obligations on ESG matters, including supply chains, would provide valuable guidance for Japan's regulatory development in this domain.

PUBLISHED: March 1, 2024

Carbon Pricing

STATUS: SOME PROGRESS

The carbon tax in Japan falls significantly below expert recommendations, hindering its effectiveness in driving behavioral changes among companies and consumers. While signals of a more ambitious approach emerged under the GX League initiative, the slow implementation schedule and existing loopholes limit the effectiveness of current carbon pricing mechanisms in reducing the majority of Japan's greenhouse gas (GHG) emissions.

Recommendations

- To expedite the transition to a low-carbon economy, Japan should swiftly adopt a more robust carbon pricing system, whether through an emission trading system, a carbon tax, or a combination of measures. The objective is to substantially increase the cost of emissions, compelling stakeholders to redirect their investments and purchases toward low-carbon products and services. This will play a crucial role in aligning Japan with international climate goals and driving tangible reductions in GHG emissions.
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Double Materiality Consideration

STATUS: **NEW**

The concept of double materiality is not fully integrated into sustainability disclosure practices. Japan has adopted the TCFD recommendations and declared support to the new ISSB standards; both frameworks are based on a single materiality approach.

Recommendations

- Japan should incorporate the concept of double materiality into its sustainability disclosure framework. This involves not only considering the impact of sustainability issues on the company but also the impact of the company on broader societal and environmental factors. This comprehensive approach provides stakeholders with a more holistic view of a company's sustainability performance.
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PUBLISHED: March 1, 2024

Low-Carbon Transition Plans Disclosure

STATUS: **NEW**

While companies are improving GHG emissions reporting and engaging in global disclosure frameworks such as CDP and TCFD, concerns persist about weaknesses in low-carbon transition plans supporting the achievement of long-term decarbonization goals.

Recommendations

- The Japanese government should mandate companies to disclose comprehensive low-carbon transition plans as part of their sustainability reporting. Transition plans should be defined based on leading international frameworks such as TPT. This should include clear targets, timelines, strategies to transition to low-carbon practices, and regular reporting of progress.
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PUBLISHED: March 1, 2024

Plastic Waste Reduction

STATUS: **SOME PROGRESS**

Despite the implementation of a well-accepted sorting policy for efficient plastic waste collection, Japan grapples with significant challenges at the source. The nation continues to consume substantial quantities of single-use plastic items and is the second largest consumer of plastic per inhabitant after the U.S. Although the ban on free single-use plastic bags since 2020 is in place, it has not induced a substantial shift in the mindset of Japanese consumers and businesses regarding the issue of excessive plastic consumption.

Recommendations

- The Japanese government should implement comprehensive measures to tackle the issue of plastic waste at the source. This includes strengthening regulations on single-use plastics and promoting alternatives. Additionally, public awareness campaigns should be intensified to educate citizens on the importance of reducing plastics. Collaborations with industry stakeholders and international best practices should guide the development of a robust plastic waste management strategy.
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PUBLISHED: March 1, 2024

Food Waste Reduction

STATUS: SOME PROGRESS

Despite efforts, Japan still produces a substantial amount of food waste annually, equivalent to one bowl of rice per inhabitant per day.

Recommendations

- Japan should implement targeted measures to reduce food waste significantly. This involves promoting awareness campaigns, incentivizing businesses to adopt sustainable practices in food production and distribution, and implementing strict regulations to minimize food waste throughout the supply chain.
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PUBLISHED: March 1, 2024

Renewable Energy Support, Coal Phase Out

STATUS: SOME PROGRESS

While there is progress in renewable energy initiatives, additional investment and policy support is required to fully unlock the real potential of Japan for these decarbonized, local sources of energy. Japan is still supporting a narrative in favour of coal power, through the use of unproven, controversial technologies.

Recommendations

- The Japanese government should increase its commitment to renewable energy investments, offering financial incentives and policy support to companies engaged in renewable energy projects. This includes promoting research and development in renewable technologies and creating a favorable environment for the adoption of clean energy solutions, including those provided by non-Japanese companies. Clearer signals of a coal phase-out should be given, to facilitate reorientation of investments towards clean sources of energy; uncertain technologies such as ammonia co-firing should not be used as excuses to maintain investments in coal power plants in Japan and in foreign countries.
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PUBLISHED: March 1, 2024

Regulations Against Greenwashing

STATUS: NEW

Lack of robust regulations against greenwashing undermines the credibility of sustainability efforts and makes it more difficult for consumers and investors to direct their purchasing or investment decisions towards truly sustainable options.

Recommendations

- The Japanese government should establish and enforce stringent regulations against greenwashing. This involves defining clear criteria for sustainable practices, implementing standardised reporting frameworks, and imposing penalties for misleading or false sustainability claims. This will ensure transparency and build trust in sustainability initiatives.
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PUBLISHED: March 1, 2024

Science-Based Sustainability Education for Adults

STATUS: **NEW**

Despite the widespread presence of Sustainable Development Goals (SDGs) in mainstream communication, there exists a significant misunderstanding of their true implications among Japanese consumers and businesses. Current sustainability education predominantly targets children, leaving a critical gap in addressing the climate emergency.

Recommendations

- The Japanese government should encourage media outlets to adopt a science-based approach in their coverage, curbing greenwashing and ensuring accurate reporting. Empowering Non-Profit Organizations to act as independent evaluators of public policies and advocates for sustainability is essential. Additionally, incentivizing companies across all industries to implement comprehensive sustainability education programs for their workforce will foster a culture of environmental responsibility, driving meaningful change at all levels of society.
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PUBLISHED: March 1, 2024

Gender equality

STATUS: **NO PROGRESS**

Japan faces a declining population, impacting its economy. At the same time, Japan performs poorly in global gender gap benchmarks. Gender equality efforts could not only contribute to creating a more inclusive society, but also help Japan address the challenges of a declining workforce.

Recommendations

- The Japanese government should implement comprehensive policies to support working mothers, reduce the gender pay gap (currently the second-largest among OECD countries), and ensure access to stable employment opportunities. This includes investing in affordable childcare, promoting flexible work arrangements, and fostering workplace cultures that encourage gender diversity.
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PUBLISHED: December 2, 2022

Overall sustainability governance

STATUS: **SOME PROGRESS**

Japan under former Prime Minister Suga joined other countries in announcing that Japan will be carbon neutral by 2050. While the announcement was met with fanfare at the time, some of the momentum seems to have been lost. Not only where there no immediate follow-up, but concrete implementation has been slow.

Recommendations

- To improve the overall integration of sustainability and social responsibility requirements into its economy, Japan needs to improve accountability and display more transparency on current situations and challenges, long-term goals, and concrete plans supporting the achievement of these goals.
 - National announcements such as the Carbon Neutrality 2050 (pledged in 2021) or the more recent "New Capitalism" plan still need to be translated into actual transformative policies able to guide businesses and investments in the right direction.
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Climate action, responsible consumption and production

STATUS: SOME PROGRESS

To decouple economic growth from environmental degradation, increase resource efficiency and promote sustainable lifestyles, Japan needs to invest in renewable energy or energy savings technologies and align its business models to circular-based-economy through government promotion as well. Regarding responsible consumption and production, despite efforts on food loss and waste reduction, additional actions are still needed to further reduce food waste: it is estimated that 5.22 million tons of food waste is still produced annually in Japan.

Recommendations

- Japan should continue to invest and support development and integration of more renewable energy.
- Japan should do its utmost to decrease volume of food waste.

PUBLISHED: December 1, 2022

Tax treaties

STATUS: **PROGRESS**

Japan recently concluded new tax treaties with Morocco and Colombia and is in negotiations with several other countries to conclude new treaties or update existing treaties. The EBC welcomes treaties that include the exemption of withholding tax on royalties, qualified dividends and interest. However, its treaties with many EU Member States still need to be renegotiated and no treaties have been concluded with Cyprus, Malta or Greece (although a treaty with Greece is under negotiation).

Recommendations

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

PUBLISHED: December 1, 2022

Pillar Two model rules for domestic implementation of a global minimum tax

STATUS: **NEW**

The rules and guidance published by the OECD define the scope and set out the mechanism for the so-called Global Anti-Base Erosion (GloBE) rules under Pillar Two, which will introduce a global minimum corporate tax rate set at 15%. The GloBE rules provide for a co-ordinated system of taxation intended to ensure large MNE groups pay this minimum level of tax on income arising in each of the jurisdictions in which they operate.

Recommendations

- The EBC recommends that the introduction of Pillar Two rules in Japan should be minimise administrative burdens and be sensitive to the impact on and overlap with Japanese Controlled Foreign Corporation rules.

PUBLISHED: December 1, 2022

Centralise local tax

STATUS: **NO PROGRESS**

While progress has been made in digitalising tax procedures to simplify administration, taxpayers who operate throughout Japan must still file local tax returns in numerous municipalities and have to make dozens, sometimes hundreds of tax payments three times a year, and to apply for tax refunds where due.

Recommendations

- The EBC recommends centralising the administration of local taxes by the national Government or, as similar to Consumption Tax, centralise tax payment by the local Government where the head office of the taxpayer is located.
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PUBLISHED: December 1, 2022

Extended tax return filing periods

STATUS: NO PROGRESS

Japanese rules require companies and individuals to file tax returns no later than two to three months after the end of the calendar or fiscal year. The extremely short deadlines in Japan compromise the quality of tax filings and the working and family lives of those preparing the returns, while driving up expenditure on overtime. International comparison of the cost incurred for tax compliance shows that Japan has the highest level among developed countries.

Recommendations

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

PUBLISHED: December 1, 2022

Directors' compensation

STATUS: NO PROGRESS

There has been no further movement on recent tax reforms that relaxed the rules for the deductibility of directors' compensation. The rules governing the deductibility of director compensation do not go far enough to achieve the stated aims of the tax reform to develop Japan as a Global Financial Center.

Recommendations

- Align the rules in line with international standards and allow deductions for directors' compensation in principle unless there is an identifiable risk that the level of compensation is excessive or unreasonable; or is being used to manipulate the level of taxable income.

PUBLISHED: December 1, 2022

Income and Inheritance Taxes

STATUS: NO PROGRESS

High income tax rates continue to negatively affect the attraction of new talent and the retention of long-term residents.

Recommendations

- Consider further tax policy measures such as reducing rates or increasing thresholds to attract international talent and expertise that extend beyond the financial services industry.
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Tax policies to reduce carbon emissions

STATUS: **PROGRESS** **SOME PROGRESS**

The 2021 Tax Reform Proposals included a new "carbon neutrality investment incentive", which provides the opportunity for either accelerated depreciation or a tax credit for companies that invest in assets or infrastructure leading to reduced carbon emissions. The EBC supports the use of tax incentives as a tool to promote behaviour that will reduce carbon emissions, but as with many other tax incentives introduced by the Japanese Government in this and past tax reform proposals, the incentives do not go far enough to stimulate the desired results.

Recommendations

- Greater use of tax incentives to encourage companies to reduce their carbon emissions. This may be done by one or more of the following: (i) increasing the scope of assets and infrastructure covered by the incentive, (ii) increasing the amount of the tax credit; (iii) simplifying the process for obtaining the tax incentives. Moreover, the Japanese Government should also consider more aggressive use of a high carbon tax as a penalty for failing to reduce carbon emissions, which may be more effective at changing corporate behaviour than the proposed carbon neutrality investment incentive, which rewards reductions in carbon emissions.

Tax policies to promote innovation

STATUS: **PROGRESS** **SOME PROGRESS**

Bold incentives are crucial for the Japanese Government to successfully achieve its policy objectives for digital transformation. The 2022 tax reform further relaxed the requirements for the tax incentives for promoting open innovation and extended the applicability of the incentives, set to expire on 31 March 2022, by two years to 31 March 2024. The direction of travel in this area is positive and encouraging. However, much more must be done to maintain Japan's global competitiveness and improve its attractiveness as a location for global innovation. The scope of activities remains too restrictive in scope (both in terms of access and benefit) to be a deciding factor in a foreign company's choice between potential innovation locations.

Recommendations

- Enhance the scope and scale of innovation tax policy to maintain and improve Japan's international attractiveness as a location for innovation, and consider targeted policies for foreign and start-up companies.

PUBLISHED: May 14, 2024

Shelf-life and sustainability

STATUS: **NEW**

While this issue is not based on any law or regulation, food products or beverages that do not have at least 2/3 left of the shelf-life when reaching the supermarkets, or any other retail outlet, are difficult to sell. This means that European products that due to distance have to be transported for a relatively longer period of time are more difficult to sell. It is also true for domestic products, that when reaching end of shelf-life are often discarded despite being OK for consumption. This does, unfortunately, lead to food waste. The EBC believe that the authorities have a responsibility to better promote sustainability in the food and beverage sector.

Recommendations

- Japan should promote sustainability in the food and beverage sector and as part of this better explain that food can safely be bought and consumed during the shelf-life.

PUBLISHED: May 14, 2024

Organic

STATUS: **PROGRESS**

The EU and Japan have since before the EPA an organic equivalence arrangement covering plant based organic products. After some successful changes to the system this arrangement is today working well. However, it only covers products of plant origin, leaving out organic products of animal origin. As the EU has a lot of organic products to offer, the EBC believes that the two authorities with the help of the EU member states should continue talks on expanding the coverage to also include products of animal origin. It should be noted that Japan has agreements with the US, Canada, Switzerland and Australia that covers both plant and animal origin. As this arrangement will expire in 2026, the EU and Japan should also continue to ensure the continuity of the organic equivalence by negotiating a new organic international bilateral agreement.

Recommendations

- The EU and Japan should continue talks on mutual recognition of organic foods with animal origin.
-

Tariffs & quotas

STATUS: **GOOD PROGRESS**

With the implementation of the EU-Japan EPA, and the removal or reduction of tariffs, EU products now have an improved market access. The EBC has big hopes that this will also translate to more European food products in the shopping bags of Japanese consumers. It is however important that these liberalisations are implemented without the use of stringent safeguard measures and that also TRQ administration is improved.

Recommendations

- It is of utmost importance that the quota management system is predictable and easy to use.
 - The lottery system that “covers” some of the TRQ in case there is more demand than volume available creates problems due to low predictability. This is the situation for TRQ2 and cheese.
 - There needs to be a balance between allocation to historical importers and newcomers. This will lead to a maximisation of the usage.
 - TRQ11 should be re-defined so that drink related products (coffee and tea) and food related products (food preparations and dough) are put in two different TRQs.
-

Food additives, enzymes and processing aids

STATUS: **PROGRESS**

Differences in the lists of additives and enzymes approved by Japan and other major markets are still common. Examples of these are iodised salt, amidated pectin and TBHQ. While the EBC has seen progress in Japan's approval of additives, the approval process still remains an obstacle,. EU and Japan should use the EPA to further strengthen the work in this field. Despite announcements that the EPA would result in faster approval times, there are still areas of improvement. Some of the usage lacks logic, such as sorbic acid in jams is OK, while if the jam is diluted (hence less sorbic acid), it is not allowed.

Recommendations

- Japan should harmonise its definition of food additives to exclude processing aids which as per its definition technical function does not remain active in the product after it has been produced. Japan should ensure that standards of use in Japan are not in conflict with international standards of use, such as potassium sorbate and nutrition fortifiers.
 - Japan should also harmonise the specifications of food additives, such as purity, definition of specific food additives and size of molecules.
 - Japan should not set up unique requirements/practices for enzyme registration. An example is artificial gastric digestion data.
 - Japan should explicitly communicate why commonly used additives are not approved for use in Japan. Japan should make certain that approval times are decreased as discussed in the EPA. Currently, the consultation period can be very long.
-

Malt and quota management system

STATUS: **RESOLVED**

Japan had a tariff quota system for malt even from before the EPA, which introduced a quota for EU origin malt. However, only companies manufacturing beer themselves or importing exclusively for the use of a particular brewery were allowed to apply for a quota, discriminating against traders wishing to import on their own account for selling to multiple customers in small volumes or on short notice. Following multi-year efforts by the EBC and the EU, this was remedied in late 2021, opening the door to importers to provide for a large variety of EU-origin malts even in smaller quantities for the flourishing craft beer market, and for non-brewery users. However, an administrative burden remains, which is unreasonable considering the quota is not fully utilized and all eligible quota applications are being granted.

Resolved

- Japan should abolish the tariff on EU malt so that there is no need for European suppliers to use the quota.

PUBLISHED: May 14, 2024

Food contact

STATUS: **SOME PROGRESS**

Materials that come in contact with food, such as wrapping, packaging, plates, cups etc have to fulfil the rules set out by the Food Sanitation Act. Japan already introduced a list of materials that would allowed to be used for the above-mentioned purpose. Several other markets are also using positive lists. This exercise, however, proved difficult for foreign organisations due to a lack of updated comprehensive information in English. The Japanese Government should create route to accept direct application from suppliers in other countries. In addition, there seems no harmonization in the case of mechanical recycled food contact material. According to the guideline which was notified on 28 March 2024, ingredient waste synthetic resin for mechanical recycled resin should comply to Japan positive list. It means that Europe cannot export foodstuff in mechanically recycled synthetic resin container into Japan if the exporter cannot prove the origin waste synthetic resin is aligned with the Japanese positive list.

Recommendations

- Japan should allow resins allowed in the EU and the US.
 - Japan should urgently publish updated comprehensive information in English.
 - Japan should provide guidance on how to know which polymer group a specific compound belongs to. Also that is easy to identify the various compounds. Currently some compounds are classified differently in Japan.
 - Japan should make it possible for overseas producers to apply directly in regard to having compounds approved, as this would deal with the issue of confidentiality.
 - Japan should make use of ISO standards as tests methods, as to avoid specific testing for the Japan market.
 - Considering current sustainability conscious circumstances, Japan should develop a scheme to accept mechanically recycled synthetic resin from waste resin in EU as food contact material.
-

PUBLISHED: May 14, 2024

Separate registration by each importer

STATUS: NOT PRIORITISED

Some European suppliers are using either non-exclusive importers/distributors or using different distributors for different market segments. Currently, each importer has to register the products despite the products already being approved and registered by another importer. This creates additional administrative work. The EBC would like for there to be a system where the brand owner can appoint several importers that can share a registration

Recommendations

- Japan should create a system where a product registration can be shared by multiple appointed importers.

PUBLISHED: May 14, 2024

Testing and approvals

STATUS: NO PROGRESS

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

Recommendations

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

PUBLISHED: May 14, 2024

Best before labelling

STATUS: NO PROGRESS

Best before dates in Japan have to be written in a special order. Unfortunately the order for Japan is not commonly used outside of Japan. While ingredients lists do not change if the production methods stay the same, best before dates constantly change and it can therefore be difficult for the producer to affix for the Japanese market, leaving the importer to do this.

Recommendations

- Japan should allow alternative best before dates if this is properly explained on the label of the products, such as DDMMYYYY. This is currently possible for pet food.

PUBLISHED: December 11, 2023

Liquor taxes

STATUS: NO PROGRESS

Japan is reducing the tax on beer and increase the taxes on *happoshu* and “new genre” beverages in three phases (2020, 2023, and 2026), ultimately to 157 yen/litre. However, taxes on wine will be raised in two phases (2020 and 2023), making it equal to the reduced tax rate for sake, at 100 yen/litre. Taxes on spirits, not subject to the upcoming tax hikes, are high at 370 yen/litre if less than 37% ABV plus an additional 10 yen/litre for each additional percentage of ABV.

Recommendations

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

Lot Codes and Decoded Products

STATUS: **PROGRESS**

In Japan, the display of producer lot codes (traceability information) on liquor products is not mandatory, although it is recommended in the administrative guidelines of the Ministry of Health, Labour and Welfare (MHLW). The importance of traceability information has been recognized by regulators in key regions and countries of the European Union, the United States, Australia and Great Britain amongst others such as Singapore. 31 out of 34 OECD countries mandate the use of lot codes on the labels or containers of alcoholic beverages and prohibit the removal, tampering with and covering up of lot codes. The EBC has called on the Japanese Government since 2010 to take more proactive measures to resolve the issue and protect the safety of Japanese consumers. The EBC thus welcomes the NTAs intent to issue regulation to address the issue as expressed in meetings with the JWSIA and other sector associations this April and stands ready to work with the \nta on such draft regulation. We have been informed by the JWSIA that, in a meeting with the NTA, the agency shared their intention to take action to solve this issue. We believe that this opens up a window of opportunity to address this long-standing issue. This was then followed by another meeting with the NTA on 21 April. During this meeting, the NTA indicated that it would like to exchange opinions with industry (JWSIA and other industry associations in the alcoholic beverages sector) toward the enactment of a system as an administrative measure limited (including the necessity of the system). JWSIA have agreed with that proposal and believe that we could gain a foothold and make real progress in resolving the lot-code issue in Japan. The EBC's Liquor Committee members are supportive of the introduction of regulation by the nta, which stipulates that a prepacked food product should feature an identification number or mark (like a lot number, batch number or serial number) that identifies the producing factory and production lot of the food. Ensuring traceability in the supply chain is critical towards safeguarding Japan's food safety and security. The EBC supports the NTAs intent to establish notice under Article 86 of the Liquor Trade Association Acts to eradicate the distribution of imported liquor without production lot codes. The EBC hopes to see clear progress on this issue in 2024.

Recommendations

To ensure the effective and efficient recall of prepacked food, we recommend putting in place regulation at the NTA level that:

- Make it mandatory for alcoholic beverages to have a traceability mechanism (e.g. lot/batch codes);
 - Specify that the lot identification system be based on the brand manufacturer's original lot code, which should be determined in each case by the producer, manufacturer or packager of the prepacked food. This specification is critical to ensuring that an importer, reseller or retailer cannot add a sticker with their own "lot identification" to cover the one originally put on the bottle during the production process, thereby nullifying the use of such an identification system for traceability purposes.
 - Specify that tampering with / removing lot identification is illegal and that strict sanctions are foreseen to restrict the sale of products without original lot identifications or with removed/tampered lot identification at the point of importation, as well as restricting the sale of products whose original lot code was in any way defaced or covered.
-

PUBLISHED: December 11, 2023

Wine definition

STATUS: NO PROGRESS

A loose wine definition opens the door for different products to be sold as “wine” misleading Japanese consumers and creating unfair competition for European wines, which meet the international accepted definition.

Recommendations

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

PUBLISHED: December 11, 2023

Tariff on wine

STATUS: GOOD PROGRESS

Tariffs on wine was abolished at the entry into force of the EU-Japan EPA. Japan-US Trade Agreement took into force on 1st January 2020 and tariff of wine will be completely removed in 2025.

Recommendations

- The EBC urges Japan to completely remove all tariffs on wine as anticipated.

PUBLISHED: December 11, 2023

Alcohol content labelling

STATUS: SOME PROGRESS

A Cabinet decision was taken in March 2021 that the NTA should promptly consider including alcohol content using grammes on bottles and cans. Following that, the Ministry of Health, Labour and Welfare (MHLW) in November 2023 compiled its first guidelines on alcohol drinking. The draft of its “Guidelines on Health-Conscious Drinking” details health risks associated with the consumption of alcohol. The draft will be reviewed by a panel of experts at the ministry’s committee on alcohol drinking guidelines.

Recommendations

- The EBC urges Japan to follow international standards.

PUBLISHED: December 11, 2023

Geographical indications

STATUS: 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.

Recommendations

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

PUBLISHED: November 29, 2021

Whisky definition

STATUS: **RESOLVED**

A loose whisky definition opens the door for different products to be sold as “whisky”, misleading Japanese consumers and creating unfair competition for European whisky, which meet the international accepted definition.

Resolved

- Japan has implemented a stricter definition of “Japanese whisky”.
-

PUBLISHED: November 29, 2021

Additives

STATUS: **SOME PROGRESS**

A number of wine additives were approved in the EPA negotiations, making it possible for Japan to import wines that use EU-approved additives. 23 out of 28 additives were approved by the MHLW and the rest 5 additives are still under the approval process as of September 2021.

Recommendations

- MHLW should swiftly approve additives that are in common use among other industrialized countries.

PUBLISHED: October 5, 2022

Allow investment trust with a double materiality approach

STATUS: **NEW**

Responsible investment entails both seeking financial returns and contributing to addressing environmental and social issues. Granted that the priority between the two objectives can vary from one to another, reflecting its values. Still, the investor must determine an appropriate framework with suitable KPIs and time horizons to best achieve both. From a performance management perspective, the investor should be vigilant on issuers' materiality on two dimensions, i.e., in a *double materiality* approach. One is financial materiality by asking how environmental and social issues affect issuers' financial performance. The other is environmental and social materiality by assessing the consequences of corporate economic activities on climate, people, and community. Then, the investor must allow a longer time before projects deliver a visible impact, such as GHG reductions, or transform a linear economy into a circular one. Non-financial practices of the issuers can translate into financial performance over time, and the markets would price it in as a *dynamic materiality* view advocates. ESG investing entails both seeking financial returns and contributing to addressing environmental and social issues. Whereas the statutory set-up of the publicly placed investment trust solely contemplates the former, i.e., the long-term growth of trusted assets. The "ESG integration" product may argue the importance of factoring financial materiality in aspects of ESG. Impact investing, however, can find no appropriate positioning in the Japanese market because its primary objective is to deliver measurable outcomes in non-financial matters such as climate, people, and community by assessing the consequences of corporate economic activities to them. The present system, therefore, could prevent asset managers from launching "net-zero" products in the investment trust format despite the global industry trend or movement as GFANZ (Glasgow Financial Alliance for Net Zero) demonstrates.

Recommendations

- The FSA should allow flexibility for asset managers to take a double-materiality approach and incorporate an additional environmental/ societal objective in the investment trust.
-

Encouraging Japanese households to invest for the long term

STATUS: **SOME PROGRESS**

Distributors have been changing their business model under the pressure of the “Customer oriented business”, tax incentive must follow to enable the new business model to generate positive flows towards financial products and specifically mutual funds. This is especially important after the sharp market decline across all asset classes generated by the Coronavirus turmoil, to bring back attention towards fund investing especially for new investors. In this context, boosting financial literacy will be key, at all levels and for all generations, including through the websites of Corporate Defined Contribution (DC) and iDeCo (individual Defined Contributions) platforms.

Recommendations

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

Anti-Money Laundering (AML) – Countering the Finance of Terrorism (CFT)

STATUS: **NEW**

Japanese FSA has issued several guidelines over the past 18 months to ensure the local asset management industry reaches global standard immediately, even before the change of law, on AML-CFT (including due diligence to distributors, to external managers, screening of securities portfolios). The EBC Asset Management committee issued a statement to JITA in April 2019 to ensure AML questionnaires (such as Wolfsberg questionnaires) could be posted on the website of each financial institution (such as fund distributors) or in a digital library managed by the respective industry associations to facilitate the process of due diligence.

Recommendations

- There are still on-going discussions about what should be the format of Due Diligence Questionnaires (DDQs) for fund distributors; leadership on this topic is expected from Japan Securities Dealers Association (JSDA) and banking industry associations.
-

Global competitiveness of Tokyo in regard to the operational platform

STATUS: **SOME PROGRESS**

Even if some progress can be noted, trust banks still remain behind the curve in operational efficiency, as illustrated by lack of CSA (Credit Support Annex attached to ISDA (International Swaps and Derivative Association) contracts), only partial adoption of SWIFT and of CLS (Continuous Linked Settlement), especially for pension mandates. In September 2019, Japan Investment Trusts Association (JITA) released its report on single NAV (Net Asset Value) which is a very important first step towards the modernisation of the industry. It opens the door to further discussions about the establishment of fund administrators and transfer agents in Japan, similar to the European business model. EBC Asset Management Committee had participated to the public comments organised by JITA on single NAV in May 2018.

Recommendations

- System developments to facilitate fund mergers should be encouraged to facilitate the simplification of product line-ups.

PUBLISHED: November 6, 2023

Harmonisation with global solvency and other regulatory standards

STATUS: **SOME PROGRESS**

The EBC appreciates the FSA's willingness to take a leadership role among international regulators. The FSA is steadily working toward the introduction of economic value-based solvency framework in 2025, including the release of "The progress for the finalisation of economic value-based solvency regulations" on June 30, 2023. Further alignment of local regulatory requirements with the approach of international capital standard such as Solvency II or ICS is crucial for international insurers in Japan. This would enable them to use the same methodologies in all territories and better develop group-wide risk management strategies. Such a move would, furthermore, 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 information regarding the economic value based advanced regulation framework to the FSA on these issues.

Recommendations

- Japan should accelerate reforms to achieve convergence between Japanese and global solvency standards such as Solvency II and ICS.
 - Japan should consider the approval process of an internal model for risk calculation on a new solvency regulation to evaluate the risk characteristics of each insurer correctly.
 - Benefits of internal models should be fully recognised without any standard method benchmarking or reporting.
 - No application of double standards, meaning the internal model framework should be the reference for all reporting on regulatory capital ratios.
 - 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 scopes of the Policyholder Protection Corporation should be reformed to align with introducing a new solvency regulation.
-

Product approvals

STATUS: SOME PROGRESS

The advantages of simplicity in the approval process have been articulated in our previous submissions. Incremental progress has been made however we continue to seek real enhancement in the form of a file and use system. Not only does it enhance efficiency, but it also enables the FSA to allocate resources to complex products that require more attention. Moreover, real product innovation requires insurers to offer truly new proposition to customers. At this dynamic era where our customers' needs are constantly changing due to lifestyles, ageing and technology, the insurance industry needs to catch up in offering better coverage in new diseases/illnesses as well as play a more active role in improving our customers' health. These initiatives often require global insights without necessarily locally proven experience. The current FSA product approval philosophy is to focus on proven local data and experience, this significantly hampers product innovation progress, and not in line with practices by overseas regulators, ultimately disadvantaging Japanese consumers. The EBC believes this recommendation to broaden the philosophy will also benefit also Japanese insurers. Covid-19 has led to various changes in the society including work from home and digitalisation. Simplification of the approval process is worthwhile considering to accelerate to bring new values of insurance product and services into the market. Concerning the change in the license led by FSA, the FSA should give insurers enough time in view of IT development schedule in insurers etc. Furthermore, some product approvals have taken longer which in turn has had a negative effect on the process to introduce new products responding to customers' needs on the market. Especially under these circumstances, a smoother transition is needed when the FSA personnel is rotating, as this would lessen the burden of "having to start all over." From the perspective of FSA's customer-oriented business operations, it appears that each insurance company has come to realise that insurance products whose primary purpose is to save taxes are not in line with the original intent of insurance.

Recommendations

- The FSA should introduce a system allowing insurers to register products, instead of having to obtain pre-approval. The FSA could retain the authority to conduct post-checks and issue withdrawal orders.
- The FSA should relax the requirement for new innovation to include global expertise and
- The FSA should make certain that personnel rotation affects the product approval as little as possible.

Fair competition in providing group insurance program to banks

STATUS: SOME PROGRESS

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

Recommendations

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

Distribution practices under fiduciary duties

STATUS: SOME PROGRESS

Emphasising that tax-saving is not core values of insurance, the FSA is further promoting customer-oriented business operations and collaboration with the National Tax Authority. We recognise that the FSA encourages insurers including brokers to conduct its fiduciary duties. Along with promoting fiduciary duties, the FSA has been investigating the brokers' fee system. The EBC, furthermore, appreciates the focus on the benefit of the customers, and also the possibility for industry, including European insurers, to leave comments. A statutory obligation to look out for the best interests of customers is planned. The EBC agrees with the purpose of clarifying the obligation, but would like to remind insurers that their actions should not be unnecessarily constrained. On the other hand, we believe that the current rule could be a barrier for new entrants and may not be beneficial to Japanese consumers, unbalancing with the potential risk of mis-selling. For example, insurance sales by an incorporated insurance agency to members of its parent and affiliated companies are restricted to so-called "third sector" products ("koseiin-kisei").

Recommendations

- The EBC recommends that the FSA continue to work closely with industry without drastic changes that may badly affect consumers.
- The FSA should carefully make certain that sales of innovative products are not hampered, for instance under a low-interest rate environment, while ensuring that fiduciary duties are fulfilled.
- The FSA should consider relaxing the restriction of abovementioned "koseiin kisei", beyond "third sector" products.
- Taking into account emerging new technology and evolving insurance distribution, the FSA should review the related regulations, and present a roadmap for further deregulation for the benefit of Japanese consumers.
- When looking into distribution practices, the FSA should put more emphasis on enabling the customer to choose from a wider product portfolio.

PUBLISHED: November 6, 2023

Digitalisation

STATUS: SOME PROGRESS

The insurance industry in Japan has been traditionally paper-heavy, however, especially after Covid 19 use of digital solutions are accelerated to further simplify processes, instead of focusing on face to face with paper etc., for added value services. Moreover, the progress of AI technology is remarkable. The insurance industry in Japan is currently seeking the right way to use AI solutions to improve our services for customers, after careful consideration of preventive measures against the potential risks.

Recommendations

- In setting rules for AI, Japan should continuously take a risk-based approach and carefully consider examples from other countries not to over-regulate, balancing the value creation aspect.
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Liberalisation of sales through bank channel

STATUS: NO PROGRESS

There are continued restrictions on the sale of insurance through bank channel, which should be liberalised in the interest of Japanese consumers. Proposing suitable insurance products based on a customer's intention will become more and more important. For securing effectiveness, banks would need to confirm a customer's intention properly by sorting out each customer's information and needs. From that point of view, the EBC believes it would contribute to the benefit of the customers that banks utilise customer's private information and financial information to some extent when confirming the customer's intention. We are of the opinion that inappropriate use of such information has been effectively prevented by means of the existing regulations like not to solicit borrowers or loan applicants of business loans, etc.

Recommendations

- The FSA should allow banks to sell insurance to employees of companies where banks have a lending relationship, as the current restriction deemed excessive and redundant. At the same time, certain financial information should be allowed to be used, just as is allowed in the asset management sector.
- The FSA should consider easing the restriction on using personal and financial information of customers by banks without customer's prior consent.

Expansion of Japan's role as an international financial centre

STATUS: SOME PROGRESS

The EBC recognises and appreciates that the FSA established Financial Market Entry Office in January 2021 in order to simplify market entry procedure. A dedicated website has also been launched, in addition to the revised Cabinet Office Order to amend the Regulation for Enforcement of the Insurance Business Act. The EBC also appreciates the FSA's tremendous efforts to improve provisions of English material in recent years. The EBC believes simplification of procedures and provision of English materials support foreign entities not only to enter Japan's market, but also retain the business in Japan. In addition, there have been recent proposals to create a special zone for asset management in which administrative procedures can be conducted in English, in order to facilitate the entry of foreign asset managers and others into Japan. The ECB hopes that these developments will have a positive impact on the entry of foreign insurance companies. The ECB is also aware that regulations on asset owners will be considered, but since insurance companies are also asset owners, the ECB will take care to ensure that such regulations do not have a negative impact.

Recommendations

- The FSA should expand the scopes of materials which can be submitted in English.
 - The FSA should make effort to provide English summary at least on their important documents such as guidelines, policies, etc. so that foreign insurers can more easily implement and follow them.
-

Personal data

STATUS: NOT PRIORITISED

In line with the EU's GDPR, the regulation of the personal information protection is to be more restricted. The EBC recognises that the FSA will put in place the new regulatory requirements with the Personal Information Protection Commission (PPC). The EBC recognises that insurance brokers and small medium sized enterprises handling personal data of their customers and employees would be within the scope of the regulations more than ever. The EBC recommends that the FSA, together with PPC, secure clear provisions and issue swift guidelines in responding to insurers' requests for consultation.

Recommendations

- The FSA should maintain collaboration with PPC in supervision over the evolving areas regarding data privacy to sustain appropriate and swift handling by insurers of personal data of customers.
- The FSA should make sure that the required procedures including, incident reporting, are not complicated and burdensome for the industry.

PUBLISHED: February 13, 2024

Firewall

STATUS: NO PROGRESS

Since the introduction of Japanese Firewall Rule in 1992, the information sharing restriction rule thereunder has been an obstacle for financial groups that run banks and securities firms under the same umbrella and wish to efficiently operate their businesses. Although the FSA deregulated the rule in 2022, because dual registration of sales personnel (for both bank and securities) is still not permitted, this has weakened the aim of the 2022 deregulation.

Recommendations

- Japan should restart the discussion on this point at the Financial System Council Working Group run by the FSA. We will closely look at discussions to be made there.

PUBLISHED: February 13, 2024

CBDC

STATUS: PROGRESS

In the middle of 2023, the FSA introduced a new regime of a Japanese version of Stable Coins, which must be fully backed up by legal tender. The regime, however, is being put on hold until banks put in place sufficiently robust risk control and customer protection measures. As some global banks are interested in this area, we will monitor further developments. In summer 2023, the BOJ launched the “CBDC Forum” and 3 Working Groups, following a couple of years of proof-of-concept desk-top simulation. The BOJ says there is no imminent need or concrete plan to issue CBDC in Japan, but they are preparing for the future. We will monitor further developments.

Recommendations

- The BOJ continue to make timely public releases on how they plan to tackle this issue.
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AML

STATUS: SOME PROGRESS

In the area of Anti-Money Laundering (AML), the Japanese authorities are preparing for the next round of FATF mutual evaluation scheduled for as early as in 2025. The authorities' expectation level is quite high, particularly in terms of the customer refresh cycle and timeline for screening sanctioned people. Their approach, however, is rather inflexible and not truly consistent with a risk-based approach recommended by the FATF or practiced by global banks for many years. Recently, there are signs of showing some flexibility but still not enough. In April 2024, a new regime of additional requirements of screening sanctioned people will be introduced.

Recommendations

- The EBC hopes the regime will be implemented in a flexible and practical manner so that it would not constrain cross-border banking.

Cross-border payments

STATUS: PROGRESS

On the payment front, under the leadership of G20, a global project is on-going in order to achieve faster and more seamless cross-border payment. At the same time, another global project is on-going to integrate ISO 20022 standards; implementation target is fall 2025. Each country has some uniqueness in terms of regulations, practices, and infrastructure, and Japan is no exception. We would hope the payment systems in Japan become more seamless and consistent with global systems. There is a variance in the pace of integrating ISO standards among banks.

Recommendations

- The Bank of Japan (BOJ), JBA, and other stakeholders should redouble their efforts to provide banks with related information as early as possible so that they could have more clarity and can plan ahead.
-

Foreign Bank Agency Business

STATUS: NO PROGRESS

The Foreign Bank Agency Business regime (FBAB) was introduced in 2008. Until then, the Japanese Banking Act had not clearly set out provisions governing cross-border banking services, which had been provided by banks (Japanese and foreign) for many years. Japanese banks are required to make a filing. However, foreign banks are required to obtain approval from the FSA. Even though foreign banks already had an initial banking license, they had to obtain another FSA approval for acting as an agent or intermediary on behalf of their head office and branches outside Japan. In 2017, a partial relaxation was made where a foreign bank was allowed to obtain an approval for multiple branches at once, rather than for each branch. Remaining requirements include updating the detailed profile of each branch (i.e., the more global a foreign bank, the more onerous to keep up with changes in the profile), causing foreign bank to be selective in choosing branches covered by the FBAB. No other major country has such a regime requiring another license/approval in addition to the initial banking license granted. It is unnecessarily constraining foreign banks from flexibly providing services to Japanese customers.

Recommendations

- Japan should fundamentally review the regime in order to increase its profile as an international financial centre.

PUBLISHED: December 14, 2023

Contribution to "High-quality home & community medical care" through POCT

STATUS: **PROGRESS**

To build comprehensive community care, it is necessary to enhance home healthcare and strengthen the function of family doctors. Performing a POCT (Point-Of-Care Testing) at home and community medical care is expected to improve the prognosis of patients through speedier identification of patient conditions and speedier intervention in collaboration with acute care hospitals.

Recommendations

- A reimbursement system that appropriately evaluates POCT at home and community healthcare environments should be investigated and implemented.

PUBLISHED: December 14, 2023

Establish a system to prepare for emerging infectious disease outbreaks

STATUS: **PROGRESS**

The May 2022 revision of the Pharmaceutical and Medical Device Act established an emergency approval system. In September 2023, the "Cabinet Agency for Infectious Disease Crisis Management" was established in the Cabinet Secretariat to prepare for the next infectious disease crisis. In addition, Infectious Disease Control Department was newly established within MHLW. We will continue to collaborate with the Infectious Disease Control Department in the future.

Recommendations

- IVD industry and other clinical laboratory testing-related organizations should be involved in discussions on the development of a process and system for outbreaks of emerging infectious diseases.

PUBLISHED: December 14, 2023

Global harmonisation in definition and classification of IVDs

STATUS: **GOOD PROGRESS**

Discussions are underway regarding the classification and definition of IVDs under the Pharmaceutical and Medical Device Act in preparation for the revision of the Law.

Recommendations

- EBC requests proper regulations for classification (currently classified under Pharma) and definitions/scopes, based on the special characteristics of IVDs.
-

PUBLISHED: December 14, 2023

Proper assessment of medical values and innovativeness of IVDs

STATUS: **GOOD PROGRESS**

The medical value and innovativeness of IVDs have not been directly reflected to reimbursement point discussion. Discussions are underway regarding the evaluation of innovations of IVDs for the 2024 revision of medical reimbursement.

Recommendations

- EBC requests the establishment of 'challenge applications' system for tests whose clinical usefulness had not been shown at initial reimbursement decision but has been verified/validated with actual clinical data after the reimbursement coverage.
 - In addition, the committee requested a marketability assessment for low volume tests.
-

PUBLISHED: November 29, 2021

Rationalisation of regulations on IVD and streamline operations

STATUS: **SOME PROGRESS**

Under COVID-19 pandemic, day-to-day operations have been significantly streamlined; e.g., acceleration of telework and remote meeting, elimination of sealing on official documents,

Recommendations

- Japan should further streamline the work process, through digitisation of submitted documents (paperless) and more efficient registration process as a whole

PUBLISHED: November 27, 2023

Drug pricing system

STATUS: **NEW**

Since 2015, including the drastic reform of NHI price system in 2018, the predictability of the Japanese pharmaceuticals market and the attractiveness of the market have been significantly reduced and drug lags and drug losses have become apparent due to repeated revisions of the rules for calculating NHI prices, including the introduction of Off-year revisions and a review of the scope of the PMP. In 2022, an expert panel on comprehensive measures to realise a rapid and stable supply of pharmaceuticals was set up within the Ministry of Health, Labour and Welfare (MHLW) to make a comprehensive proposal.

Recommendations

- The NHI drug price system should be reviewed in line with the recommendations of the expert panel, and drug lags and drug losses should be eliminated.
 - The rules for calculating the price of new drugs should be designed to ensure that innovation is properly evaluated and to avoid significantly lower drug prices in Japan compared to those in Europe and the US.
 - For post-launch, a system should be established whereby drug prices are basically maintained during the patent period, as in Europe and the US.
 - The current rules for calculating NHI drug prices have become a very complicated system due to repeated reviews, and should be revised to a simpler, easier-to-understand and more transparent system.
-

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

STATUS: **NEW**

The expansion of price adjustment scope by HTA significantly impairs predictability with regard to prospective drug prices, thereby undermining the position of the Japanese pharmaceutical market in the globe.

Recommendations

- Results of HTA should not impede or delay patients access to new medicines. Thus, the principle set out when the HTA system was introduced in 2019, which complements the NHI pricing system, should be maintained.
- The evaluation system should embrace assessments for additional benefits and values of new medicines, as the current system relies heavily on cost/QALY values, which cannot adequately address the value of new innovation.
- For HTA selection criterion, the scope of products subject to assessment should be limited, as Japan is still developing the system itself, which does not have an enriched capability of evaluating a large number of products. Especially, medicines for rare diseases, including designated incurable diseases, should be thoroughly excluded from the scope.
 - In addition, there is absolutely no need for additional HTA selections for post-listing designation due to market expansion and/or additional indications, as multiple recalculation systems are already implemented.
 - If the post-listing designation mechanism were to be implemented, price adjustments beyond the initial additional usefulness premiums or equivalent could be possible, which would deviate from the principle of complementing the drug price system and should be strictly forbidden.

International harmonisation (clinical trial environment)

STATUS: **SOME PROGRESS**

Room for improvement on the efficiency of clinical trials in Japan.

Recommendations

- Although various efforts to date to improve clinical trial efficiency have improved the environment for conducting clinical trials in Japan, it is essential to make improvements to achieve more efficient clinical trial operations compared to international standards in order to continue to develop innovative drugs.
 - For example, we propose to discuss the introduction of DCT (Decentralized Clinical Trial), promotion of RBA (Risk Based Approach) and cost rationalization, improvement of case accumulation capacity at individual sites, introduction of FMV (Fair Market Value) and consolidation of IRBs in order to realize efficient clinical trial operations.
-

New scheme related to new drug review and approval

STATUS: **SOME PROGRESS**

Recommendations

- Addition of "Priority review system" and legislation of "Conditional early approval system": According to the promulgation of the Amended Pharmaceuticals and Medical Devices Act on Dec. 4, 2019, "*Senkuteki Iyakuhin* (Pioneering drugs)" (legislation of "*Sakigake* designation system"), "Specific use drugs, etc." designation system, and "Conditional early approval system" were implemented on Sep 1st, 2020. For their operations, preparation of related laws based on the actual state and improvement in the relevant organisational structure and efficient implementation are required.
- Efficient implementation are required for the orphan drug designation and for the regulatory requirement to promote development of pediatric medicinal products. In addition, we propose improvement of the requirement for Japanese data (the need for Japanese Phase 1 studies in case of participation in international clinical studies).
- There is a room for further improvement in the approval review scheme for innovative new drugs in Japan compared to the U.S. and Europe. For example, in order for innovative new drugs to be approved in Japan without delay from the U.S. and Europe, a scheme similar to the Real Time Oncology Review in FDA, which is already in place in the U.S. and starts the review of new drug approval based on key results from a confirmatory clinical trial, should be introduced in Japan. We propose that a scheme similar to the Real Time Oncology Review, be introduced in Japan to shorten the period between a formal application and an approval.
- Legislation of (Post Approval Change Management Protocol) system: PACMP system has been established ahead of the application of TECHNICAL AND REGULATORY CONSIDERATIONS FOR PHARMACEUTICAL PRODUCT LIFECYCLE MANAGEMENT (ICH-Q12). After the system will be started on 1st August 2021, we call for a review of relevant laws and regulations to make the system even easier to use based on the situation of the use of the system for a certain period of time.
- The following are proposed: The review system of procedures for change control for the manufacturing process (including specifications and test methods, etc) and GMP compliance inspection system (inspection based on the risk of the manufacturing site, etc), and acceptance of the Western pharmacopoeia (USP/EP) as the official Pharmacopeia equivalent to the JP.

PUBLISHED: November 27, 2023

Awareness-Raising Activities to spread vaccinations for the elderly

STATUS: **PROGRESS**

In order to identify the real barriers to the spread of Life Course Immunization and to collect the opinions of academia to remove them, we held the "Life Course Immunization Seminar for the 100-Year Life Era". As a result, academia provided an opportunity for the government to begin reviewing its basic vaccination plan for fiscal 2023.

Recommendations

- The progress of the above review is slow, and it is necessary to appeal to the government in lockstep with the voices of other vaccine-related trade associations. To this end, it is necessary to regularly exchange opinions with other associations, take initiatives in collaboration with academia, which is one of EFPIA's strengths, and conduct smooth discussions.
-

Further improvement of the national testing process and international harmonization of regulatory requirements

STATUS: **PROGRESS**

The national examination process in Japan is gradually improving as a result of many years of discussions between industry, academia, and government. We reviewed the establishment of each article of each drug in the Biologics Standards, examined the simplification of the description while ensuring consistency of the test method between the formulations, and in 2023, it was deleted from each article of the drug in the abnormal toxicity denial test, and studies are being conducted to ensure the consistency of the description method of the test method in the pharmaceutical clause, and each company is responding to changes. In the future, we are continuing to consider test methods from animal tests to in vitro tests while holding discussions between industry, academia and government. In addition, as a state of national certification, a policy was also indicated that only SLP can be used for examination of formulations that meet certain criteria, and several items that were accepted for examination only by SLP were selected according to the standards. On the other hand, many vaccines are required to be tested by national certification, and it is still difficult to say that the double burden has been resolved. Imported products are exported after undergoing overseas national certification, but even after importation, the Japan national certification system often requires them to conduct tests again in Japan in accordance with Japan-specific biologics standards. The submission of test samples for national examinations involves the National Institute of Infectious Diseases(NIID), the MHLW, and prefectural officials, and the coordination work is a burden on companies. In particular, even when testing only in writing using SLP, one vaccine sample must be taken in the presence of prefectural officials. This is said to be a response stipulated in the Pharmaceuticals and Medical Devices Law, but it is an inefficient system and needs to be reviewed. For example, if overseas factories can randomly take vaccines in advance and send them directly to the NIID, the lead time for supplying imported vaccines will be somewhat shortened. Discussions continue on the efficiency of direct provision of sample samples and the ideal state test for SLP only. On the other hand, the integration of the NIID and the National Center for Global Health and Medicine has been decided, and there is a need for institutions that conduct national examinations and new operational changes, and it is necessary to discuss these matters as well. In addition, if pre-approval inspections are really a requirement for approval, or if only technology is to be transferred to prepare for national examinations, it is necessary to abolish pre-approval inspections and discuss how to build a new framework. EFPIA Japan will continue to request that products that have passed national examinations in Europe and the United States at least be screened only by SLP, and that the national examinations be streamlined by sample submission. We are also proposing a review of the standards for biological raw materials, which are being discussed by the AMED research group and others. It is also necessary to consider the fact that vaccines that have been widely used for a long time in Europe and other countries are extremely difficult to introduce in Japan because the information on biological raw materials contained in Star Cell Bank/Master seed does not meet the standards for biological raw materials.

Recommendations

- Strengthen cooperation with the Pharmaceuticals and Medical Devices Agency, the MHLW, and the prefectural and NIID, which are the testing organizations, or improve the efficiency of pharmaceutical review and assay functions
 - Review of sample sampling methods so that overseas manufacturing facilities can also take test samples
 - Reduction of the number of certified lots by utilizing SLP and expansion of SLP-only items, including newly approved products
-

Promote the development of vaccines with high development priorities and accelerate discussions on NIP vaccination

STATUS: **PROGRESS**

As for vaccines with high development priority, the government has requested companies to develop them, and there were many remarks from members of the council that priority should be given to discussions on routine vaccination ahead of other vaccines, and there was support to proceed to the next discussion without objection on this point. EFPIA member companies include pediatric combination vaccines, Herpes Zoster vaccines, high-dose Influenza vaccines, and RS virus vaccines

Recommendations

- Improving the predictability of NIP is being incorporated into the government's basic policy, and we will promote clear criteria for NIP vaccinations and the creation of a system that allows discussions on NIP vaccinations to begin even before vaccines are approved.

PUBLISHED: March 27, 2023

Establishment of alternatives to animal testing

STATUS: **SOME PROGRESS**

Following the addition of the reconstructed human corneal-like dermal modelling method (RhCE method) in 2019 as an alternative to the ophthalmic stimulation test that can be used in the application for quasi-drugs, guidance was issued in 2021 on single-dosage and dermal stimulation in 2022 on the evaluation system. In addition, discussions on next-generation risk assessment without using animals are still ongoing. In Japan, however, the safety evaluation of quasi-drugs with new ingredients necessarily requires results of animal experiments as a hazard evaluation of raw materials, and it cannot be said that other available scientific grounds have been sufficiently reviewed. In addition, in each country, discussions are actively underway for the development of evaluation methods that do not use animals at all, the establishment of safety evaluation methods, and the use of animal experiment results carried out for purposes other than cosmetics. Although Japan is also participating in the discussion, the policy for the safety assessment of the final product in Japan remains insufficient.

Recommendations

- Japan should promptly establish risk assessment methods for final products utilising available scientific evidence to prevent the implementation of unnecessary animal experiments. In addition, Japan should also promote the rapid development of alternative methods that do not use animals at all and the active use of such methods in the application for quasi-drugs.

PUBLISHED: March 27, 2023

Applying the same standards to all market participants

STATUS: **NO PROGRESS**

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.
-

Efficiency of notifications and applications for approval of cosmetics and quasi-drugs

STATUS: **SOME PROGRESS**

In accordance with the Digital Procedures Act, MHLW began operating online submissions in May 2021 for certain notifications or applications related to quasi-drugs and cosmetics, which had previously been required to be submitted using floppy disks and other storage media. From July 2022, the scope of operations for online submissions has been gradually expanded. This system is expected to improve the convenience of submissions, but this system simply replaces the submissions of applications, notices, etc. prepared using the MHLW's electronic application software for pharmaceuticals, etc., which was developed in April 2005, on-line. Furthermore, the prefectural authorities, the PMDA and Customs are not linked, so separate procedures are required for notification and application concerning the manufacturing and sales of cosmetics and quasi-drugs, and presentation of the necessary material for import customs clearance. It is hoped that the establishment of a system that enables the simplification and streamlining of administrative procedures for cosmetics & quasi-drugs permitting and import procedures will lead to the realisation of "digitalisation," which is stated in the national digital governance action plan.

Recommendations

- Improvements to the MHLW's electronic application software for pharmaceuticals, etc., simplification of application form and notification preparation work by reconsidering the content of descriptions and the necessity of materials required to be submitted, and linkage between application software and online submission system should realise streamlining from preparation to submission.
 - A one-stop service for administrative procedures should be realised by linking the application and notification system with the system used at the time of customs clearance.
-

Advertising representation for cosmetics and quasi-drugs

STATUS: NO PROGRESS

Fifty-five efficacy claims were defined as permissible for cosmetics in Japan in 2000. In 2011, a further efficacy claim of "making fine wrinkles due to dryness less noticeable" was added to the list. Yet the scope of efficacy claims approved in Japan is still narrower than in Europe, which hinders foreign-made cosmetics based on the latest research and technology from entering the Japanese market. Sector associations are currently studying the efficacy claim of "prevention of ultraviolet ray-derived photo-ageing" which may lead to a further expansion. In recent years, the promotion of self-care and self-medication is required for the realisation of healthy long-lived social. Daily care by cosmetics and quasi-drugs, such as wet care for atopic skin and use of suntan products to prevent skin cancer, plays an important role in maintaining health and improving the quality of life, and contributing to disease prevention and thereby curbing medical costs. Current advertising regulations, however, do not allow the importance of such care to be promoted. In addition, it is stated that "illustration of experience-and-experience discussions on indications" should not be done because it is not an objective support and there is a risk that consumers may be misled about the efficacy, etc. or safety. It is not permitted even if the content is a fact or within the scope of the approved efficacy. This an important factor and often used by the consumer when choosing a particular product. In addition, in the recent pandemic, the opinion of uses with experience has become an increasingly important information for consumers, considering the difficulty of face-to-face sales and trial of actual products at stores and the significant increase in mail order users. If it is possible to post user experience statements in the advertising of cosmetics, it will be possible to respond to the diversification of consumer demand and to communicate a wide range of information to consumers.

Recommendations

- Limitations on advertising expressions should be eased so that the role of routine care using cosmetics and quasi-drugs, such as health maintenance and disease prevention, can also be promoted.
 - "Consumers' experience" should be allowed to be used in advertising if it is the scope recognised by the cosmetics.
-

Regulations and systems for quasi-drugs

STATUS: NO PROGRESS

MHLW issued a notice of concern regarding the examination of approval of pharmaceutical shampoos, pharmaceutical rinses, and pharmaceutical soaps, and set out its examination guidelines. In July 2019, PMDA revised its application for manufacturing and marketing approval for quasi-drugs and added illustrations of how to treat applied products with the same standards and test methods as those of the attached specifications in the approved products. Along with these developments, progress has been made in improving the simplification and speed of application and examination operations. In addition, in order to facilitate the review process, a briefing for personnel in charge of the application for quasi-drug approval is held every year, and reviews are conducted based on the materials provided at the briefing sessions. However, the positioning of the materials is not clearly indicated.

Recommendations

- For quasi-drugs deemed to be identical and similar to already approval quasi-drugs, the review period should be shortened.
- When changing the approach to the review, it should be announced at the briefing session for practitioners applying for quasi-drug approval and communicated to the applicants in an easy-to-understand manner through careful explanations.

PUBLISHED: May 22, 2024

Proper evaluation of nuclear medicine diagnosis and treatment

STATUS: **PROGRESS**

Over the long term, there have been legislation on PET testing using in-hospital manufacturing and delivery of PET diagnostic reagents, and double-standard drug machines. In addition, Insurance system had only a comprehensive technical fee for PET diagnostic reagents without drug prices, but in Delivery, new technical fees for drug prices and PET imaging are expected to be established, and Insurance is also expected to become a double-standard system.

Recommendations

- In-hospital manufacturing, we proposed the establishment of a new in-hospital manufacturing fee that assumes the introduction of a technical fee for PET photography and a domestic generator.

PUBLISHED: May 22, 2024

Evaluation to improve medical treatment efficiency and reduce the burden on medical practitioners (work style reform)

STATUS: **NO PROGRESS**

Since the cap system for overtime working hours will also be eligible for doctors from 2024, there is an urgent need to reform the way healthcare professionals work. It is said that ICT and task-shifting will be effective for these issues, and it is thought that the use of diagnostic imaging programs such as medical equipment and remote ICU systems can resolve the excessive labor of doctors. However, the medical fee system has not been evaluated for the functions leading to these work style reforms, and the dissemination to medical institutions has not progressed slowly.

Recommendations

- Proposals are made to ensure that functions leading to work style reform are also evaluated on an appropriate Insurance basis.

PUBLISHED: May 22, 2024

Clarification of unprofitable products (measures to ensure stable supply)

STATUS: **NEW**

For unprofitable requests, selection requirements and standards are not clear, and it is difficult for companies to submit unprofitable requests.

Recommendations

- The development of the standard in the case of multiple products in the same function classification is proposed.
 - The academic society suggested that the Ministry of Health, Labour and Welfare provide support for the preparation of requests for continuous supply.
-

PUBLISHED: May 22, 2024

Revision of insurance coverage and functional classification of insurance medical material

STATUS: **PROGRESS**

Functional classification exceptions as a means of promoting the innovation are continuing. In addition, rapid addition as an effective means for eliminating device lag is continuing, which the EBC views positively. Integrating (rationalization) of newly classified products in the C application with existing classifications is contrary to the innovation assessment of lowering the price of innovative products and raising the price of products that do not.

Recommendations

- It does not deny the review of the functional classification based on rational grounds. To ensure transparency and predictability, it is proposed to share the specific reasons for the rationalization study and to secure the time to agree and consultation with the rationalization proposal.
- It is proposed that the function classification newly established in C classification will not be reviewed until a certain period has passed.

PUBLISHED: May 22, 2024

Foreign price reference system

STATUS: **NO PROGRESS**

Under the previous revision (R4), if the highest price in the case of three or more foreign countries exceeds the additive average of the other prices by 1.6 times, it was revised to deem the highest price to be equivalent to 1.6 times the additive average of the other prices.

Recommendations

- Proposed abolishment of the foreign price repricing system. (When it cannot be abolished, it will not be lowered if the foreign price ratio is 1 times or less on an added average that does not apply the exclusion rule, and it is proposed to relax the upper limit of the reduction by 50%.)
- It was proposed that the functional classification in which the hospital delivery price exceeds the reimbursement price (inverse Zaya) be excluded from the object classification of the foreign price repricing system from the viewpoint of stable supply.
- It was proposed that a review of 1.25 times, the comparative level of foreign prices, as well as newly listed and repriced products, be not carried out.

PUBLISHED: May 22, 2024

Reevaluation of insurance application system (challenges) based on actual usage

STATUS: **PROGRESS**

C1, C2 challenges to re-evaluate according to actual use were also institutionalized. This has paved the way for reevaluation by company entities. Challenge rights acquisitions require the submission of a research plan and may take longer to test for additional clinical usefulness.

Recommendations

- The verification implementation period for the challenge right acquisition was proposed to be 3 years.

PUBLISHED: May 22, 2024

Scope of application of programmes for medical devices including artificial intelligence and insurance coverage

STATUS: GOOD PROGRESS

The previous revision clarified the direction of Insurance listing of the programme medical equipment, but the market-entry of products with no established clinical significance and the difficulty of Insurance listing continued. For this reason, we proposed a new Japanese version of DiGA with a two-stage approval and Insurance system, which is expected to be institutionalized in the next revision.

Recommendations

- The first phase of the two-stage approval and Insurance system was introduced as the evaluation and medical treatment system, and a selection medical treatment system was proposed as the second stage option. In addition, the function that leads to the work style reform is also a point to be discussed and recommendation.
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PUBLISHED: May 22, 2024

Global standards for clinical evaluation

STATUS: NEGATIVE PROGRESS

It became necessary to collect safety information using Japan unique rules, because the investigational device used includes the subject device, the reference device, and the combination device.

Recommendations

- Japan shall review the status and requirements regarding the collection of safety information for reference devices and combination devices, and investigate the impact on the implementation of international joint trials.
-

PUBLISHED: May 22, 2024

Audit system adapted to characteristics of program medical equipment

STATUS: PROGRESS

Collaboration between the industry and the auditing department within the Ministry of Health, Labour and Welfare and PMDA, which have been strengthened. Efforts to identify and resolve issues.

Recommendations

- Establishment of regulations and examination systems based on characteristics. The EBC requests that a new early approval system is introduced utilising real-world data.
 - SaMD also requested clarification by guidance, etc. on the basic concept for utilizing the two-stage approvals system.
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PUBLISHED: May 22, 2024

Treatment of the cost accounting method

STATUS: NEW

Base material prices for newly listed products are, in principle, calculated by the similar function comparison method. However, if the price is 0.5 times or less of the foreign average price, from the viewpoint of stable supply, there is a system for applying for calculation using the cost calculation method. However, since there is no foreign price for products that have not yet been released in foreign countries, this rule is not applicable.

Recommendations

- In order to secure the stable supply of the products which have not been released in foreign countries, the price lower limit in the cost accounting system is proposed.

PUBLISHED: November 21, 2022

Procedures for suspension of supply

STATUS: NEW

There is a current situation in which negotiations for the adjustment of alternatives are entrusted to the company after reporting on the suspension of supply.

Recommendations

- The EBC requests that support from the Government for the adjustment of alternatives. The timing of a request for consideration of supply from the MHLW to an academic society should be taken into account the timing of the announcement of supply suspensions by companies.

PUBLISHED: November 29, 2021

QMS mutual recognition and global standards

STATUS: SOME PROGRESS

Some progress was shown in conformity with the global standards. Formal participation in the MDSAP (Medical Device Single Audit Program) assists further development of discussions for conformity with the global standards.

Recommendations

- Japan shall eliminate the differences in requirements of the QMS ministerial ordinance, and conform with the global standards for the product group classification.
-

Mutual recognition and global standards of medical equipment license

STATUS: **SOME PROGRESS**

The approval examination period of the PMDA was shortened by the enforcement of the Japanese PMDA law and performance was improved.

Recommendations

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

PUBLISHED: November 29, 2021

Promoting partnerships with the EU

STATUS: SOME PROGRESS

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

Recommendations

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

PUBLISHED: November 29, 2021

Supporting BASA negotiation between EU and Japan

STATUS: SOME PROGRESS

The EBC welcomes the signature on June 22, 2020 of the 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 the signature of this agreement between Japan and Europe, its ratification remains to be achieved.

Recommendations

- With the entry into force of the BASA, the EU and Japan now need to add additional activities, such as, maintenance, spare parts and training activities to the BASA. These segments are currently not included in the agreement and the EBC believes that the inclusion of these segments would be beneficial to both the European and Japanese aeronautical industries.

PUBLISHED: October 21, 2024

Tax reform

STATUS: **PROGRESS**

Eco-car Tax Incentives and the Automobile Tax Environmental Performance Levy will remain unchanged until the end of 2023 and so will the current preferential treatment for EVs, etc. for the next three years.

Recommendations

- The penetration of electric vehicles (EV) in Japan is currently at a low level. We need to accelerate the spread of xEVs that will contribute to achieving carbon neutrality. System reforms that increase the burden on users should be avoided. We would like to request consideration of tax reform to accelerate the spread of xEVs such as EVs, PHEVs, and FCEVs.
- Car users in Japan are subject to excessive and complex taxes compared to other countries. We request to simplify automobile-related taxes and drastically reduce the burden on users.

PUBLISHED: October 21, 2024

Connectivity related (including automated driving)

STATUS: **PROGRESS**

Concerning the certification of CS/SU management system compliance , which was a prerequisite for applying for SU permission for vehicles in use, which we requested since last year, the authorities responded in a timely manner so that we could utilize the CS/SU management system compliance certificate obtained from overseas authorities. We appreciate it. However, we believe that it would be desirable to further streamline the procedures for the SU permit system for vehicles in use. MIC has begun to acquire the 5.9GHz band, which is used in Europe and North America as an ITS frequency. Though it is necessary to formulate by 2030 a new communication method in addition to the existing 760MHz ITS, the method, which has a large impact on vehicle development is unclear, as it also relates ETC using DSRC.

Recommendations

- To enable quick market actions and improve convenience for consumers, the government should review the rationalization of permit application procedures for specified modifications to registered vehicles. Japan should decide on the ITS communication method as soon as possible through international cooperation.
-

Introduction of International Whole Vehicle Type Approval (IWVTA)

STATUS: **SOME PROGRESS**

International harmonization of standards and certifications is progressing year by year through the initiatives of the authorities towards the realization of a complete IWVTA. Many non-tariff barriers have been reduced; We are grateful to the authorities. However, although international harmonization is progressing, even after the introduction of the IWVTA system in July 2018, standards for equipment subject to IWVTA are still insufficiently harmonized, such as passenger car exhaust emission, fuel/electricity consumption (UN-R154). There are still devices and systems that are not covered by IWVTA for obtaining type approval for the entire vehicle, and thus utilization of IWVTA (UN-R0) is not progressing. In addition, practical issues remain. Together with the authorities, we are reviewing certification procedures such as ENFORCEMENT PROCEDURE FOR MOTOR VEHICLE TYPE CERTIFICATION.

Recommendations

- Japan should aim for a complete mutual recognition system for vehicle type approval as soon as possible.
- Through international harmonization, Japan's unique requirements, such as the definition of the same vehicle type, should be reduced, aiming for IWVTA.
- Furthermore, efforts should be made to streamline type designation inspections by utilizing equipment type certification obtained overseas.

Electrification and fuel efficiency standards

STATUS: **PROGRESS**

In the FY2023 budget, the government continues to seamlessly implement xEV purchase subsidy measures, and has also requested approximately 107.6 billion yen for FY2024. We are very grateful. The government also has set up a study group to promote the development of charging infrastructure and begun considering deregulation of the voltage restrictions, etc. In addition, local governments such as Tokyo are expanding purchase subsidies for xEVs. Starting in 2025, Tokyo will require all new apartment houses to be equipped with charging equipment.

Recommendations

- We would like to ask for the government's continued support for vehicle purchase subsidies for xEVs. We would also like to request that at least the current conditions be continued, or even extended further.
- As the capacity of xEV batteries increases, charging efficiency is required. For voltage restrictions specific to Japan (DC450V/750V), the government has set up an investigative committee and has begun moving toward deregulation of some (private electrical facilities). We should continue to take into account trends in other countries and collaborate with related organizations to ease regulations from the user's perspective, including general electrical facilities.
- Regarding recycling and reuse of batteries, we will cooperate with the parties concerned to improve the operation of the current joint recovery system. In addition, if an institutional framework to promote recycling and reuse of batteries is considered, we believe that it is important to create an appropriate scheme that can be addressed by imported cars.
- In the review of passenger car fuel efficiency standards, the introduction of flexible measures should be considered.

PUBLISHED: November 29, 2021

Tyres

STATUS: **RESOLVED**

Jisha 502 specifies that every approved tyre has to be listed in JATMA's Year Book. Although tyres fulfilling the applicable UNECE regulation are perfectly legal, and of course safe, in Japan, JATMA refuses to include tyres that are not in complete compliance with Japanese regulations. This puts European tyres at a disadvantage.

Resolved

- JATMA now includes UNECE-compliant tyres.

PUBLISHED: November 29, 2021

Aftermarket

STATUS: **NO PROGRESS**

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

Recommendations

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

PUBLISHED: November 29, 2021

Harmonisation

STATUS: **SOME PROGRESS**

The EBC appreciates the success of the harmonisation originating from the EU-Japan EPA. This is nothing short of a success. Following this positive step, the EBC hopes that for new technologies, such as automated and connected driving, safety standards, electric and alternative fuel vehicles this will continue. It is important that the momentum is not lost.

Recommendations

- To continue on the harmonisation work so that new technologies do not risk running into the need of double-testing or in worse case scenario not being able to be introduced to the market
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Globalisation of the automobile industry and promoting information exchange

STATUS: **SOME 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.

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.

PUBLISHED: January 29, 2024

Auction system for wind power

STATUS: SOME PROGRESS

After the award of Round 1 auction in December 2022, the government postponed the ongoing Round 2 process and started revising the auction system for the next rounds considering the energy scrutiny situation, which had dramatically changed due to the Ukraine war.

Recommendations

- It is particularly important for policy makers to 1) ensure the fairness and transparency of the competitive environment, and 2) promote planned, continuous and large-scale offshore wind power generation.

PUBLISHED: January 29, 2024

Transmission and distribution

STATUS: SOME PROGRESS

Japan's transmission network is centred on its production sites, with the main transmission at 500kV. The frequency converter stations (FC) connecting the 50Hz and 60Hz networks offer only limited additional capacity. Furthermore, the limited interconnections between the individual EPCOs represent a real risk to security of supply. In contrast, European and US grids have extensive plans for use of High Voltage Direct Current (HVDC), which offers more flexibility in energy flows between regions, enables large integration of renewable into the system and also enables long cable connection by subsea or land. The Organization for Cross-regional Coordination of Transmission Operators (OCCTO) ensures network balance by designing national Master Plans. It is encouraging to the ongoing discussion to connect Hokkaido and Tokyo with HVDC subsea cables.

Recommendations

- The legal unbundling in April 2020 should implement regulations that will ensure security of supply and fair market mechanisms based on wider grid interconnections and look into increasing ownership or operation separation to further ensure the independence of Transmission and Distribution System Operators (TDSOs).
 - Japan should do more to increase interconnection capacity between TDSOs, achieving fair electricity transactions and encouraging mergers between TDSOs for logical and reasonable decision making.
 - The TDSOs should look into further harmonisation of technical standards by integrating individual requirements and also adopting European standards for products and systems to achieve cost efficiency.
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Nuclear energy and nuclear safety

STATUS: **SOME PROGRESS**

Prime Minister Fumio Kishida announced a plan on August 24th 2022 of making up to a total of 17 reactors operational by summer 2023 and constructing new “next generation” nuclear power plants. Of the 33 currently considered to be operable, 12 have so far been restarted, all pressurised water reactors. Japan's Mitsubishi Heavy Industries is developing a design of "SRZ-1200", a 1.2-million-kilowatt advanced light water reactor with Kansai EPCO, Hokkaido EPCO, Shikoku EPCO and Kyushu EPCO, to develop a next-generation nuclear power reactor. The consortium aims for mid-2030 completion. Also, The Tohoku Electric Power Company plans to reactivate the Onagawa-2 reactor (825 MW) in February 2024 and Chugoku plans to restart its reactor of Shimane 2 (BWR-5 with a 2436MWt thermal capacity) in August 2024., after seismic reinforcement and safety tests to be cleared. It would be the first BWRs to be restarted since 2011. Japan's restart of more nuclear power plants would help ease Europe's energy supply fears during the winter as more liquefied natural gas (LNG) will become available to the global market. On the other hand, electricity bill rising for the past year of 20% for households and of 30% for businesses may enhance a new lead for Japanese government's policies in the upcoming years. In fact, it pushes the government to reimplement subsidies to the Japanese Utilities and cash pay-outs to households and firms. It is worth noting that all the Japanese utilities that have restarted shutdown nuclear power plants (Kansai, Kyushu and Shikoku EPCOs) returned to profit in the 2023 financial year. The more restarts there are over the next two fiscal years, the more price rises can be contained accordingly. This may be affected by the sharp falls in the yen that pushes up prices of imported goods. Mainly, costs for coal have tripled within the last year, and the price of natural gas has doubled in the same period.

Recommendations

- Japan should increase cooperation with international organisations to improve global nuclear safety. Japan should strengthen its cooperation with international organisations to improve the nuclear safety culture, with a view to enhancing dialogue between operators and the safety authority. This direct dialogue is necessary to share safety issues and risks in a way that is both constructive and demanding.
 - Japan should continue and accelerate its efforts to restart a maximum of idled reactors to achieve the 2030 decarbonisation objectives.
 - Japan should promote fuel multi-recycling to reduce waste and further boost energy self-sufficiency.
 - The Japanese Government should commit proactively to put into practice its long-term plan for the replacement of ageing reactors to achieve the energy mix targets, including maintaining sufficient manpower to restart the current fleet and its future replacement.
 - Last but not least, the more space is made available on existing sites, the more new capacity can be built in the future. This should encourage the Japanese government and operators to continue and accelerate their efforts to dismantle and decommission obsolete reactors, particularly large used components. The expertise developed in Europe could be put to good use in this context.
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Solar energy

STATUS: SOME PROGRESS

The principal impediments to sustainable growth of utility and commercial-grade solar energy are: still rather discouraging reverse auction system which do not meet planned allocations, cumbersome procedure for obtaining special permits for land re-zoning for non-agricultural use, and the prospect of potential curtailment in certain power grids, which affects project financing. Additional challenges that Japanese utility companies may soon encounter are managing cost effective solutions to integrate decentralised and intermittent renewable generations into the existing power grid. While Japan has focused extensively on solar power as a renewable energy source, the EBC believes that it must continue to encourage development of this important source of renewable energy. This must be carried out ambitiously with realistic targets, aimed at increasing the safety and reliability of the energy supply.

Recommendations

- Adopt and recognise internationally accepted certification standards for solar modules, system components and design qualifications, rather than enforcing existing “Japan-only” component and certification standards.
 - Adopt an accreditation scheme to support the acceptance of test results, reports and certificates from any accredited certification body, whether domestic or foreign, based on available international standards.
 - Incentivise and create standardisation programmes for the EPCOs to use to contract PV project construction to an emerging class of engineering and design companies, with the aim of reducing grid connection costs and lead times.
 - Incentivise rooftop PV (PhotoVoltaic) installation as an alternative to power plants in remote areas requiring substantial land conversion, and facilitate PV installations for self-consumption in industrial and commercial sectors.
 - Encourage further grid interconnections to reduce the occurrence and adverse impact of curtailment, utilise existing pump storage power generation plants, use and improve battery storage, provide technical and regulatory frameworks for floating PV plants, and consider new technologies, such as conversion to hydro for further PV integration.
 - For the remaining FIT (Feed-In Tariff) projects under construction, project developers are forced to remain with previously selected PV modules and applied plant capacity, if they wish to maintain the earlier FIT (Feed-In-Tariffs) agreements. This practice not only results in failure to take advantage of recent technical developments, but in some cases has also resulted in unfavourable detail design. A certain level of flexibility with respect to design variations would easily avoid such situations, while maintaining the goal to clear the project pipeline.
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Coal

STATUS: NO PROGRESS

Japan imports 200 million tonnes per year of coal of which 110 tonnes are consumed for power generation. There is a coal ambiguity: 100 inefficient coal plants (22 giga watt, GW) need to close before 2030, but 11 GW of “high efficient” new coal plants are under construction. The idea of co-burning ammonia and coal (20/80) in order to reduce the CO₂ emissions is not a great solution. The most economical way to enact the energy transition in Japan is to convert existing coal power plants to another energy source (natural gas emits 50% less CO₂, or biofuels). Coal fired power plants can survive in Japan, but they should not run on coal in the future. If Japan’s coal fired power plants were to converted to natural gas, the 46% target carbon reduction would immediately be obtained, way before 2030. The expectations for CCS (Carbon Capture Storage) and H₂/ammonia appear high within the Japanese government but for the moment none of these solutions comes with any proven large-scale deployment.

Recommendations

- Japan should convert existing coal plants into plants using other energy sources, such as natural gas or biofuels.
 - Japan should be less dependent on technology that is not yet ready for large-scale development.
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Wind farm certification

STATUS: **NEW**

Japan should implement a drastic reform on the offshore wind farm certification process. The current setup has been inducing lengthy and unpredictable process which serves as a bottleneck for earlier financial closure and subsequent COD. Below are several suggestions for improvement.

Recommendations

- **Duration for certification:** The certification process should be completed in 1 - 1.5 years which is typical in Europe. It currently takes 3 - 4 years in Japan.
 - **Transparency in design codes:** The design codes and guidelines should be upgraded to provide more clarity on the acceptable design processes (e.g., setting up design conditions, the design methodologies and techniques, allowable criteria). This minimizes ambiguities and provides more transparency and predictability in certification process. This also reduces the time currently consumed in certification process for endorsing any new process/methodology to fill in such ambiguities. Additionally, ambiguities in design codes should be proactively clarified by the government with assistance of subject matter experts (not limited to academia) and should not be implemented in certification process of any commercial project as this would definitely increase the burden of developers and stretch out the duration of certification process.
 - **Step-by-step approval process:** The submissions (e.g., Design Basis-A, B and C) should be reviewed, commented and/or approved within a pre-determined duration (e.g., 2 weeks). Currently, the submissions are approved only at the end of the certification process. This setup hinders efficient certification process as this allows, for instance, Design Basis-A to be reviewed and commented many months after its submission. This practice would extend the duration of certification process because it would require re-dos of relevant design works as most of early submissions are inputs for subsequent design processes.
 - **Document-based review process:** The certification process should be document-based approach. Namely, developers furnish documents which contain all information necessary to justify the proposed design and certification body returns the documents with its comments (e.g., Approved, Approved with comment or Not approved). This provides more transparency and efficiency than the current setup. The current practice is meeting-based approach and most of the communication is made verbally. There is also constrain in time and opportunity as such meeting is held only once in every one or two months and the duration is only 2 hours. It is quite a challenge for developers to explain their design details and receive comments.
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Supply chain constraints

STATUS: NO PROGRESS

The industry has already seen some indication that supply chain capacity to support Japanese projects would be insufficient in coming years. The following measures should be undertaken to address this issue.

Recommendations

- Japan shall have a robust supply chain which can supply sufficient products and services when required. Excessive expectations for the formation of domestic supply chains could be an obstacle to accelerating development of offshore projects. It is necessary to create an environment in which domestic and foreign suppliers can make large investments based on future market size projections.
 - Increase market predictability for supplies by shortening the time between bidding and the start of operations with regulatory reform of permitting procedures (e.g. Wind farm certificate, EIA) and providing a long-term roadmap for project formation. Expanding the scale of each offshore wind project to 1 GW or larger level would enhance the market predictability.
 - Establish and implement strategic policies to enhance the competitiveness of Japanese suppliers in international market while welcoming non-Japanese suppliers to Japan for providing their products/ services which are already proven in international market. These two concepts should not be regarded as conflicting with each other. Both policies would support each other in facilitating the robust supply chain of the offshore wind in Japan and Asia.
 - Allow to employ products, services, specifications, inspection methodologies, etc. which comply with international codes and standards but might not be aligned with Japanese ones. This would attract and encourage more non-Japanese suppliers to provide their products and services to Japan. Japan shall be an attractive market for non-Japanese suppliers because the offshore wind supply chain is "Seller's market" now and is expected to remain so for the next several years. This means suppliers enjoy and will enjoy luxury to select markets which are more profitable and less risky. It is worth noting that some suppliers are showing their reluctance for entering Japan or continuing their business here.
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Demand response

STATUS: **PROGRESS**

Amid the shortage of supply capacity since the Great East Japan Earthquake, Demand Response (DR) is on its way to commercialization. After a four-year demonstration project, as a public offering of balancing reserve by TDSOs from FY2016, it is transitioning into the Capacity Market operated by OCCTO as a dispatchable peaking resource from FY2024 onward. In addition, the increased need for demand-side resources has been signalled in both the wholesale energy market (JEPX), in the wake of the recent global energy crisis and soaring fuel costs, and the balancing market due to the expanding introduction of renewable energy resources in Japan. While the Government of Japan (GOJ) has been working to design a system in which DR is integrated into market mechanisms, a certain amount of know-how has been accumulated through the active competition among DR aggregators and their operation under tight supply-demand conditions. As a result, the effectiveness of DR has become widely known to the public. The legal status of aggregators as “Specified Wholesale Suppliers” has just been clarified in the Electricity Business Act, effective from FY2022. Most recently, a further expansion of incentive-based DR was presented at the GX Execution Conference as a measure to tackle immediate power supply shortage.

Recommendations

- The EBC request that various systems be designed in a consumer-first manner that ensures consumer acceptance, predictability, and continuity.
 - The Japanese Government should design a system that enables both aggregators and consumers to make decisions on DR participation based on the economic rationality of price signals from various wholesale markets.
 - As indicated in the Clean Energy Package for Europe, the EBC requests that institutional design and market rules be developed so that not only retailers, but also independent aggregators can smoothly engage in DR operations in Japan.
 - Finally, to achieve Carbon Neutral target by 2050, the Government of Japan should consider the early introduction of equipment-point metering (sub-metering) so that not only DR, but also clean zero-emission distributed energy resources, including storage batteries, rooftop solar power, and electric vehicles, can participate in various wholesale markets.
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Marshalling port

STATUS: NO PROGRESS

Japan should expand/upgrade the already-selected marshalling ports (Akita, Noshiro, Kashima and Kitakyushu) and/or develop additional marshalling ports and make them ready preferably by 2027 so that all or most of the round 2 and 3 projects would be able to start their offshore installation campaign from 2028 and to make the wind farms operational by 2030. Considering the ambition of Japan to introduce 5.7GW offshore wind capacity by 2030 and the rapid growth in a unit capacity of offshore wind turbines, we recommend Japanese authorities to take into account the following elements to ensure marshalling ports would not hinder the mentioned Japan's ambition.

Recommendations

- A single marshalling port should have sufficient capacities and functions which can support installation of foundations and/or wind turbines equivalent to 1-2 GW every year. In specific;
 - Large area for storing foundations, turbines, cables, etc. and for preassembling works
 - Long and/or multiple quays to allow several vessels for unloading and/or loading out simultaneously
 - Sufficient bearing capacity for assembling and storing a tower for a 20MW wind turbine
 - Sufficient bearing capacity at quay side where a next generation Jack Up Vessel (e.g., 3,200 ton lifting capacity) can jack up for loading out foundations for a 20MW turbine.
 - A single marshalling port should have sufficient capacities and functions which can support installation of foundations and/or wind turbines equivalent to 1-2 GW every year. A marshalling port should be large enough to attract and encourage companies to start providing the services necessary for offshore wind development (e.g., bunkering, food/water supply, vessel repair & maintenance works) with reasonable price.
 - A large marshalling port should allow itself to have emergency response capabilities (e.g., rescue, salvage, prevention of oil pollution) which is also essential for offshore wind development.
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Wind energy

STATUS: **SOME PROGRESS**

This issue has been expanded and is now represented by [Auction system for wind power](#), [Supply chain constraints](#), [Marshalling port](#), and [Wind farm certification](#).

The development of wind energy is essential for Japan to reach its CO2 emissions targets and to achieve net-zero emissions by 2050. 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. The establishment of “the Public-Private Council” which serves as a platform of discussion between the offshore wind industry and the central Government was extremely encouraging, as was the “Vision for Offshore Wind Power Industry” published by the Council setting an ambitious target to sanction 10GW of offshore wind projects by 2030 and 30-45GW by 2040. Now with the 1st round of auctions being closed and awaiting result announcements, the offshore wind markets in Japan are gaining momentum.

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 and cabotage rules.
- 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 establish a standard for compensation to fishermen, to ensure that subsidies for offshore wind power is used efficiently and transparently.
- Japan should focus on and officially support development in areas with good wind conditions and access to consumption centres to enable investors to build utility-scale wind farms.
- Since Japan's offshore wind potential is located in deeper waters, Japan should continue to play an active role in supporting the development of the floating offshore wind industry. As this is globally an emerging technology and industry, Japan can still position itself as an industrial hub (supply chain) for this industry. The focus should now shift from technology demonstration to cost improvements through changing the support focus to larger scale floating wind farms.
- Japan should introduce regulations for offshore wind development in the exclusive economic zones too, and not only for territorial water, since most of Japan offshore wind potential is located in the former.

PUBLISHED: November 21, 2022

Life Cycle Assessment (LCA) and Environment Product Declaration (EPD)

STATUS: **NEW**

LCAs and EPDs are becoming more common both as suppliers are disclosing the information as part of their transparency efforts and as buyers are requesting this to fulfil their environmental goals and requirement. In the EU, some standards, such as EN 15804+A4 for the construction related materials, and platforms for EPD, such as Environdec, are being used. In Japan we have Ecoleaf. As more and more data are being covered by LCA and EPD it is important that there is harmonisation between various systems to avoid that additional costs. This can become significant considering the number of products of a given company. It should be mentioned that some collaboration already exists.

Recommendations

- Japan and the EU should harmonise or mutual recognise LCA systems and EPD. Both in so far as standards and registration platforms.

PUBLISHED: November 21, 2022

Waste shipment out of Japan for treatment in European world-class facilities

STATUS: **PROGRESS** **SOME PROGRESS**

Japan has introduced a three-year notification period for waste shipment procedure, which makes situation better than little time after agreement. However, the notification process of Basel waste is still very slow due to inefficient procedures. For instance, for transit and passing countries, Japanese authorities don't apply the tacit consent rule toward non-OECD countries and hold the procedure until all the transit countries approve it. These complicated procedures are required even for pre-authorised facilities which benefit from extremely low risk to human health and the environment.

Recommendations

- Review the amount and type of data needed by Japanese authorities during the notification process.
 - Speed up at authorities the notification process to bring it to an acceptable level similar to the speed of other
 - Japanese Government should allow negative value material to leave Japan using transparent guidelines.
 - Review Japanese system for waste classification to enable a closed loop system for scarce metals between Japan and Europe.
 - A fast-track system between Japan and Europe should be implemented for pre-authorised facilities
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Workers' safety labelling for chemicals

STATUS: 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, eg. alumina. There is also a lack of information in English.

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.
 - EU and Japan should better harmonise this area to avoid the need for different labelling.
-

Chemical substance control law

STATUS: PROGRESS 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. Some harmonisation was achieved thanks to the EU-Japan EPA but many areas are still either not harmonised or the registration has to be done separately.

Recommendations

- Japan and the EU should harmonise their registration systems or mutually recognise test results and supporting documents, and also make certain that products are not classified differently in the two regions.
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Tariff issues

STATUS: GOOD PROGRESS PROGRESS

With the entry into force of the EU-Japan EPA, tariffs have been removed on metals with EU origin. This is something that benefits not only European suppliers but also the Japanese industry that is dependent on these products and is under pressure from low cost countries. However, due to the global nature of the material sector some metals will not be able to benefit from the EU-Japan EPA. For this to be achieved Japan will have to remove tariffs on a worldwide basis. Moreover, industrial materials imported into Japan are occasionally subjected to arbitrary tariff classifications and revisions. Regional Customs offices do not apply classification rules on a consistent basis and the appeal mechanism is both time-consuming and costly, without any guarantee that the outcome will be in line with international practice.

Recommendations

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

PUBLISHED: November 27, 2023

Satellites

STATUS: NO PROGRESS

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

Recommendations

- The EBC advocates closer space agency cooperation in satellite technology development and applications, with pro-active promotion and execution of industrially and commercially meaningful cooperation projects.
- The Government of Japan should increase cooperation with Europe through the procurement of high-quality satellite systems or equipment in fields related to national security among others. 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.

PUBLISHED: November 27, 2023

Launchers

STATUS: SOME PROGRESS

Europe and Japan are developing their respective next generation heavy-lift launchers Ariane 6 and H3 almost simultaneously. Both sides will need to develop enhanced versions to stay competitive. As many development items will be the same, cooperation will be mutually beneficial. The space agencies of both parties are already cooperating on some items of future enhancements. A plan for a balanced mutual backup agreement to reduce delays in launching government satellites was evaluated positively by Japan's space authorities in the past. Now we need to establish a concrete framework to implement such a backup scheme.

Recommendations

- Japan and Europe should step up cooperation on the future evolutions of their respective new generation launchers. ArianeGroup and the new structure of Europe's heavy launcher industry make it easier to realise industry-led cooperation on development.
 - 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.
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Space debris and situational awareness

STATUS: **SOME PROGRESS**

Near-Earth space is a key resource for society, as crucial as Earth-bound resources. Space debris threaten vital current space systems and the availability of the resource for future projects. New micro-satellite constellations and other projects make a strong "space situational awareness" indispensable. Japan and Europe have a shared problem in making core small launchers of solid motor rockets, because micro-debris may arise from combustion gases ejected by solid motors. Both Japan and Europe are leaders in debris policies, and there is a high awareness about preserving the space environment.

Recommendations

- Japan and Europe should continue increasing the scope of their cooperation in space situational awareness.
 - Japan and Europe started a cooperation discussion on the Electro Dynamic Tether debris removal device. A strong support by JAXA is appreciated.
 - We recommend that Japan and Europe consider cooperating at government level on the debris problem incurred by the operation of core solid motor launchers as well as the soil contamination problem.
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General environment

STATUS: NO PROGRESS

The approval system for satellite projects and the handling of future PPP projects hold risks of protectionism. The EBC advocates increasing, not reducing, trade and cooperation. More openness to European industry would benefit Japan. This especially as Europe provides many technologies free from “black-box” technology concealment policies. In the U.S., billionaires expand their assets further on the basis of the U.S.’s large government demand, with an impact on the commercial market. American companies with enormous capital and a large governmental market solidify their competitiveness through physical concentration. China and India are also rising. Japan and Europe are facing common threats never experienced before. In both Japan and Europe, development funds and government demand are limited. In order to maintain a space industry and an independent access to space, establishing a strategic partnership should be urgently considered. After the Russian invasion of Ukraine, Russia suspended Arianespace’s Soyuz launcher operations. This suspension and the delay of Ariane 6 cause a European launch capacity shortage. The potential of the idea of the Japan-Europe mutual backup of institutional satellite launches is getting bigger and bigger.

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 continued Japanese cooperation with European space agencies. Space agencies on both sides can compare their projects at an early stage and take advantage of cooperation opportunities.
- The European Space Agency (ESA) should consider establishing a permanent representation in Japan.
- Japan should also encourage more cooperation between the Japanese and European space industries on satellite platforms and ground systems.
- The EBC believes that boosting Japan-Europe cooperation is indispensable in order to respond to the rapidly changing space environment and common threats, and requests that action be taken to make this possible.
- The discussion of Japan-Europe mutual backup cooperation regarding institutional satellites should resume.
- An agreement regarding the treatment of sensitive information should be signed between Japan and Europe (ESA, EC, ...) to facilitate the mutual backup of institutional satellites.

PUBLISHED: December 1, 2022

Procurement

STATUS: NO PROGRESS

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

Recommendations

- The Government of Japan should regard the use of European defence and/or dual use equipment as a part of fostering the security collaboration with European nations and widen its supplier base. The Government of Japan should strategically promote collaboration and consider EU industries as partners of choice to deliver the next Mid Term Defence Plan 2023/2028 and beyond. It would significantly benefit the operation of the Self-Defence Forces in terms of Life Cycle Cost reduction and would benefit both European and Japanese industries throughout the increased international collaboration opportunities.
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Industrial collaboration

STATUS: NO PROGRESS

The EBC notices that the increase in the Japanese defense budget during the last few years is mostly benefiting the US industry, which absorbs almost all the increase. At the same time, only a few Japanese companies are trying to be active on the global market. To make matters worse, strict export control, especially in terms of third country transfer, is discouraging companies and leading to missed out collaboration opportunity with European companies.

Recommendations

- In order to foster cooperation between Japanese and European industries in the defense domain, especially with the view of addressing third country markets, the Government of Japan should present a more precise framework in terms of practical expectation (main technologies, operating field, priorities) and actively motivate Japanese companies to enter into a cooperative mode with their European counterparts.
- The EBC recommends a closer dialog between the European Defense Agency (EDA) and its counterparts in Japan, ATLA (Acquisition, Technology & Logistics Agency) and METI (Ministry of Economy, Trade and Industry), to promote industrial partnerships between Japanese and European companies. More specifically, Japanese officials could also explore and promote in a beneficial way, joining as a third party, the new defense initiatives implemented by the European Union to foster industrial cooperation between member states in specific areas of mutual interest.
- The Government of Japan should also 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 industries.

PUBLISHED: November 29, 2021

High costs at Japanese airports and new Tourism Tax proposal

STATUS: **SOME PROGRESS**

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

Recommendations

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

PUBLISHED: November 29, 2021

Coronavirus

STATUS: **PROGRESS**

The Government must facilitate and support airlines in the short-term so that it can change from activities focusing on passenger traffic to freight traffic. It is also imperative that whatever aid is offered to domestic operators if also offered to the domestic activities of foreign airliners

Recommendations

- The Japanese Government should improve the situation for freight transport, especially at Haneda. At the same time, it should be possible for airliners to, in a flexible manner, to increase its freight transport capacity in place of its passenger traffic capacity.
 - Airliners should be able to retain its slots even if temporarily due to the Coronavirus, they reduce their traffic.
 - The Government should include foreign airliners domestic activities when and if offering monetary support to the airline industry.
 - Sufficient resources need to be dedicated to new screening procedures at airports for arriving international travellers in order to alleviate long waiting times and passenger load restrictions for inbound flights .Further restriction on inbound passenger loads will reduce the airlines abilities to ramp up operations and meet expected demand.
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Airport infrastructure

STATUS: **SOME PROGRESS**

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

Recommendations

- HND should continue opening up to international traffic, including flights to and from Europe
- More space for catering and cargo suppliers should be allocated at HND, in order to increase efficiency and reduce costs for operators.
- Additional car park facilities should be added at HND to alleviate waiting times for parking spaces. This would improve quick access to the airport.
- Numbers of immigration staff should be increased at all international airports as waiting times are
- 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.

PUBLISHED: April 14, 2023

Sustainability

STATUS: **NEW**

The logistics sector is active globally all over the world and plays a major role to reach a carbon neutral society. While there are some progress in Japan, the EBC believes that there is still plenty of improvements that can be made. We are at the same time fully aware that many of the policies are globally decided.

Recommendations

- The Government of Japan should set goals and initiate subventions to stimulate the industry and the market to invest and use more environmental-friendly logistic processes.
- Japan should together with the EU take the lead to make the logistics sector more sustainable.
- As part of the working hours limitations, Japan should implement policies that make it possible to transport bigger loads, such as double or larger trailers.

PUBLISHED: April 14, 2023

Future delivery modernisation

STATUS: **SOME PROGRESS**

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. The situation has further worsened with the Corona virus.

Recommendations

The Government of Japan should:

- Support and enable use of larger vehicles for inter-city movement to reduce the number of vehicles and drivers required. This would also be inline with the new limitations on working hours for truck drivers.
 - 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. It is not uncommon that all boxes are already used.
 - 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”. Failed deliveries are still very common.
-

Labour shortage

STATUS: **SOME PROGRESS**

Given Japan's projected population decline and ageing society, it is anticipated that the current shortage of available labour will continue, severely impacting the logistics sector as expansion of e-commerce drives up demand. The logistics sector is especially vulnerable as many of the long-haul drivers it employs have reached or are reaching retirement age. In order to continue meeting the demand for logistics services, it is important that the Government puts in place practical strategies to improve the availability of labour in the short- and medium-term. The EBC appreciates the various initiatives put forward by the Government. However, many of them do not quite hit the target but are held back by limitations either in scope or by administrative restrictions. There is a particular concern around the short-term challenge, since potential solutions such as the use of new technologies, including autonomous driving, and increased use of automation in freight handling will only become available in the long term. From 2024, the legislation will change so that drivers will not be able to work for more than eight consecutive hours.

Recommendations

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

NACCS

STATUS: **NO PROGRESS**

The NACCS (Nippon Automated Cargo and Port Consolidated System) is a well-used system in Japan for among other things customs clearance. While it gives direct access to the service of the Japan Customs, many other agencies and ministries are less connected to NACCS. This means that some data has to be duplicated. Examples of these data are: trucking, warehousing, forwarding activities, airlines and shipping activities. There are still many legacy components.

Recommendations

- NACCS should be more accessible for non-registered companies. This would also improve the compliance efforts of companies.
 - Japan should expand NACCS so that more data related to logistics can be included and accessed as well.
 - Expanding the number of entries that can be made on one declaration. The current 99 lines are too few.
-

COVID-19

STATUS: NOT PRIORITISED

Over a year after its outbreak COVID19 continues to affect the logistics sector. With travel restrictions all over the world, and in particular in Japan, operations are hampered. There is a need for transparent and long-term regulations and guidelines.

Recommendations

The Government of Japan should:

- Issue clear guidance regarding use of ports in relation to operation and quarantine.
 - Do its utmost to keep ports open with minimum changes to operations while ensuring that the necessary precautions are taken.
-

Tokyo Port operating hours

STATUS: NOT PRIORITISED

From 19 July to 6 August 2021, during the Olympics, the opening hours for picking up containers will be expanded so that it is possible to pick up from 07.30am to 04.00am the following day. This is something that the EBC views in a very positive light. Under normal circumstance the pick-up hours are between 08.30am to 16.00. As the cargo handled by Tokyo Port, or any other port in Japan, has relatively compared to other ports in the world drastically decreased, we believe extended opening or operating hours will make the port more attractive to use.

Recommendations

- The EBC request that the extended opening hours are made permanent, and that other ports in Japan follow suit.
-

Authorised Economic Operator (AEO)

STATUS: SOME PROGRESS

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

Recommendations

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

Digitalisation

STATUS: NO PROGRESS

With ever increasing traffic, of not only physical goods, but also of accompanying documents, logistics companies are under increasing strains. While the core of the problem does not lie with a regulation or a standard, but rather with the behaviour of the stakeholders, the Japanese Government should support and promote a digitalisation of the sector. Currently, there are still many situations where orders are made either over fax or over phone or where documents are delivered physically. With an improved digitalisation, not only will logistics cost go down, but times from order to delivery will do the same. Needless to say digitalisation will also help to cope with the Coronavirus situation, as it is currently very difficult for the logistical sector to, for instance, work from home.

Recommendations

- The Government together with the various sector organisations should work to enhance digitalisation within the logistics sector. This would improve the competitive advantage of the Japanese market.
 - Japan should look into reducing the amount of required documents that is required to be in paper form. This is particularly burdensome in regard to time stamps.
 - Together with digitalisation, Japan should also modernise the process and just not make a manual process digital. Try to eliminate some of the requirements.
-

Retrospective application

STATUS: NOT PRIORITISED

With the implementation of the EPA, and the need for additional information on the origin status, some companies decided not to apply for preferential treatment, and instead paid the third country duty. With the changes adopted by Japan Customs where importers making use of the statement on origin issued by the exporter do not have to provide any additional information this issue has thankfully been resolved. However, in Japan, contrary to the EU, there are very few chances to recover the paid duties. Implementing retrospective application would also increase the usage rate of the agreement, something that both Japan and the EU would benefit from.

Recommendations

- The EBC recommends Japan to introduce retrospective application of the EPA so that businesses can recover the cost of not being able to use the EPA despite products having EU origin.
-

Customs clearance and declaration

STATUS: **RESOLVED**

Currently, Japan limits which customs procedures can be carried out in a region where a company is not physically present or if a customs related licence is not issued for that region. The current set-up makes it difficult for foreign logistics companies, and also small and medium-sized Japanese companies, to expand the reach and coverage of their customs clearance businesses. Deregulation of customs jurisdictions, allowing remote filing of clearances at locations independent of the territory of the responsible customs office, would increase flexibility and improve capacity planning for customs brokerage operators. The EBC therefore welcomes the proposals from the MoF to liberalise customs and introduce further improvements.

Resolved

The Government of Japan has:

- Committed to implementing the proposed policy on customs jurisdictions, especially on remote filing.
- Enabled greater flexibility in terms of where quarantine shipments can be checked. Checks carried out in special bonded warehouses should be facilitated.
- Removed the caps on customs clearance charges and allow free and fair pricing to be set by the market.
- Streamlined the reporting and administration requirements of the various customs authorities to provide more standardised interpretation and application of customs rules and reporting requirements.

PUBLISHED: February 7, 2023

Introduction of open and optimised railway solutions

STATUS: **SOME PROGRESS**

Product development in Japan is dominated by operators who appoint manufacturers to develop new products according to the specifications defined by every operator 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 standardised off the shelf” is far more common. Additionally, we have observed in recent years that the uniqueness of the Japanese market is being exported outside of Japan, in particular within JICA (Japan International Cooperation Agency) financed projects. This is true even for railway markets where international standards are already established.

Recommendations

- The Government of Japan should promote and encourage open and optimised railway solutions, as a way to boost competition in the domestic market and export prospects for Japanese manufacturers under EU-Japan mutual cooperation.
 - The Japanese Government should also encourage the utilisation of open and optimised railway solutions in JICA financed projects overseas.
 - 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

STATUS: NO 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 such as cross acceptance for this industry. The EBC believes that it will be mutually beneficial for Japanese operators to work together with the European operators and suppliers to identify common requirements in new technologies such as 5G communication, train autonomy, AI/IoT (Artificial Intelligence/Internet of Things) for condition-based maintenance (CBM) and cyber security.

Recommendations

- Japan should establish a working group to identify minimum common requirements acceptable to both private and public railway operators depending on the needs for railway service from society. This could be different for urban networks compared to non-urban networks, and for high speed lines compared to conventional lines and subways.
- EU and Japan shall continue the work in the technical committee set up by the EPA to further harmonise standards and regulations.
- The Japanese authorities should take a more active role in setting up a conformity assessment scheme.
- There should be a system for using certifications and tests results from one operator when marketing products to another operator, to avoid complete or partial repetition of testing already conducted.

Public procurement

STATUS: SOME PROGRESS

The public procurement market continues to be an important market and with the improved access thanks to the EU-Japan EPA, which resulted in the removal of the Operational Safety Clause. The EBC believes that the Central Government has a role to play to inform and support regional and local government on how to set up procurement procedures that are in line with the WTO GPA (World Trade Organization Government Procurement Agreement) and the EPA.

Recommendations

- The Government of Japan should ensure that, when planning renewal of systems with new technologies such as CBTC (Communication-Based Train Control) as well as planning new lines or line extensions, local governments and entities covered by the WTO GPA abide by or use the GPA as guidance to set up a proper public procurement scheme.
 - The Japanese Government should promote off-the-shelf solutions.
 - There should be better clarity regarding incorporated operators that are still fully or partially owned by regional or local Governments.
-

Operational Safety Clause (OSC) and public procurement

STATUS: **RESOLVED**

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.

Resolved

- 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.

PUBLISHED: December 15, 2022

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

STATUS: **PROGRESS**

Japan Patent Office's "*Guide to Licensing Negotiations involving Standard Essential Patents*" released in June 2018 has not created issues after its release, neither the latest 2022 update on it. However, the guidance published in 2020 and 2022 by METI has created some confusion among SEP licensors and licensees. It seems that Japan would like to create a detail process to conduct SEP licensing, that might be quite challenging to create a balance between licensors and licensees. For licensors the main problem is so called "hold out", where the licensees try to avoid, or delay, the payment as much, or as long, as possible. For licensees the main claim is too high royalty demands. EBC will monitor the impact and fairness of these the newly established principles and processes, and further updates on them, in regard to the European telecommunication industry.

Recommendations

- Japan's regulators should follow the international licensing practices and legal doctrines without trying to re-invent the wheel. To help to understand the international situation better, Japan should continue the communication with European Commission, European Patent Office, and other European organisations to harmonise the regulations, or at least not to divert from international practices, related to Standard Essential Patent licensing. It would be beneficial to future innovativeness (including 6G R&D) of Japan to encourage a healthy and balanced licensing practices of intellectual properties. Overregulation is not good, but one should let the existing legal system to resolve any disputes.

PUBLISHED: December 15, 2022

Future-proof radio regulation for mobile equipment

STATUS: **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. The EBC welcomes an MIC's report issued in December 2020 studying the periodical inspection of 5G/4G mobile radio base stations, and MIC amended the relevant regulation in 2022 according to the report.

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.
-

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

STATUS: **SOME PROGRESS**

The EBC is pleased that MIC has been working to ensure additional spectrum allocation bands to address the increasing demand for mobile broadband and emerging new use cases of the vertical industries. The EBC recognises that MIC has allocated spectrum bands (3.7 GHz, 4.5 GHz and 28 GHz bands) for IMT-2020 in April 2019, and additional band (2.3GHz) in April 2022, and the plan for allocating additional bands (4.9GHz, 26 GHz and 40 GHz).

Recommendations

- Japan should continue working for globally or regionally harmonised spectrum allocations for mobile use.
- Japan should engage actively in agenda item 1.2 of WRC-23.
- Japan should continue the process for allocating 5G spectrum, to facilitate the development of 5G equipment for its planned commercial service, considering the outcomes of the agenda item 1.13 of WRC-19 and the mid-band spectrum needs for 5G.

Establishing common technical standards and certification procedures

STATUS: **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".

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