OH-EBASHI
大江橋法律事務所

OH-EBASHI LPC & PARTNERS NEWSLETTER

2025 Spring Issue

Articles

Oh-Ebashi Newsletter Editorial Team

Seigo Takehira / Partner
Takashi Hirose / Partner
Hisako Matsuda / Registered Foreign Lawyer
Hajime Taniuchi / Partner
Yuichi Urata / Partner
Miriam Rose Ivan L. Pereira / Counsel
Nicholas Robin Jesson / Registered Foreign Lawyer

For inquiries, questions or comments, please contact us at newsletter_japan@ohebashi.com.
[Website] https://www.ohebashi.com/en/

Key Regulatory Considerations for Pharmaceuticals and Medical Devices in Japan

Kochi Hashimoto
kochi.hashimoto@ohebashi.com

I. Introduction

Japan's healthcare market is undergoing a significant transformation driven by an aging population and technological innovation. Among the various regulated sectors, pharmaceuticals, especially those used with prescriptions or guidance, and medical devices stand out as two of the most strictly controlled areas, requiring careful navigation by foreign companies seeking market entry.

Within these sectors, regulatory challenges vary widely, but marketing authorization and advertising regulations are particularly critical due to their complexity and differences from those in other regions. Many foreign companies attempting to enter Japan's healthcare market face difficulties in adapting to Japan's unique requirements, making these two areas especially important to understand when formulating a market strategy.

This article focuses on these key regulatory aspects, offering practical insights to help foreign businesses seeking to enter Japan's healthcare market anticipate potential hurdles and align their operations with Japan's legal framework.

II. Pharmaceutical Regulations in Japan

In Japan, the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices ("**PMD Act**")[1] governs the regulation of pharmaceuticals, quasi-drugs, cosmetics, medical devices, and regenerative medicine products to ensure their quality, efficacy and safety. The PMD Act also establishes measures to prevent and mitigate public health risks arising from the use of these products.

1. Pharmaceuticals

Under the PMD Act, companies wishing to manufacture and sell pharmaceuticals must obtain marketing approval for each pharmaceutical from the Minister of Health, Labour and Welfare ("**MHLW**"), in addition to securing a license to engage in pharmaceutical marketing activities.

As illustrated below, licenses are categorized based on the type of pharmaceutical. A first-class marketing license for pharmaceuticals is required to market prescription pharmaceuticals (pharmaceuticals that require a physician's prescription).[2] A second-class marketing license for pharmaceuticals is required to engage in the manufacturing and marketing of pharmaceuticals used with prescriptions or guidance other than prescription pharmaceuticals,

1. Act No. 145 of August 10, 1960.
2. PMD Act, art. 12(1).

pharmaceuticals requiring guidance, and OTC pharmaceuticals.[3]

<table>
<tr><th>Major Category</th><th colspan="2">Subcategory</th><th>Marketing Authorization License for Pharmaceuticals</th></tr>
<tr><td rowspan="3">Pharmacy-Only Pharmaceuticals</td><td rowspan="2">Pharmaceuticals Used with Prescriptions or Guidance</td><td>Prescription Pharmaceuticals</td><td>First-Class</td></tr>
<tr><td>Pharmaceuticals Used with Prescriptions or Guidance other than Prescription Pharmaceuticals</td><td rowspan="5">Second-Class</td></tr>
<tr><td colspan="2">Pharmacy-Made Pharmaceuticals</td></tr>
<tr><td>Pharmaceuticals Requiring Guidance</td><td colspan="2">N/A</td></tr>
<tr><td rowspan="3">OTC Pharmaceuticals</td><td colspan="2">Schedule I Pharmaceuticals</td></tr>
<tr><td colspan="2">Schedule II Pharmaceuticals</td></tr>
<tr><td colspan="2">Schedule III Pharmaceuticals</td></tr>
</table>

It is important to note that this is not a tiered system, and holding a first-class marketing license for pharmaceuticals does not permit engagement in activities covered by a second-class marketing license for pharmaceuticals.

The PMD Act defines "**marketing**" as the act of selling, leasing or providing pharmaceuticals that have been manufactured or imported either by the holder of marketing authorization itself or by an outsourced entity.[4] The holder of marketing authorization assumes final responsibility for the quality and safety of its products as the initial point of distribution in the market.

Furthermore, the PMD Act distinguishes between "marketing" and "manufacturing." Entities engaged in the manufacturing of pharmaceuticals must obtain a manufacturing license for each production facility based on the specific manufacturing processes undertaken.[5] Even if a company holds a marketing license, it must obtain a separate manufacturing license if it intends to manufacture products in-house.

For pharmaceutical sales, in principle, companies must be licensed as a proprietor of a pharmacy or pharmaceutical wholesale distributor. However, exceptions exist such as when holders of marketing authorization or manufacturers supply products to a proprietor of a pharmacy or other holder of marketing authorization. In practice, many holders of marketing authorization obtain distribution licenses to ensure a stable supply chain.

3. *Id.*, art. 12(1).
4. *Id.*, art. 2(13).
5. *Id.*, art. 13(1) and (2).

2. Medical Devices

The regulatory framework for medical devices in Japan is similar to that of pharmaceuticals as both are subject to corporate-level business regulations and product-specific marketing requirements. However, the specific regulatory requirements differ. Medical devices are classified into three categories based on the level of risk they pose to human health: specially controlled medical devices,[6] controlled medical devices[7] and general medical devices.[8] Each category requires different types of approvals and notifications.

Class	Category	Marketing Business License	Sales & Leasing Business	Marketing Approval	Examples
IV	Specially Controlled	First-Class	License	Approval	Pacemakers, Artificial Heart Valves, Stent Grafts
III	Specially Controlled	First-Class		Certification/ Approval	Dialyzers, Artificial Bone, Ventilators
II	Controlled	Second-Class	Notification	Approval/ Certification	MRI Devices, Electronic Endoscopes, Digestive Catheters, Ultrasound Devices, Dental Alloys
I	General	Third-Class	Not Required*	Notification	In Vitro Diagnostic Devices, Scalpels, Forceps, X-ray Films

*For "**Specially-Designated Medical Devices Requiring Maintenance**," a license for sales and leasing businesses is required.

For specially controlled and controlled medical devices, some require marketing approval from the MHLW, while others may be marketed based on a certification issued by a registered certification body. In contrast, general medical devices only require notification to the MHLW and do not require separate approval or certification. Thus, the regulation of medical devices is characterized by increasing degrees of certification as the level of risk they pose to the human body increases. Entities engaged in the marketing of medical devices must obtain a marketing business license, even if they only handle general medical devices.

Unlike pharmaceuticals, where the licenses are not granted in a tiered-system and separate licenses are required for first-class and second-class marketing activities, marketing licenses for medical devices are granted in a tiered-system, and companies with a higher-tier license (first-class marketing license for medical devices) are able to engage in lower-tier activities (such as activities requiring a second-class marketing license for medical devices) without obtaining an additional license.

Regarding manufacturing, unlike pharmaceuticals, which generally require a manufacturing license, medical device manufacturers are only required to register each production site. For sales, businesses dealing in specially controlled medical devices must obtain a license from the relevant prefectural governor, whereas those handling controlled medical devices only need to submit a notification to the prefectural governor of the region. General medical devices do not require any sales license or notification.

6. *Id.*, art. 2(5).
7. *Id.*, art. 2(6)
8. *Id.*, art. 2(7).

Additionally, specific regulations apply to the leasing and repair of medical devices, requiring compliance with distinct regulatory frameworks.

III. Advertising and Promotional Regulations

1. The PMD Act and Advertising Standards

Healthcare products, including pharmaceuticals and medical devices, play a crucial role in human health. Misuse or overuse can lead to serious health risks, making the provision of accurate and appropriate information essential. To this end, the PMD Act and the Advertising Standards for Pharmaceuticals and Medical Devices (Notification by the MHLW, September 29, 2017, No. 0929-4) prohibit misleading advertisements, exaggerated claims, and advertisements that imply endorsement by medical professionals.

Additionally, pharmaceuticals used with prescriptions or guidance that require a physician's diagnosis or prescription and medical devices excluding home-use medical devices and certain exceptions are generally prohibited from being advertised to the general public. Consequently, advertisements in mass media, such as television commercials and newspapers, viewable by the general public are not allowed.

The Advertising Standards for Pharmaceuticals and Medical Devices apply not only to pharmaceuticals but also to medical devices. However, the Guidelines on the Interpretation and Considerations for the Standards for Adequate Advertising of Pharmaceuticals, etc. (Notification No. 0929-5 by the Pharmaceutical Safety and Environmental Health Bureau) state that the unique characteristics of advertising for both pharmaceuticals and medical devices should be taken into account, and that a uniform approach should be avoided.

2. Sales Information Provision Activities Guidelines

As to sales information provision activities for pharmaceuticals used with prescriptions or guidance, the Sales Information Provision Activities Guidelines established by the MHLW set forth specific guidelines to ensure the appropriateness of such activities.

These guidelines require compliance with several key principles, including ensuring that information on efficacy, effects, dosage and administration remains within the scope of approved indications, prohibiting false or exaggerated claims, and prohibiting disparagement of competing products. Additionally, they explicitly mandate the balanced provision of efficacy and safety information, including adverse effects, prohibit the selective disclosure of information, and require that information be provided based on scientific and objective evidence.

3. Fair Competition Codes

The Fair Competition Codes are industry self-regulatory rules established by industry associations and certified by the Japan Fair Trade Commission and the Commissioner of the Consumer Affairs Agency pursuant to Article 31(1) of the Act Against Unjustifiable Premiums and Misleading Representations.[9]

There are separate Fair Competition Codes for Pharmaceuticals Used with Prescriptions or Guidance and Fair Competition Codes for Medical Devices, each setting forth rules governing the provision of premiums and other inducements. The purpose of these codes is to restrict the improper provision of premiums, thereby preventing unfair inducement of customers, ensuring autonomous and rational decision-making by customers, and promoting fair competition among businesses.

9. Act No. 134 of May 15, 1962.

Violations of the codes may result in penalties such as fines or expulsion from the industry association. Moreover, adherence to these codes serves as an important safeguard because businesses that comply with them are deemed compliant with the Act Against Unjustifiable Premiums and Misleading Representations and other relevant laws.

4. Promotion Codes

In the promotion of pharmaceuticals used with prescriptions or guidance, companies are required to adhere to industry-specific ethical standards. The Pharmaceuticals Promotion Code, established by the Japan Pharmaceutical Manufacturers Association, serves as a self-regulatory framework for pharmaceutical companies. This code incorporates the advertising regulations under the PMD Act, the Standards for Adequate Advertising of Pharmaceuticals, the Sales Information Provision Activities Guidelines, and the Fair Competition Code for Pharmaceuticals Used with Prescriptions or Guidance. It sets forth behavioral standards for medical representatives and establishes rules governing promotional materials.

For the promotion of medical devices, the industry is regulated by the Medical Device Promotion Code formulated by the Japan Federation of Medical Devices Associations ("**JFMDA**"), a leading industry organization. Under this code, member companies are prohibited from providing monetary benefits, goods or services to medical institutions or healthcare professionals that may influence the adoption or appropriate use of medical devices. It also prohibits the provision of services without reasonable justification.

Furthermore, JFMDA's member organizations have established their own self-regulatory standards for sales and advertising practices, tailored to the characteristics of the products and business models of their respective members.

IV. Conclusion

This article has provided an overview of the key legal and regulatory requirements for pharmaceuticals used with prescriptions or guidance and medical devices in Japan. The regulations governing marketing authorization, advertising and promotional activities play a critical role in shaping companies' market entry strategies and business operations.

In particular, navigating Japan's stringent licensing system and advertising regulations requires careful planning and thorough preparation. Ensuring compliance with these legal requirements is essential for achieving long-term business success.

Beyond the topics covered in this article, the pharmaceutical and medical device industries in Japan are subject to a wide range of regulations and industry practices that may impact business operations. Companies entering this market are encouraged to seek specialized guidance to ensure compliance and develop a well-informed strategy.

We hope this article serves as a valuable resource for companies considering expansion into the Japanese healthcare market.

Back to List of Articles

Changes to Childcare Leave, Caregiver Leave and Other Measures for the Welfare of Caregiving Workers under Japanese Law

Kentaro Kondo
kentaro.kondo@ohebashi.com

I. Introduction

Since its enactment in 1991, Japan's Act on Childcare Leave, Caregiver Leave, and Other Measures for the Welfare of Workers Caring for Children or Other Family Members (the "**Child and Family Care Leave Act**")[1] has been revised several times in line with changes in workers' work styles, increase of dual-income families and the number of women advancing in society as well as drastic changes in how childcare and nursing care should be provided with the population rapidly aging.

The amendments to the Child and Family Care Leave Act will take effect in two stages on April 1, 2025 and October 1, 2025, and impact important issues for employers. However, the enhancement of support systems to balance work and childcare or nursing care will help companies secure essential human resources from leaving and reduce the number of employees resigning. This is crucial since, particularly after Covid-19, the birthrate has been declining at an accelerating pace throughout Japan, while in contrast, the so-called "2025 problem," where the first baby boomers who were born soon after WWII are now becoming over 75 years old, is emerging and nursing care is becoming an inevitable issue for more and more people.

II. Amendments concerning Childcare

1. Overview

On May 31, 2024, the Act on the Partial Amendment to the Act on the Welfare of Workers Who Take Care of Children or Other Family Members Including Child Care and Family Care Leave and the Act on Advancement of Measures to Support Raising Next-Generation Children (Act No. 42 of 2024) was promulgated to partially amend the Child and Family Care Leave Act and the Act on Advancement of Measures to Support Raising Next-Generation Children (the "**Next-Generation Children Act**").[2]

The amendments mainly aim to: (a) expand measures to realize flexible work styles based on the age of children, (b) expand the obligation to publicly disclose the status of childcare leave taken by employees and promote measures to support the development of the next generation, and (c) prevent employees from quitting due to caregiving.

This article will introduce the major amendments that will have a substantial impact on labor management for employers.

1. Act No. 76 of 1991, as last amended by Act No. 42 of 2024.
2. Act No. 120 of 2003, as last amended by Act No. 42 of 2024.

2. Amendments Effective from April 1, 2025

(a) Revision of the Child Nursing Leave

Under the current law, an employee who is caring for a pre-elementary school child may take up to five days[3] of child nursing leave per year under certain conditions. If an employee requests leave to care for a child, as a general rule, the employer cannot refuse such request.[4] Due to the amendment that will take effect on April 1, 2025, the scope of employees eligible for child nursing care leave will be expanded with additional grounds for such leave. In particular, child nursing leave will be available not only to employees with pre-elementary school children but also (i) those who have children who have not yet finished their third grade of elementary school, and (ii) employees who have been continuously employed for less than six months.

Besides the current grounds for nursing care leave, (i) classroom closures due to infection, and (ii) attendance of the entrance or graduation ceremonies of their children will be added as grounds for such leave.

In light of the additional grounds for taking such leave, the name of the leave will be changed from "nursing leave" to "leave for nursing, etc."[5]

(b) Expansion of Overtime Work Restrictions

The current law states that (i) off-scheduled time work, (ii) overtime work, and (iii) late-night work must be restricted upon the request of an employee who is raising children, subject to certain conditions. Specifically, employees who are raising pre-elementary school children may request restrictions on overtime work and late-night work, but only employees raising children under three years old may request restrictions on off-scheduled time work.[6] Once the amendment takes effect on April 1, 2025, eligibility for the restriction on overtime work will be broadened and any employee raising a pre-elementary school child may request it.[7]

(c) Telework as an Alternative to the Shortened Working Hour System

Under the current law, employees raising children under three years old may request that they adopt a shortened working hour system. However, if there is specific work for which it would be inappropriate to apply such system, then employees engaged in that work may only be exempt from this shortened working hour system by concluding a labor-management agreement, and they would be required to take alternative measures.[8] Once the amendment takes effect on April 1, 2025, telework will be one of those measures.[9]

(d) Expansion of the Obligation to Publicly Disclose the Status of Male Employees Taking Childcare Leave

The obligation to publicly disclose the status of male employees taking childcare leave was introduced by an amendment to the Child and Family Care Leave Act that took effect on April 1, 2023. Under the current law, employers with more than 1,000 full-time employees must publicly announce within three months after the end of each fiscal year the percentage of male employees who took childcare leave, etc., in the previous fiscal year.[10]

---

3. 10 days per year if the employee has two or more pre-elementary school children.
4. Child and Family Care Leave Act, arts. 16-2(1) and 16-3(1).
5. *Id.*, as amended, art. 16-2(1).
6. Child and Family Care Leave Act, Chapters 6-8.
7. *Id.*, as amended, art. 16-8(1).
8. Child and Family Care Leave Act, art. 23(1) and (2).
9. *Id.*, as amended, art. 23(2)(i).
10. Child and Family Care Leave Act, art. 22-2.

Once the amendment takes effect on April 1, 2025, the requirement will change and the number of employers subject to this obligation will expand to cover those employing more than 300 full-time workers.[11]

(e) Promotion of Telework[12]

Under the amendment that will take effect on April 1, 2025, an employer will be required to make an effort to take measures so that employees raising children under three years old can choose telework as their work style.[13]

3. Amendments Effective from October 1, 2025

(1) Measures to Realize Flexible Working Hours During Childcare

Under the current law, only employees raising children under three years old are eligible to use the shortened working hour system or alternative measures, such as changing their starting time of work. However, under the amendment that will take effect on October 1, 2025, employers will be required to select and adopt two or more of the following five measures to realize flexible working styles during such period:[14]

(a) Change the starting time of work, etc.;
(b) Telework, etc.;
(c) Establish and operate childcare facilities, etc.;
(d) Grant leave to support compatible childcare and work; and
(e) Provide a shortened working hour system.

(2) Expansion of the Obligation to Inform and Confirm the Intention of Employees about Work, Childcare Balance, etc.

Under the current law, when an employee informs the employer of a pregnancy or childbirth, the employer must inform such employee about the childcare leave system and the department within the company where the leave request may be made. The employer must also confirm the employee's intention to take such leave.[15]

Once the amendment takes effect on October 1, 2025, in addition to informing each employee about the details of the available support systems for balancing work and childcare and the method of submitting requests, the employer must inquire about the employee's intentions concerning balancing work and childcare, and give consideration based on the employee's intentions.[16]

The MHLW published an example of a written form which can be used for the individual notification and confirmation of an employee's intentions.[17] However, even after giving it due consideration, the employer can lawfully refuse to take the measures requested by the employee, such as when it would be impossible to take such measures. In such cases, it is essential for the employer to explain the reasons for such difficulty to the employee.[18]

---

11. *Id.,* as amended, art. 22-2.
12. Telework is defined as work performed by employees using information and communication technology outside the office (Guidelines for the Promotion of Appropriate Introduction and Implementation of Telework of the Ministry of Health, Labor and Welfare ("**MHLW**")).
13. Child and Family Care Leave Act, as amended, art. 24(2).
14. *Id.,* art. 23-3(1).
15. Child and Family Care Leave Act, art. 21(1).
16. *Id.,* as amended, art. 21(2).
17. *See* https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/000103533.html (in Japanese).
18. *See* MHLW, *"Q&A on the Child Care and Family Care Leave Law Amended in 2024,"* Q2-35.

III. Amendments concerning Nursing Care

1. Expansion of the Scope of Employees for Nursing Care Leave

Under the current law, employees who (a) work two or fewer days per week, or (b) have been continuously employed for less than six months, can be excluded from taking nursing care leave by concluding a labor-management agreement with the representative of the employees.[19]

Under the amendment that will take effect on April 1, 2025, however, the second exception will be removed, so after such amendment takes effect, it will no longer be possible for employers to exclude employees who have been continuously employed for less than six months from taking the nursing case leave.

2. Obligation to Inform and Confirm the Intention of Employees when Nursing Care is Requested

Under the current law, employers are not required to either inform employees about the nursing care leave system or confirm their intention to use such system, as employers are required to do with respect to the childcare leave system, but under the amendment that will take effect on April 1, 2025, employers will be obliged to inform and confirm the intent of employees regarding the nursing care leave system.[20]

3. Providing Early Information regarding Support Systems for Balancing Work and Nursing Care

As a measure to inform employees early about existing support systems, the amendment that will take effect on April 1, 2025 obliges employers to provide each employee information on the details of systems that support balancing work and nursing care at an appropriate time to provide such information, such as the day the employee reaches the age of 40.[21]

4. Establishment of a Work Environment to Prevent Nursing Care Employees from Resigning

Under the amendment that will take effect on April 1, 2025, employers will be obliged to take one of the following measures to ensure that applications for nursing care leave and nursing care, etc., are handled appropriately:[22]

(a) Provide training on the nursing care leave, the nursing care leave balance support system, etc.;
(b) Establish a consultation system for nursing care leave and nursing care leave balance support;
(c) Collect and provide information on examples of cases of nursing care leave taken by employees and use of the nursing care leave balance support system; and
(d) Inform employees of the company's policy on promoting the use of nursing care and the nursing care leave balance support system.

5. Promotion of Telework

Under the amendment that will take effect on April 1, 2025, the employer will be obliged to make an effort to take measures so that those employees who care for family members in need of nursing care can choose telework as their work style.[23]

IV. Concluding Remarks

Employers must be prepared to meet the expanded employee welfare obligations under the upcoming amendments discussed above. If an employer violates any of the obligations under the Child and Family Leave Act, including the amended requirements, the MHLW may impose corrective actions. Failure to comply with the said agency's recommendations may lead to the

19. Child and Family Care Leave Act, art. 16-6(2), proviso of art. 6(1), and art. 6(2).
20. Child and Family Care Leave Act, as amended, art. 21(2).
21. *Id.*, art. 21(3).
22. *Id.*, art. 22(2) and (4).
23. *Id.*, art. 24(4).

company's name being publicly disclosed. Therefore, it is essential for employers to properly understand the amendments and adapt internal working rules accordingly. Moreover, appropriate compliance with the amended Child and Family Leave Act will help prevent employees from resigning. From this perspective, employers must update their labor management systems.

Back to List of Articles