大江橋法律事務所
OH-EBASHI

OH-EBASHI LPC & PARTNERS NEWSLETTER

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Dear friends, clients and colleagues,

We are delighted to send you this inaugural issue of Oh-Ebashi LPC & Partner's English Newsletter. This will be delivered to you by e-mail quarterly, and will contain short articles relating to legal developments within Japan.

Japanese laws and legal practice are constantly changing and being updated. Through this Newsletter, we hope to keep you abreast of important developments within the country and, as necessary, help you make timely and informed decisions.

We hope you enjoy reading this first issue of our Newsletter. Should you have any questions about your specific industry or area of law, or wish to know more about our firm's services, please do not hesitate to contact us.

Shiro Kuniya
Managing Partner

Articles

Protecting Personal Information Beyond the Borders of Japan

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More than a decade ago, on May 30, 2003, the Act on the Protection of Personal Information was promulgated to regulate the acquisition, reporting, use, maintenance, protection, disclosure, correction and deletion of personal information (the “Original Act”)1. The original Act was amended on September 9 last year, expanding the scope of its application and regulating the provision of personal information to third parties in foreign countries, among others (the “New Act”). The amendments will take effect from the date to be specified by a Cabinet Order within two years from September 9, 2015, or on September 9, 2017, at the latest. By far, the said amendments are the most significant ones that have been made to this law. Foreign companies and their subsidiaries in Japan must now prepare for the potential impact of these changes on their handling, use or protection of personal information beyond the borders of Japan.

Some of the major changes are discussed below.

The New Act has a broader scope of application than the Original Act. It will extend to situations where a business operator acquires the personal information of persons in Japan in the course of providing goods or services to them, and then uses in a foreign country such personal information or any anonymous information derived from such personal information. The provision of personal information to third parties in foreign countries will also be regulated as discussed later herein. Moreover, if a business operator or any of its employees provides or misappropriates personal data for the purpose of obtaining an illicit gain for itself or any third party, whether inside or outside of Japan, then such business operator or employee will be subject to the criminal penalties under the New Act.

The significant exemption that is currently being enjoyed by many subsidiaries in Japan will disappear. Under the Original Act, business operators who do not own a database that has identified more than 5,000 individuals on any single day within the past six months are exempted from the obligations imposed by the said Act. The New Act, however, has abolished such exemption and thus, any business operator that has a database of personal information for business use regardless of the volume of personal information collected must fulfill the obligations imposed by the New Act.

The provision of personal information to third parties outside Japan will be regulated under the New Act. Personal data must not be provided to

a third party in a foreign country without first obtaining the consent of the subject individuals unless (i) the situation falls under one of the exceptional cases specified under the New Act where consent is not required, (ii) such foreign country has been identified by the rules of the Personal Information Protection Commission (the “Commission”), which is to be newly established under the New Act, as having a system of protecting personal information at a level equal to that of Japan under the New Act, or (iii) such third party has established a system compliant with the standards to be provided by the rules of the Commission as is necessary to continuously take measures equal to the measures required to be taken under the New Act. The provision of personal information to third parties in foreign counties must also be recorded under the New Act, except in the cases described in item (i) above.

As to the consent requirement, although the above restriction on the provision of personal data to a third party overseas is yet to take effect, an individual's consent to the provision of his or her personal information before the effective date of the New Act will be deemed consent for purposes of complying with the New Act.

Lastly, under the New Act, the Commission may provide foreign authorities with information that the Commission deems helpful for the enforcement by the latter of foreign personal information protection laws. To use such information in criminal investigations abroad, however, the requirements of further consent of the Commission and reciprocity must be met. Consent will not be given though for cases involving political crimes and acts which are not considered crimes under Japanese law if committed in Japan.

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1. In particular, the Original Act provides for the proper acquisition and handling of personal information; obligation to give notice of the purpose of the use thereof at the time of the acquisition; limitation of the use thereof to the purpose; maintenance of personal data accuracy; security control measures; supervision of employees and processors; restrictions on the provision of personal data to third parties; disclosure, correction, addition, deletion and discontinuance of personal data upon request; and processing of requests and complaints.

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New Surcharge System under the Act Against Unjustifiable Premiums and Misleading Representations

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The Act Against Unjustifiable Premiums and Misleading Representations (the "Act")1 aims to protect the interests of general consumers in Japan and prevent misleading representations in transactions relating to products and services. In essence, once an entity that sells or provides products or services makes a representation to general consumers in Japan, such representation will be subject to the Act, which now imposes surcharges, even if the entity does not have any physical office in Japan.

Significant amendments to the Act

In June and November 2014, two significant amendments were made to the Act, which amendments are now in full force and effect.

These amendments were brought about by a series of incidents that attracted major public attention in Japan in the fall of 2013 when some well-established restaurants and hotels served dishes using ingredients that differed from those indicated in their menus. Following these incidents, the Act was amended in June 2014 (the "June 2014 Amendment") requiring the relevant entities to develop and improve their internal systems to prevent misleading representations on their products/services, including setting up compliance systems. The June 2014 Amendment took effect on December 1, 2014. Consequently, the Consumer Affairs Agency of Japan (the "Agency") released the Guidelines for Management Measures that Entities Should Implement with regard to the Offering of Premiums and Representations (the "Management Measures Guidelines"), which provide examples of measures that entities should refer to in developing and improving their internal systems.2

In November 2014, the Act was amended to primarily impose “surcharges” -- an economic disadvantage -- on entities that make misleading representations and at the same time introduce a refund system (the “November 2014 Amendment”). The November 2014 Amendment not only enhanced the deterrent effect of the Act but also, through the refund system, promoted the recovery of damages incurred by general consumers due to misleading representations. The November 2014 Amendment took effect on April 1, 2016.

Outline of the surcharge system

A brief outline of the surcharge system under the Act and some appropriate responses are discussed below:

(1) The Agency may impose a surcharge on an entity that makes a misleading representation about the superiority of the quality, etc., of the products or services, or a misleading representation making the price and other conditions concerning the products or services more favorable than they actually are.3 The surcharge is calculated by multiplying the amount of the sales of the products and services that are the subject of the misrepresentation for the period during which the relevant misleading representation was made (covering sales up to 3 years) by 3%.4 Making an accurate calculation of such relevant period is a complicated task, for which consultation with a Japanese lawyer with the necessary expertise is recommended.

Notwithstanding the foregoing, no surcharge will be imposed if (a) the entity that made the misrepresentation conducted its business with the care required under normal commercial practice, such as checking the information that served as the basis for the relevant misleading representation, and (b) such entity was not negligent.5 Similarly, no surcharge will be imposed in cases where the amount of the surcharge will be less than 1.5 million yen.

Moreover, if the entity gave the affected consumers a refund in accordance with the prescribed requirements and procedure, then the surcharge amount will be reduced.6 While in some countries such as Korea, a refund is favorably taken into account for entities that made a misleading representation, no similar arrangement seems to be available in other countries that have adopted a surcharge system; this makes the Act under the consumer law system of Japan unique.

Whether the prescribed refund should be made, however, must be considered carefully by the entity that made the misleading representation. On one hand, doing so may not satisfy consumers and could result in consumers boycotting the entity's products or services, or losing confidence in the entity and all of its products/services. On the other hand, paying only the surcharge may help avoid the foregoing risks; however, this can result in an undue financial burden on the relevant entity as well as trigger reputational risks. All the circumstances and relevant facts must therefore be properly considered before an appropriate option is chosen.

(2) To prevent misleading representations from being made, specific measures consistent with the Management Measures Guidelines, and which are reasonably necessary and appropriate, taking into account their business and internal arrangements, must be implemented by all entities that sell or provide products and services to consumers in Japan. Thus, all entities, whether or not they have physical offices in Japan, must review their internal systems to see whether they comply with the June 2014 Amendment and the Management Measures Guidelines. In addition, in view of the complexity involved in conducting such review, it is recommended that the review be done with the assistance of experienced lawyers.

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1. Generally referred to in Japanese as 景表法 (Keihyo-ho).
2. The examples provided are not exhaustive.
3. Art. 8, the Act.
4. Id.
5. Art. 8, the Act.
6. Art. 10 and 11, the Act.

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Revisions to Employee Invention Provisions under the Patent Act

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On April 1, 2016, the revisions to Article 35 of the Patent Act relating to inventions made by employees (hereinafter, "employee invention")1 came into effect. These revisions now make it possible for an employer to have the right to the patent to an employee invention from the very beginning subject to certain conditions, enabling companies to obtain and manage patents smoothly. The revisions also clarify the incentives for employees and allow companies to achieve successful innovation in view of the competitive environment of the global economy. Some key points to remember on the recent revisions are discussed below.

Employer's right to the patent to an employee invention

Under the previous Article 35 of the Patent Act, the right to the patent to an employee invention belonged to the employee inventor the moment the invention is completed. In order for the employer to acquire such right to the invention, an assignment of such right from the employee to the employer was required. Such previous scheme gave rise to the possibility of assignments by the employee of the right to the patent to an invention to multiple parties.2

To prevent such multiple assignments, the recent revisions to Article 35 of the Patent Act now make it possible for the right to the patent to an employee invention to be vested in the employer from the very moment the invention is completed, subject to the condition that the said scheme is provided in the contract with the employee, the work regulations or any other stipulation in advance.3

Broader form of consideration for the employee inventor

Under the previous Article 35 of the Patent Act, if an employer obtains the right to the patent to an invention from an employee (including any exclusive license thereto), the latter had the right to receive "reasonable value," which, however, was limited to monetary compensation.

Under the new paragraph 4 of Article 35 of the Patent Act, the employee now has the right to receive "a reasonable amount of money or other economic benefit"4 as consideration for his invention. The

scope of what is considered an economic benefit has, to some extent, become broader. For instance, according to the guidelines published by the Ministry of Economy, Trade and Industry (METI),5 paid vacations, stock options, a chance to study abroad or promotions with salary increases are now accepted as economic benefits.

Guidelines on procedures for the setting of standards and the grant of benefits to employee inventors

Under paragraph 4 of the previous Article 35 of the Patent Act, if a contract, work regulation or any other stipulation has provided the value to be paid to an employee for an employee invention, the payment of such value was presumed reasonable if the employer went through certain procedures, which included negotiations with the employees to set the standards for determining the value, disclosing those standards to the employees, and consulting the employees on the calculation of such value (collectively, the "Procedures"). However, despite this presumption, there were still some opinions that it was not clear to what extent an employer had to implement the Procedures for the payment not to be considered unreasonable.

To give concrete examples of the Procedures and to enhance the predictability of the reasonableness of the "amount of money or other economic benefit," on April 22, 2016,6 METI published guidelines, taking into account the opinions of the Industrial Structure Council, which consists of the representatives of labor and industry, and academics.7 The guidelines illustrate what would be considered reasonable Procedures. Although not binding on judicial authorities, judicial authorities may still observe the guidelines when deciding cases brought before them since such guidelines were established after consultations with the Industrial Structure Council.

Based on the foregoing, it would be advisable for companies to check the relevant employment contracts, work regulations and any other stipulations of their Japanese subsidiaries to see if they have adopted, and are now consistent with, the foregoing revisions relating to employee inventions.

1. An employee invention is defined as an invention which, by the nature thereof, falls within the scope of the business of the employer, and was achieved by an act(s) categorized as a present or past duty of the said employee, and which was performed for the employer (Art. 35, the Patent Act).
2. Multiple assignments were still technically possible even if the transfer of the right to the patent to an employee invention from the employee to the employer was provided in the contract with the employee, the work regulations or any other stipulation.
3. See Para. 3, Art. 35, the Patent Act.
4. See also Paras. 5 and 7, Art. 35, the Patent Act.
5. METI Public Notice No. 131, April 22, 2016.
6. Id.
7. Para. 6, Art. 35, the Patent Act.

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New Law to be Passed to Regulate Clinical Research Partnerships in Japan

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Advances in medical technology cannot grow without the requisite collaboration between medical professionals and healthcare companies. However, there exists an inherent conflict of interest in their relationship since the primary purpose of healthcare companies such as pharmaceutical and medical device companies is to make profit while the mission of medical professionals such as physicians is to save patients' health and lives. Historically, improprieties in their opaque partnership have caused some issues in the healthcare industry.

In 2004, the World Medical Association (“WMA”) adopted a statement concerning the relationship between physicians and commercial enterprises, which was later amended in 2009,1 setting guidelines for

such relationships, including the need for full disclosure thereof. In response to the WMA's statement, major countries began establishing their own disclosure rules. This is now a world-wide trend. For example, the United States promulgated the so-called "Sunshine Act" in 2010, which has been enforced since 2013.2 In the Japanese healthcare industry, the Japan Pharmaceutical Manufacturers Association and the Japan Federation of Medical Devices Associations have adopted their own Transparency Guidelines for their members.3 These self-regulated guidelines, however, are not legally binding and there are no substantial sanctions for non-compliance therewith.

Given the above circumstances, the Clinical Research Act bill (the "Bill") has been submitted to the 190th Diet after it was reviewed by the Ministry of Health, Labor and Welfare (the "MHLW"). The Bill will clarify certain procedural requirements for clinical researches and mandate the disclosure of information about the funding thereof.4 This Bill is expected to promote patient care and prevent clinical research partnerships from being tainted by any impropriety, which will thereby promote much-needed industry-government-academia collaboration the right way.

Key features of the Bill

1. Regulation of Clinical Researches

(1) Requirements for Specified Clinical Researches

Specified Clinical Researches will be subject to certain procedural requirements. "Specified Clinical Researches" refer to (i) clinical researches on unapproved medicines and off-label drugs under the Pharmaceuticals and Medical Devices Act, and (ii) clinical researches on medicinal drugs of pharmaceutical companies that are funded by such companies.5 A researcher who wishes to conduct a Specified Clinical Research must comply with the Clinical Research Implementation Policy (the "Implementation Policy") of the MHLW, which requires the researcher to monitor the status of the implementation of the Specified Clinical Research, provide indemnification and medical treatment in the event of any health hazard, and manage conflicts of interest as well as submit an implementation plan (the "Implementation Plan") to the MHLW in advance.6 A researcher must also obtain informed consents from patients, protect their private information, and maintain records of the Specified Clinical Research being implemented.7

(2) Authorized Clinical Research Examination Committee

A new Authorized Clinical Research Examination Committee (the "Committee") will be created to examine the Implementation Plans.8 The composition thereof will be approved by the MHLW.9 Currently, the ethical examination committee of each medical institution is in charge of reviewing clinical research plans, however, such committee has failed to function well in a number of cases. The setting up of the new Committee aims to improve this review process and strengthen measures against adverse events.

(3) Reporting of and Response to a Serious Disease

If a serious disease is suspected to be caused by a Specified Clinical Research, then a researcher must submit reports to both the Committee and the MHLW.10 Thereafter, the researcher must take the necessary measures if recommended by the Committee.11

(4) Administrative Guidance by the MHLW

The administrative guidance by the MHLW will be stronger. In particular, if the Implementation Policy is breached, then the MHLW will order an improvement or correction.12 If such order is not followed, then all or part of the Specified Clinical Research in question may be suspended and sanctions may be imposed. The MHLW may also directly order the suspension of the Specified Clinical Research or take other measures if deemed necessary to prevent the occurrence or spread of any harm to health and sanitation.13

2. Regulation of Funding by Healthcare Companies

Healthcare companies must sign written agreements to fund Specified Clinical Researches for their medical products.14 They must also disclose any funding to medical professionals such as doctors.15 Funding will include manuscript writing fees and honoraria as well as research funds and scholarship donations, but will not include entertainment expenses. If a company commits a funding violation, then the MHLW will issue a warning, and if not heeded, the name of the violator may be made public.16

The new law will take effect from the date determined by the Cabinet Order within one year from the date of its promulgation.17

1. WMA Statement concerning the Relationship between Physicians and Commercial Enterprises, http://www.wma.net/en/30publications/10policies/r2/index.html.
2. 42 U.S.C. §1320a-7h, https://www.ssa.gov/OP_Home/ssact/title11/1128G.htm.
3. See, e.g., http://www.jpma.or.jp/english/policies_guidelines/pdf/transparency_gl.pdf.
4. The Bill has been carried over to the next Diet.
5. Art. 2(2), the Bill.
6. Id. Art. 3 and 4.
7. Id. Art. 8, 9 and 11.
8. Id. Art. 22.
9. Id.
10. See, Id. Art. 12(1) and 13.
11. See, Id. Art. 12(2).
12. See, Id. Art. 19.
13. See, Id. Art. 18.
14. See, Id. Art. 31.
15. See, Id. Art. 32.
16. See, Id. Art. 33.
17. See, Id. Supplemental Provisions, Art. 1.

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PRACTICAL TIPS FOR DOING BUSINESS IN JAPAN

Remaining Difficulties After Removal of Residence Requirement for Representative Directors

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In setting up subsidiaries in Japan, foreign companies used to find it difficult to meet the requirement of having at least one resident representative director especially when they have yet to identify appropriate candidates for this position. This is no longer a problem.

No more residence requirement

More than a year has passed since the Ministry of Justice of Japan abolished on March 16, 2015 the above residence requirement. The Legal Affairs Bureau (the "Bureau") has since then been accepting applications for registration of new companies without any representative director residing in Japan. While this promotes foreign investments, there are still some practical difficulties in establishing new companies without resident representative directors.

Opening a bank account to set up a company

The biggest hurdle is the opening of a bank account in a Japanese bank. To establish a Japanese company, it is common to open a bank account in the name of the incorporator (which is often either the individual to be appointed as the representative director of the new company after its establishment or the foreign parent company itself) for the purpose of receiving the fund for the initial paid-in capital from the foreign parent company. While seemingly simple, in practice, it is often difficult to open a bank account at a Japanese bank for a foreign individual not residing in Japan or a foreign company not having an office or representative in Japan. This complexity is brought about by various banking regulations that mandate a strict screening process (e.g., anti-money laundering, etc.). Moreover, supporting documents may have to be translated into Japanese.

The new company opening its own bank account

After a non-resident foreign individual or parent company successfully opens a bank account in Japan to receive the initial paid-in capital and the new company is then duly set up and registered with the Bureau, the next hurdle would be for such new company to open its own bank account. For this purpose, Japanese banks also implement a strict screening process, which may be more difficult for a newly established company without a resident representative director. Communications and discussions with the bank, including supporting documents to be submitted thereto, would all normally be done in Japanese.

Based on the foregoing, whether it be the incorporator of the new company or the newly established company itself, navigating the various requirements for the opening of a bank account in Japan remains difficult even after the removal of the resident requirement. Thus, the

assistance of a lawyer experienced in dealing with such matters is recommended.

On a final note, the requirement for a foreign company operating its business continuously in Japan to appoint at least one resident representative (not a director) is still effective under the Japanese Companies Act.

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