Key Regulatory Considerations for Pharmaceuticals and Medical Devices in Japan

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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>
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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.