

TOGETHER TOWARDS A MORE SUSTAINABLE FUTURE

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The EBC Report on the
Japanese Business Environment

Message from the EU Ambassador

Two years since the start of their implementation, the EU – Japan Economic Partnership Agreement (EPA) and Strategic Partnership Agreement (SPA) are boosting our ability to deliver tangible benefits for businesses in Europe and in Japan.

Today the COVID-19 pandemic, the growing impact of climate change and environmental challenges make the EU – Japan cooperation more necessary than ever.

At the EU – Japan summit on 27 May 2021 our leaders launched the [EU-Japan Green Alliance](#), which will boost coordinated efforts on both sides to accelerate climate and environmental action. Through this alliance, we will deepen our cooperation on the energy transition, environmental protection, regulatory and business cooperation, R&D, sustainable finance and facilitating the transition in third countries.

The EU and Japan also collaborate to promote global standards and comprehensive – including regulatory – approaches to digital policies and technologies. As the EU wants to make the next ten years our “digital decade”, we will work with Japan on emerging technologies, critical materials, 5G and 6G, artificial intelligence, data, and platforms. This will boost the competitiveness of both the EU and Japan and facilitate setting standards in multilateral fora.

In addition to these new areas of intensified cooperation, full implementation of the EPA will remain a joint priority. This year, on EPA’s 2nd anniversary, the EU and Japan agreed to important improvements to the agreement. The [list of protected Geographical Indications \(GIs\) from EU countries and Japan](#) now includes an additional 28 GIs for each side. Also, exporting vehicles to the other side has become easier, as we agreed to extend the list of safety requirements that will not require double approvals. This includes green technologies, such as hybrid and hydrogen-fuelled vehicles. Japan has also recently authorised in its territory several EU oenological practices in accordance with the EPA, which will greatly facilitate further the EU wine exports to this important market.

In order for the EPA to be successful, we need to make sure that European companies are well aware of the EPA and know how to make use of it. I am happy to note that the use of EPA by European operators has increased considerably in the second year of implementation, but there is still room for improvement. We will continue our outreach efforts and provision of information and web tools to help our businesses to benefit from it, and hope to see even larger uptake of its utilisation in the years to come.

In this context, I am delighted to address the 2021 report of the European Business Council (EBC) on the Japanese business environment. This EBC report is a crucial tool to guide us in our implementation work, and to help us to follow the functioning of the EPA on the ground. Through this report, and its other activities, the EBC plays a key role in ensuring the EPA’s success.

As always, the EU Delegation to Japan continues to look forward to a close cooperation with the EBC and its members, to support our industry in accessing the Japanese market and to consolidate and expand the cooperation between the EU and Japan.

Patricia FLOR

Ambassador of the European Union to Japan

Head of the Delegation

Message from the EBC

Every year for the past 20 years, the EBC has welcomed you to a new White Paper. From that perspective, nothing has changed. However, things will not be the same from now on. We would like to welcome you to the first EBC digital White Paper named *Together Towards A More Sustainable Future*.

Instead of printing a White Paper once a year, the digital White Paper will give us the opportunity to always present you the most updated issues and recommendations. It will also provide us with the possibility to better follow an issue over time, to add changes, and to keep issues that have been resolved. In previous years, issues that had been resolved were removed from the White Paper to make space for more pressing issues.

The digital White Paper will make it easier for our readers to find what they are more interested in. Tags will be attached to each issue, such as “urgent,” “resolved,” the “year” and the “committee” that is covering this issue. There is also an option to print out the issues.

2021 has continued to be a year of change. COVID-19 is still here, although we might start to see the light at the end of the tunnel. Will this mean that we will be back to pre-COVID times? We believe that the resounding answer to that is no. We have seen that the way we work has changed. Today, remote working and web meetings are the norm, and while we are confident that we will have more physical interactions soon, some of the changes will be permanent.

The EU-Japan Economic Partnership Agreement has now entered its third year. It continues to provide improvements, both thanks to agreed points that are only later implemented, such as tariff reductions, and perhaps more noteworthy, the inclusion of previously not included non-tariff measures. We have already seen some improvements in this area, for instance public procurements for offshore wind, and the EBC continues to inform the EU Delegation of issues that are of interest to the European industry in Japan.

The EBC work is made possible by the continuing support of its stakeholders, especially the European national Chambers of Commerce, their corporate members that join the EBC and other business organisations represented in Japan. Together with the Delegation of the European Union to Japan and the European national embassies in Tokyo, who keep offering their unique insights and guidance, we all work towards making European business more successful in Japan. We are grateful to the EU Delegation that brings up issues with the Japanese authorities that are stopping the trade relation between the EU and Japan to reach its full potential.

We also gratefully acknowledge all sponsors and supporters who have made this publication possible and whose names are listed at the end of the Report. The EBC is committed to helping Europe and Japan reach new levels of mutual trade and economic growth. We approach these challenging times with unwavering optimism as Europe and Japan continue to strengthen their relationship.

And with those words, again, welcome to the first EBC Digital White Paper!

Michael Mroczek

President, European Business Council in Japan
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BUSINESS FUNDAMENTALS

CROSS-COMMITTEE ISSUES

PUBLISHED: November 30, 2021

Travel restrictions

STATUS: NEW URGENT

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.

Recommendations

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

HUMAN RESOURCES

PUBLISHED: November 29, 2021

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, and new ways of sourcing foreign labour. 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.

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. 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.

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.

PUBLISHED: November 29, 2021

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. 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.
Extend the payback period and expand pay-back to include the company contributions for leaving expats.

PUBLISHED: November 29, 2021

Border control, Immigration legislation and policies

STATUS: SOME PROGRESS

Whilst respecting the Government's efforts to restrict the spread of COVID-19 with its border controls, it is requested to ease priority business visa entry restrictions for foreign nationals. The ongoing entry restrictions are negatively impacting an increasing number of both Japanese and foreign businesses, that rely on the entry to Japan of key management and skilled personnel and engineers, vital for the Japanese economy. 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

Allow for the processing of priority business visas for entry to Japan of essential personnel.

Provide a greater level of immigration policy transparency for businesses and permanent residents.

Ensure that vaccination certificates, received overseas by Japanese nationals and foreign permanent residents, are recognized by the Government and planned digital vaccine passports.

Extend the scope of on-line visa applications and visa extensions.

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.

INTELLECTUAL PROPERTY RIGHTS

PUBLISHED: January 26, 2022

Legislation to prohibit the importation of counterfeits "for personal use"

STATUS: SOME PROGRESS

The importation of counterfeit goods for "personal use" will be restricted by the end of 2022 thanks to the revision of the Trademark Law. However, it will be necessary to keep a close eye on the Customs Act and related notifications, which will be reviewed in light of the revised Trademark Law, to see what

kind of changes can be made and whether effective results can be obtained.

Recommendations

In order not to render the new regulations invalid, necessary provisions should be made to anticipate the excuses that sellers of counterfeit goods may come up with, such as that the goods are a gift from a friend abroad, and to place the legal presumption and burden of proof on the importer.

Measures should be implemented to provide relief to consumers who have purchased counterfeit goods without knowing it.

Consumers should be made aware that they will no longer be able to purchase or import counterfeit goods.

Measures should be taken against sites selling counterfeit goods, fraudulent sites, and spoofed sites on overseas servers, such as removing the sites from search engines.

PUBLISHED: January 26, 2022

Strengthening and continuation of actions to eliminate counterfeit products from Japanese or foreign capital B2C and C2C websites

STATUS: SOME PROGRESS

As mentioned previously, Japanese capital B2C and C2C websites have been proactive in taking measures against counterfeit goods, and have achieved a certain degree of success. It is worth appreciating that while attempting to detect and eliminate counterfeit products by analysing image information using computer systems, they have maintained a system of voluntary patrols by man power, based on the cooperation with right holdere. However, it is also the fact that countermeasures against counterfeit products have not yet been taken in respect to some internet flea markets, being targeted as counterfeit -selling market from China. On the other hand, foreign capital B2C sites seem to focus their attempts to detect and eliminate counterfeit products by analysing image information using computer systems, while showing an attitude of cooperation with rights holders. The types of counterfeit products and the way they are sold are constantly evolving, and such information is first detected by consumers and rights holders. Furthermore, we do not even know whether computerized systems for detecting and eliminating counterfeit products will work effectively. Therefore, it is clear that the extent of cooperation with rights holders and other factors must be re-examined. The "Act on the Protection of the Interests of Consumers Using Digital Trading Platforms" enacted in April 2020 may strengthen the verification of the identity of sellers and the confirmation that notations are correctly made based on the Act on Specified Commercial Transactions etc. However, the new law does not include penalties, it only stipulates an obligation to make efforts. It is therefore necessary to keep a close watch on future developments.

Recommendations

It is necessary to continue to monitor whether the enforcement of the identification of sellers based on the "Act on the Protection of Interests of Consumers Using Digital Trading Platforms" and notations

based on the “Special Commercial Code” are properly implemented. If not, the law and regulations should be strengthened by taking advantage of its provisions for future revision.

Although the government has already endeavoured to call for the joining of non-participants ISP (Internet Service Provider) companies to the dialogue forum where SP companies and right-holders discuss countermeasures against counterfeit products in order to build relationships between rights holders and website operators, this policy should continue in the future.

LEGAL SERVICES

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.

PUBLISHED: November 29, 2021

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.

RETAIL & WHOLESALE

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.

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.

PUBLISHED: November 29, 2021

Labelling

STATUS: SOME PROGRESS

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

Recommendations

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

PUBLISHED: November 29, 2021

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.

Japan should simplify its *Denan* Law, avoid introducing further unique Japanese requirements and make certain that detailed information on standards and their application are readily available in English.

PUBLISHED: November 26, 2021

Limitations on selling liquor via telecommunication channels

STATUS: NO PROGRESS

The retail sale of liquor across prefectural borders via any telecommunication channel (including the internet) is restricted. Furthermore, grandfathering old licences is unfair to new entrants.

Recommendations

Japan should abolish the telecommunication channel limitation within the liquor retail licence system.

Japan should stop the practice of grandfathering licences.

PUBLISHED: November 21, 2021

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.

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.

CONSUMER GOODS

FOOD & AGRICULTURE

PUBLISHED: November 29, 2021

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 transparent and easy to use.

There should be no requirements that TRQ volumes applied for should already be covered by sales contracts.

The lottery system that “covers” some of the TRQ is very difficult to use, due to low predictability.

Japan should change the system for those quotas that are completely utilised to a system of allocation using historical data with a portion dedicated to newcomers.

PUBLISHED: November 29, 2021

Food additives, enzymes and processing aids

STATUS: SOME PROGRESS

Differences in the lists of additives and enzymes approved by Japan and other major markets are still common. While the EBC has seen progress in Japan’s approval of additives, the approval process still remains an obstacle, and an overall lack of transparency. EU and Japan should use the EPA to further strengthen the work in this field. Despite announcements that the EPA would result in faster approval times, this has not been realised.

Recommendations

Japan should harmonise its definition of food additives to exclude processing aids which as per its definition do not remain in the product after it has been produced. The same should apply for nutrition fortifiers. Japan should ensure that standards of use in Japan are not in conflict with international standards of use.

Japan should also harmonise the specifications of food additives, such as purity, definition of specific

food additives and size of molecules.

The Ministry of Health, Labour and Welfare (MHLW) should put the same focus on enzymes as it has on food additives and actively approve enzymes that are well established in other major markets.

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.

PUBLISHED: November 29, 2021

Malt and quota management system

STATUS: GOOD PROGRESS

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 has now been remedied in late 2021, opening the door to importers to provide of 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.

Recommendations

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

PUBLISHED: November 29, 2021

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. MHLW has for this purpose asked for public comments and for industry to submit substances that they want to include on the list. This has also been done through the WTO notification procedure. However, the list does not contain all substances used in existing (from before June 2020) yet. Japan government should revise and open the list swiftly and accept if there are requests to add new substances. Moreover, Japan government should create route to accept direct application from suppliers in other countries. If there is no harmonisation as well as a procedure of exemptions as is the case in the EU and the US, European suppliers and Japanese buyers run the risk of not being able to import the products to Japan.

Recommendations

Japan should allow resins allowed in the EU and the US.

Japan should make it possible for overseas producers to apply directly in regard to having compounds approved.

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

PUBLISHED: November 29, 2021

Separate registration by each importer

STATUS: NEW

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: November 29, 2021

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.

PUBLISHED: November 29, 2021

Best before labelling

STATUS: NEW

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 says 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

LIQUOR

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

Liquor taxes

STATUS: NO PROGRESS

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

Recommendations

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

PUBLISHED: November 29, 2021

Decoded products

STATUS: SOME PROGRESS

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

Recommendations

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

PUBLISHED: November 29, 2021

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: 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: November 29, 2021

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 removed gradually.

Recommendations

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

PUBLISHED: November 29, 2021

Alcohol contents notation

STATUS: NEW

A Cabinet decision was taken in March 2021 that the NTA should promptly consider including alcohol content using grammes on bottles and cans.

Recommendations

The EBC urges Japan to follow international standards.

PUBLISHED: November 29, 2021

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.

FINANCIAL SERVICES

ASSET MANAGEMENT

PUBLISHED: November 29, 2021

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.

PUBLISHED: November 29, 2021

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.

PUBLISHED: November 29, 2021

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.

INSURANCE

PUBLISHED: November 29, 2021

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. However, 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 relevant information to the FSA on these issues.

Recommendations

Japan should accelerate reforms to achieve convergence between Japanese and global solvency standards.

Japan should consider the approval process of an internal model for risk calculation on a new solvency regulation to evaluate the risk characteristics of each insurer correctly.

The Solvency Margin calculation methodology should be further aligned with international capital standards such as Solvency II or ICS.

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.

The results of five-year monitoring should be well embedded in the implementation.

The pace of progress should be carefully monitored considering the risk of COVID19.

PUBLISHED: November 29, 2021

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. Recently under COVID19, the FSA requested that no exemptions were for claim payments in connected to COVID. 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."

Recommendations

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

PUBLISHED: November 29, 2021

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.

PUBLISHED: November 29, 2021

Distribution practices under fiduciary duties

STATUS: SOME PROGRESS

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. 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 29, 2021

Digitalisation

STATUS: NEW

The insurance industry in Japan has been traditionally paper-heavy and EBC welcomes recent efforts by the industry associations and the regulator to digitalize more processes, including communication with clients. The regulation update on 21 January 2021 is an important step forward to facilitate non face to face client communication utilising modern communication tools. Covid19 impact will have lasting impact on the way insurance companies and clients interact and the EBC believes that digitalisation should be accelerated to further simplify processes, instead of focusing on face to face with paper etc., for added value services.

Recommendations

The FSA should continuously consider digitalised solutions such as customers' consent on provisions of sales materials and confirmation of receipts.

PUBLISHED: November 29, 2021

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: November 29, 2021

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 be 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 views, 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 use, 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

PUBLISHED: November 29, 2021

Expansion of Japan's role as an international financial centre

STATUS: NEW

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.

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 guidelines, policies, etc. so that foreign insurers can more easily implement and follow them.

HEALTH SCIENCE

IVD (IN VITRO DIAGNOSTICS)

PUBLISHED: November 29, 2021

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

STATUS: NEW

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 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 healthcare environments should be investigated and implemented

PUBLISHED: November 29, 2021

Implementation of Emergency Use Authorization (EUA) Process and Speedy Access of required tests by EUA

STATUS: NEW

In the event of COVID-19 pandemic, needs of transparent process like EUA were recognized. With such process, clinical tests with certain level of quality and performance can be speedily provided to the public.

Recommendations

Requests for implementing EUA and speedy market delivery of all tests required in the event of emerging infectious disease (including IVD, LDT, and research reagents, not limited to medical applications)

PUBLISHED: November 29, 2021

Global harmonisation in definition and classification of IVDs

STATUS: SOME PROGRESS

It is necessary to develop new regulatory system, in order to meet the recent trend where new types of IVDs for medical decisions, those for prognosis and risk assessment and those based on advanced technology are increasing. This should be based on the global classification defined by International

Medical Device Regulators Forum (IMDRF).

Recommendations

For the purpose of global harmonisation, Japan should expand the definition (scope) of IVDs and define classification based on intended use and risk.

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 29, 2021

Evaluation 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, and the evaluation results of new and improved items at *Chuikyo* have not been published.

Recommendations

At the time of insurance coverage, the evaluation points for the medical values and innovativeness of the listed IVD shall be specified and disclosed.

PHARMACEUTICALS

PUBLISHED: November 29, 2021

Drug pricing system

STATUS: NEGATIVE PROGRESS

The price maintenance premium (PMP), which was drastically revised negatively with the drug pricing system reform in 2018 was slightly revised regarding its product criteria in the pricing system reform in 2020. However, the revision was very limited, and we believe that further revision is necessary to improve the pricing system during the patented period. Additionally, at the off-year price revision of 2021, approximately 60% of the new drugs under patent period was subject to revision and therefore

result in a revision with a huge impact to the predictability of drug price post-launch. With these continuous reforms of the pricing system, the attractiveness of the pharmaceutical market in Japan has been declining significantly.

Recommendations

Pricing system should have predictability and fairness to enable appropriate evaluation of innovation. Differentiate off-year price revision from the regular biennial price revision and limit the target products to those products with significant deviation rate only.

Consider overhaul of the pricing system to a simple, easy-to-understand and transparent one as the current system has become extremely complicated due to repeated revisions.

PUBLISHED: November 29, 2021

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

STATUS: NO PROGRESS

Recommendations

As a system, such as the current system in Japan, that heavily relies on cost per QALY to evaluate the value of a drug cannot appropriately appraise the drug value, additional factors should be incorporated in the appraisal.

The number of products assessed should be limited as Japan does not yet have a well-established HTA capability and at present is unable to assess a large number of products.

HTA should not restrict or delay patients' access to new drugs.

PUBLISHED: November 29, 2021

International harmonisation (clinical trial environment)

STATUS: SOME PROGRESS

Recommendations

Clinical trial environment in Japan is improving owing to various efforts to increase efficiency in clinical trials. However, more improvement is required in the area of cost optimization and in increasing the number of subjects per study site.

Japan should further enhance the efficiency of drug development by taking advantage of the new guidelines on multi-regional clinical trials (ICH E17, GENERAL PRINCIPLES FOR PLANNING AND DESIGN OF MULTI-REGIONAL CLINICAL TRIALS) that was published in June 2018.

PUBLISHED: November 29, 2021

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, "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.

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.

VACCINES

PUBLISHED: November 29, 2021

Awareness-Raising Activities to spread vaccinations for the elderly

STATUS: SOME PROGRESS

We held EFPIA Vaccine Webinar with the theme, "Consideration of life course vaccination especially now with the COVID-19 pandemic". It was agreed to start developing guidance on mutual communication between physicians and the recipients.

Recommendations

Japan will carry out large-scale nationwide temporary vaccinations of COVID-19 vaccines which they have never experienced before. Expectations for vaccines are very high as people are frustrated from limitation in activities for over a year. However, this situation can also cause people to overreact to side effects and effectiveness of vaccines. As such, we need to urgently provide communication guidance on vaccination to physicians.

PUBLISHED: November 29, 2021

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

STATUS: SOME PROGRESS

Although the national test process in Japan has been slightly improved for some products, there are still some parts that are not consistent with the international standards. For example, abnormal toxicity test may be required as a test item which has already been abolished in Europe and the US. In addition, monographs of the Minimum Requirements for Biological Products (MRBP) require Japan-specific

general test methods including many animal studies. In the process of pre-approval testing for new vaccine application, enactment of MRBP monographs, preparation of the SLP template and submission of samples for the national test, multiple organizations are involved and the coordination among these multiple organizations is a burden on companies. In addition, the authority which is responsible for national testing is different from that for file reviewing, resulting in duplicated review process. However, the division of roles between the regulatory authority and the testing institution is unclear. Additionally, attendance of prefectural officer at the domestic manufacturing site is necessary during sampling of the test samples, making it substantially impossible to conduct sampling at the overseas manufacturing sites. Therefore, the lead time to supply imported vaccines cannot be shortened. Furthermore, when national testing performed by using only SLP, sampling of test samples is performed in accordance with the regulations. This is a waste of resources and products. Listing in MRBP is immediately required when a new vaccine is approved in Japan. If similar products are listed in MRBP, the new product will need to be in compliance with the respective monograph despite differences in product characteristics. It is practically impossible to introduce vaccines that has been widely used for a long time in Europe, etc. as the information on raw materials included in the master cell bank and/or master seed may not meet the criteria required by standard for biological ingredient (SBI).

Recommendations

Optimize collaboration of PMDA and MHLW which are responsible for file review, and National Institute of Infectious Diseases (NIID) and prefectural offices which are responsible for national testing
Revision of the sampling method for national testing which enables companies to conduct sampling process at overseas manufacturing sites.

Rationalization of national testing processes including reviewing documents only or reducing the number of test lots by utilizing SLP

Discontinuation of immediate listing of new vaccines on MRBP.

Harmonization of Japanese requirements with international standards, including discontinuation of abnormal toxicity testing, replacement of in vivo testing with in vitro testing, and interchangeability of WHO and European pharmacopoeia general testing methods.

Reconsideration of SBI application for bio-derived materials contained in the master cell bank and/or master seed in the vaccine products approved in EU countries.

PUBLISHED: November 29, 2021

Incorporate recommended vaccines into NIP and promote the development of combination vaccines

STATUS: SOME PROGRESS

NIP for rotavirus vaccine was launched in October 2020. Regarding the NIP for mumps vaccine, MHLW evaluation vaccine subcommittee discussed that it is necessary to conduct a large-scale survey of more than 100,000 cases to realize the frequency of aseptic meningitis caused by existing mumps

vaccination, which is difficult to conduct. This discussion may have made it more difficult for mumps vaccine to be part of the NIP. Discussions on development of priority vaccines such as combination vaccines have not progressed.

Recommendations

Regarding the NIP for mumps vaccine, the solution should be discussed thoroughly together with the academia such as AMED team study, and for the government, industry and academia to work together to aim for early NIP for mumps vaccine. These activities should lead to the early introduction of combination vaccines.

The national government is considering adopting NIP predictability improvement in "HONEBUTO" policy. We will promote the establishment of a clear standard for adopting regular vaccinations and a system that allows discussions on regular vaccinations to begin even before the vaccine is approved.

COSMETICS & QUASI-DRUGS

PUBLISHED: November 29, 2021

Applying the same standards to all market participants

STATUS: NEW

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.

PUBLISHED: November 29, 2021

Expansion of 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 realization of healthy long-lived social. Routine care by cosmetics and quasi-drugs, such as moisturizing care for atopic skin and the use of sunscreen products to prevent skin cancer, plays an important role in maintaining health and preventing illness, but current advertising regulations do not admit to emphasize its importance.

Recommendations

Regulations related to advertising expressions should be eased so that the role of routine care products using cosmetics and quasi-drugs, such as health maintenance and disease prevention, can also be promoted.

PUBLISHED: November 29, 2021

Regulations and systems for quasi-drugs

STATUS: NO PROGRESS

The 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 presented a mock-up on how to treat products with the same standards and test methods as those of the attached specifications of approved products. These developments are expected to lead to improvements in the quasi-drug review system, but simplification and acceleration of the application and review process have not been assured. 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. For instance, a new item is approved because it is identical to an already approved quasi-drug only when the precedent of approval has been presented, however, this is not mentioned at all in the notification, etc. issued by the MHLW.

Recommendations

MHLW should shorten the review period for quasi-drugs for which review guidelines have been created and which are believed to be identical to already-approved quasi-drugs.

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

using public comments in advance.

PUBLISHED: November 21, 2021

Establishment of alternatives to animal testing

STATUS: SOME PROGRESS

The restructured human corneal liberation method (RhCE method) has been newly introduced. This can be used as an alternative method for eye stimulus testing for quasi-drug applications. In Japan, however, the safety evaluation of quasi-drugs with new ingredients necessarily requires results from animal experiments for the hazard evaluation of that particular raw material. At the same time, in other countries, discussions are being actively promoted on the development of evaluation methods without using any animals, the establishment of safety evaluation methods, and the utilisation of animal experiment results carried out for purposes other than cosmetics, but the policy for safety evaluation of final products in Japan remains unchanged.

Recommendations

In light of recent significant changes in the concept of safety assessment of final products, Japan should establish risk assessment methods for final products using available scientific evidence in order to prevent unnecessary animal experiments, while promoting the development of alternative methods that do not use animals at all.

PUBLISHED: November 21, 2021

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

STATUS: SOME PROGRESS

The Government enacted the "Basic Act on the Advancement of Public and Private Sector Data Utilization" in December, 2016, which stipulates the use of necessary measures for determining online usage for administrative procedures in principle. However, in regard to cosmetics and quasi-drugs, notifications and applications have to be made using floppy discs or in paper form. On the other hand, export reports using the NACCS (Nippon Automated Cargo and Port Consolidated System) can be used electronically. 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. In FY2019, MHLW acquired budgets for online application and notification procedures such as pharmaceuticals and medical devices. However, it would be difficult to simplify and expedite the application process simply by submitting the file from the current MHLW version of the software for electronic applications such as medical products without changing the form or the description of the application form and the registration form. The construction of a system which enables efficient administrative procedures which maximises the utilisation of an IT platform is expected.

Recommendations

An online notification and application system should be established for submitting Notifications on the Manufacture and Sale of Cosmetics and Applications for Approval of Quasi-Drugs. This system should be linked to the Customs clearance system to provide a one-stop service for application procedures. Improvements should be made to the specifications of the application form, the registration form, and the "MHLW-version software for electronic applications such as medical products" in order to simplify and expedite administrative procedures.

MEDICAL EQUIPMENT

PUBLISHED: November 29, 2021

Revision of insurance coverage and functional classification of insurance medical material

STATUS: NO 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.

Recommendations

Japan shall continue to prove the insurance reimbursement pricing system based on the product characteristics of special materials.

Japan shall also expand the scope for applications for improvement premiums.

PUBLISHED: November 29, 2021

Foreign Price Reference System

STATUS: NO PROGRESS

In the previous revision, the comparative level of foreign price adjustments for newly listed products (1.3 → 1.25 times) was lowered. Regarding the recalculation of listed products, the amount of reduction (75/100 → 50/100) has been revised.

Recommendations

Japan shall continue to abolish the foreign price recalculation system and to create a system that takes exchange rate fluctuation risks into account while maintaining a comparative level.

PUBLISHED: November 29, 2021

Expansion of Insurance application system (C2-Challenge) based on actual usage

STATUS: SOME PROGRESS

The C1 Challenge based on the actual use has been institutionalised, paving the way for the re-evaluation. However, but the technical fee for the diagnostic treatment equipment is excluded from this re-evaluation. This is one of the major issues in the next revision.

Recommendations

Japan should introduce C2 Challenge of re-evaluation of diagnostic equipment just as is possible for Category 1 products.

PUBLISHED: November 29, 2021

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

STATUS: SOME PROGRESS

While multiple program medical devices have been approved and covered by insurance, there are still many medical devices that are not covered by insurance.

Recommendations

Japan shall continue to clarify the scope of application of program medical devices and cover them under the healthcare insurance system.

PUBLISHED: November 29, 2021

Mutual recognition and global standards for clinical evaluation

STATUS: SOME PROGRESS

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

Recommendations

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

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.

PUBLISHED: November 29, 2021

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.

INDUSTRY

AERONAUTICS

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.

AUTOMOBILE

PUBLISHED: January 26, 2022

Tax system reforms

STATUS: SOME PROGRESS

Japan has taken a two-year measure to ease drastic change for clean diesel passenger cars, which European carmakers have actively introduced to the Japanese market. However, Japan still imposes excessively heavy taxes on the purchase and ownership of automobiles compared with other countries.

Recommendations

Japan should simplify the structure of automobile taxation and further reduce the tax burden for users. The GOJ should further reduce automobile taxes and automobile tonnage taxes in order to secure fair taxation system between registered vehicles and kei-cars.

Japan should show the future direction of changes in tax systems and incentives on a medium- and long-term basis so that European vehicle importers can prepare for future changes.

PUBLISHED: January 26, 2022

Safety standards/standards for automated driving

STATUS: SOME PROGRESS

GOJ has incorporated the new UN Regulations for automatically-driven new vehicles (R155/R156 /R157). On the other hand, for the CS/SU management systems (MS) of the vehicles in use including organization requirements, additional approval must be obtained in Japan.

Recommendations

For the CS/SU upon software modification for vehicles in use, Japan should accept COC (Certificate of Compliance) of UN-R155/R156 obtained overseas when granting approval for the specified modification.

The GOJ should share information about the progress of the regulatory development in a timely

manner in order to provide the opportunities for obtaining feedback from overseas to promote the international harmonization of policies and regulations.

PUBLISHED: January 26, 2022

Introduction of International Whole Vehicle Type Approval (IWVTA)

STATUS: SOME PROGRESS

GOJ is expected to adopt the emission regulations (R154) based on the UN Worldwide harmonized Light duty driving Test Procedure (WLTP) by the summer of 2021, making a great leap forward. On the other hand, even after the introduction of the IWVTA system in July, 2018, it is still incomplete and for the devices subject to IWVTA, type approval on whole vehicle cannot be obtained, and there exist Japan-unique regulations that remain applicable. Due to these factors, the use of UN-R0, designed for mutual recognition of type approvals between Japan and the EU, is not progressing.

Recommendations

Japan should eliminate Japan-unique regulations that remain applicable such as the immediate front/left requirements by establishing international regulations, etc.

Japan, in close cooperation with the European Commission, should realize a complete system of mutual recognition of type approvals on vehicles by expanding the scope of the IWVTA system to cover all requirements of the vehicle type approval systems of Japan and Europe.

PUBLISHED: January 26, 2022

Electrification and fuel efficiency standards

STATUS: SOME PROGRESS

The GOJ formulated the Green Growth Strategy in December 2020, and in order to achieve carbon neutrality by 2050, GOJ is conducting various investigations at the government level for materialization.

Recommendations

To promote the spread of EV/PHEVs, it is necessary to develop and expand charging infrastructure. In particular, the expansion of public fast chargers in central Tokyo, higher output, and the expansion of charging equipment in apartment buildings should be promoted as quickly as possible.

The policy direction for several years should be clearly announced that incentives/subsidies shall be continued and expanded in a stable manner to the maximum extent possible to help the spread of BEV and PHEVs" including shortening the minimum years of required ownership. In order to promote the spread of EV/PHEVs by legal systems, Japan should introduce a credit system and/or flexible measures etc., in the interim review on the 2020 and 2030 passenger car fuel efficiency standards, slated for the summer of 2021 onward.

For the ongoing 2020 passenger car Fuel Efficiency standards, the threshold of 90% rule should be

carefully reviewed in order to accelerate diffusion of EV and PHEVs.

AUTOMOTIVE COMPONENTS & AFTERMARKET

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

PUBLISHED: November 29, 2021

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.

ENERGY

PUBLISHED: November 29, 2021

Transmission and distribution

STATUS: SOME PROGRESS

Japan's transmission network is centred on its production sites, with the main transmission at 500kV. The frequency convertor stations (FC) connecting the 50Hz and 60Hz networks offer only limited additional capacity. Furthermore, the limited interconnections between the individual EPCOs represent a real risk to security of supply. In contrast, European and US grids have extensive plans for use of High Voltage Direct Current (HVDC), which offers more flexibility in energy flows between regions, enables large integration of renewable into the system and also enables long cable connection by subsea or land. It is encouraging to see the draft 6th Plan for grid enhancement between Hokkaido, Tohoku and Tokyo area for further renewable deployment of 4GW.

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.

Japan should consider interconnections with other countries using HVDC connections. In principle, this is same as LNG carriers which is another way of energy transportation for import and export.

PUBLISHED: November 29, 2021

Nuclear energy and nuclear safety

STATUS: SOME PROGRESS

In the 2021 Basic Energy Plan draft, the Japanese Government confirmed that nuclear energy would remain a core constituent of the Japanese energy mix, as it is targeting 20~22% of nuclear generated electricity in FY2030 (from 4.3% in 2020). The nuclear power plant fleet reached a new milestone on 23 June 2021 with the restart of the Kansai EPCO's Mihama 3 reactor, the first one to be connected to the grid since 2018. The Takahama 1 and 2 reactors should also have been restarted in June of the same year, but the operator could not complete the construction of anti-terrorism facilities on time. In the near future, the issue of ageing plants will become a key concern, not only through plant lifetime

extensions, but also through replacement of reactors, some set to be 60 years old by the mid-2030s. Furthermore, it is essential that nuclear long-term sustainability is based on a reliable and efficient approach to safety concerns, smooth implementation of a back-end policy for recycling spent fuel, and final disposal of radioactive waste.

Recommendations

Japan should increase cooperation with international organisations to improve global nuclear safety. Japan should accelerate the restart of the 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 develop a 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.

PUBLISHED: November 29, 2021

Wind energy

STATUS: SOME PROGRESS

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 29, 2021

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.

PUBLISHED: November 29, 2021

Coal

STATUS: NEW

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 be 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.

SPACE

PUBLISHED: November 29, 2021

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 quantity of inquiries and topics under investigation are significantly increasing.

Recommendations

The EBC advocates closer space agency cooperation in satellite technology development and applications, with pro-active promotion and execution of industrially and commercially meaningful cooperation projects.

The Government of Japan should increase cooperation with Europe through the procurement of high-quality satellite systems or equipment in fields related to national security 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 29, 2021

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, but no agreement is in sight due to lack of political leadership.

Recommendations

Japan and Europe should step up cooperation on the future evolutions of their respective new generation launchers. Ariane Group 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.

PUBLISHED: November 29, 2021

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.

We recommend that Japan and Europe consider cooperating at government level on the debris problem incurred by the operation of core solid motor launchers.

PUBLISHED: November 29, 2021

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.

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.

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 request that action is taken to make this possible.

DEFENCE & SECURITY

PUBLISHED: November 29, 2021

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.

PUBLISHED: November 29, 2021

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.

TRANSPORTATION & COMMUNICATIONS

AIRLINES

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: NEW

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 airlines 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.

PUBLISHED: November 26, 2021

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.

LOGISTICS & FREIGHT

PUBLISHED: November 29, 2021

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: November 29, 2021

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:

Enable use of larger vehicles for inter-city movement to reduce the number of vehicles and drivers required.

Allow and encourage the use of autonomous vehicles by delivery companies.

Increase the subsidy for non-proprietary “open” parcel lockers and simplify the application process for such subsidies. In particular switching from the pre-installation to a post-installation application process should accelerate the deployment of parcel lockers. 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.

PUBLISHED: November 29, 2021

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.

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.

PUBLISHED: November 29, 2021

NACCS

STATUS: NEW

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.

Recommendations

Japan should expand NACCS so that more data related to logistics can be included and accessed as well.

PUBLISHED: November 29, 2021

COVID-19

STATUS: SOME PROGRESS URGENT

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.

PUBLISHED: November 29, 2021

Tokyo Port operating hours

STATUS: NEW

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.

PUBLISHED: November 29, 2021

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

PUBLISHED: November 29, 2021

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 require to be in paper form. This is particular burdensome in regard to time stamps.

PUBLISHED: November 29, 2021

Retrospective application

STATUS: NO PROGRESS

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.

RAILWAYS

PUBLISHED: November 29, 2021

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: November 29, 2021

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.

PUBLISHED: November 29, 2021

Conformity assessment and mutual recognition of testing and certification

STATUS: SOME 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 EBC Railways Committee 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).

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.

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.

PUBLISHED: November 29, 2021

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.

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.

TELECOMMUNICATIONS EQUIPMENT

PUBLISHED: January 27, 2022

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

STATUS: SOME PROGRESS

Japan Patent Office's "Guide to Licensing Negotiations involving Standard Essential Patents" released in June 2018 has not created issues after its release. However, the guidance published in 2020 and the 2021 work to create a new guidance by METI has created confusion among SEP licensors and licensees. Also in 2021 the JPO initiated a new process to update its 2018 Guide document. It seems that Japan would like to create a perfect process to conduct SEP licensing, that might be quite challenging. For licensors having a "perfect" process would be beneficial, as the main problem is the so called "hold out", where the licensees try to avoid, or delay, the payment as much or as long as possible. 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 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. Overregulation is not good, but one should let the existing legal system to resolve any disputes.

PUBLISHED: January 27, 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.

Recommendations

Japan should adopt future-proof radio regulation for mobile equipment so that emerging technologies can be swiftly deployed. It is worth studying the technology-neutral approach, especially for unlicensed bands such as 5GHz.

Japan should review its radio regulation to ensure it avoids imposing undue requirements on radio base stations, especially in respect of AAS (Active Antenna Systems). In particular, the outcomes in MIC's report in December 2020 should be implemented in the regulation so that the measurement in the periodical inspection of radio performance at antenna or equivalent monitor ports can be exempt.

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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 the plan for allocating additional bands (2.3GHz, 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.

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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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