Overview

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Welcome to our Blog Series!

This blog series aims to provide a comprehensive overview of pharmaceutical and healthcare regulations in Japan through a Q&A format, offering fundamental yet extensive information.
In this first article, we will outline a broad overview of the regulatory landscape. From the next post onward, we will delve into detailed explanations for each product category, including Pharmaceuticals, Medical Devices, *in vitro* Diagnostic (IVD) Products, and Regenerative Medicine Products.
We hope this series will be a valuable resource for those interested in entering the Japanese market, conducting clinical trials in Japan to collect data on Asian populations with an eye on the broader Asian market, or simply seeking to understand Japan's healthcare regulations.

1-1. What is the Legislation Framework for Pharmaceuticals, Medical Devices, and Other Healthcare-Related Products Regulatory in Japan?

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the PMD Act) is the principal legislation governing Pharmaceuticals (this category includes *in vitro* Diagnostic (IVD) Products), Quasi-Pharmaceutical Products, Cosmetic Products, Medical Devices, and Regenerative Medicine Products.

The PMD Act provides a comprehensive regulatory framework covering aspects such as marketing authorization, business licenses, and labeling and advertising regulations.

In addition to the PMD Act itself, the regulatory framework consists of cabinet orders and ministerial ordinances issued under the PMD Act (including various ordinances such as GLP, GMP, GVP, GQP, and QMS) as well as ministerial notices issued by the Ministry of Health, Labour and Welfare (the MHLW). These notices provide regulatory interpretations and operational guidelines, having practical importance in Japan.

Voluntary guidelines published by industry associations are not legally binding, but they may serve as useful references for ensuring compliance with relevant laws and regulations as well as providing industry standards.

1-2. What Are the Product Categories Defined Under the PMD Act?

The PMD Act classifies regulated products into the following categories:

- Pharmaceuticals
- Quasi-Pharmaceutical Products
- Cosmetic Products
- Medical Devices
- *In vitro* Diagnostic (IVD) Products
- Regenerative Medicine Products

1-3. What Are "Pharmaceuticals" Under the PMD Act?

Under the PMD Act, "Pharmaceuticals" are defined as:
(i) Substances listed in the Japanese Pharmacopoeia;
(ii) Substances intended for use in the diagnosis, treatment, or prevention of diseases in humans or animals; or
(iii) Substances intended to affect the structure or functions of the human or animal body, excluding Medical Devices and other separately defined categories (i.e., Quasi-Pharmaceutical Products, Cosmetic Products, and Regenerative Medicine Products).

Further details on the regulations for Pharmaceuticals and IVD Products will be covered in later posts on this blog.

1-4. What Are "Quasi-Pharmaceutical Products" Under the PMD Act?

Under the PMD Act, "Quasi-Pharmaceutical Products" are defined as non-device substances with mild effects on the human body that are any of the following:
(i) Products used for the purposes of:

- Prevention of nausea or other discomfort, bad breath, or body odor,
- Prevention of heat rash, chafing, or skin irritation, or
- Prevention of hair loss, promotion of hair growth, or hair removal;

(ii) Products used for pest control for human or animal health, targeting rats, flies, mosquitoes, fleas, and similar organisms; or
(iii) Products intended for the diagnosis, treatment, or prevention of diseases in humans or animals, or those intended to affect the structure or function of the human or animal body (i.e., those with pharmaceutical purposes), which are specifically designated as Quasi-Pharmaceutical Products by the Minister of Health, Labour and Welfare.

The overall regulatory framework for Quasi-Pharmaceutical Products is similar to that for Pharmaceuticals. Each product requires marketing authorization, and businesses engaged in marketing or manufacturing must obtain the corresponding business licenses. Unlike Pharmaceuticals, a sales license is not required for retail distribution.

1-5. What Are “Cosmetic Products” Under the PMD Act?

Under the PMD Act, “Cosmetic Products” are defined as products that are mild in their effects and are intended for use on the human body in a manner such as application, spraying, or similar methods to:

- Cleanse the body,
- Beautify,
- Enhance attractiveness,
- Alter appearance, or
- Maintain healthy skin or hair.

The range of effects for Cosmetic Products is defined by a MHLW notice (last revised on July 21, 2011), which specifies 56 categories of effects, including those on the hair, scalp, skin, nails, lips, and teeth. Cosmetic Products cannot claim effects beyond those listed in this notice.

Businesses engaged in marketing or manufacturing of Cosmetic Products must obtain the corresponding business licenses, while a sales license is not required for retail distribution.
As for Cosmetic Products, the ingredients must comply with the “Standards for Cosmetics” (MHLW Notification dated September 29, 2000). In principle, all ingredients need to be listed on the product packaging, and marketing authorization for each individual product is not required; instead, a notification submission prior to marketing by the license holder is sufficient.

1-6. What Are “Medical Devices” Under the PMD Act?

“Medical Devices” are defined as instruments, apparatuses, or other similar devices (excluding Regenerative Medicine Products) intended for use in the diagnosis, treatment, or prevention of diseases in humans or animals, or intended to affect the structure or function of the human or animal body, as specified by cabinet order.

Further details on the regulations for Medical Devices will be covered in later posts on this blog.

1-7. What Are "*in vitro* Diagnostic (IVD) Products" Under the PMD Act?

"In vitro Diagnostic (IVD) Products" are defined as Pharmaceuticals intended exclusively for use in the diagnosis of diseases, which are not directly used in the bodies of humans or animals.
As such, *in vitro* Diagnostic (IVD) Products are classified as a type of Pharmaceutical in Japan.
Further details on the regulations for *in vitro* Diagnostic (IVD) Products will be covered in later posts on this blog.

1-8. What Are "Regenerative Medicine Products" Under the PMD Act?

"Regenerative Medicine Products" are defined as the following items (excluding Quasi-Pharmaceutical Products and Cosmetic Products) as specified by cabinet order:
(i) Products to be used for the purposes of medical or veterinary care as listed below that are obtained after culturing or other processes using human or animal cells:

- Reconstruction, repair, or formation of the structure or function of the human or animal body, or
- Treatment or prevention of diseases in humans or animals;

(ii) Products intended for the treatment of diseases in humans or animals that contain genes to be introduced into human or animal cells, where these genes are expressed within their bodies.

Further details on the regulations for Regenerative Medicine Products will be covered in later posts on this blog.

1-9. How Are "supplements" Regulated in Japan?

Supplements are regulated as food unless they are marketed as Pharmaceuticals, in which case they require marketing authorization and must comply with all other requirements under the PMD Act.

As food products, supplements can be classified either as Food with Health Claims (FHC) - which is further divided into Food for Specified Health Uses (FOSHU, "*TOKUHO*"), Food with Nutrient Function Claims (FNFC), and Food with Function Claims (FFC) - or as general food products. Depending on the category, selling these products requires either individual permission, self-accreditation, or notification.

For FHC products, claims about the health function of either the product itself or its ingredients are permitted as applicable to each FHC sub-category. However, in any case, health claims on any category of food products must not be medicinal or therapeutic - otherwise, this violates the PMD Act that prohibits “advertisement for unapproved drugs.”

The Food Labelling Act sets forth regulations on the advertising and promotion of food (including supplement products) and prohibits false and exaggerated advertising. The Act against Unjustifiable Premiums and Misleading Representations also prohibits misleading representations that portray any items as being significantly superior to how they actually are in reality.

Regarding licensing, certification, etc. of FHC, as well as food labeling, the Consumer Affairs Agency is the regulatory body in charge. Regarding the food safety aspect, the Food Sanitation Act and its relevant regulatory authority (the MHLW) are also relevant.

1-10. What Approvals and Licenses Are Required to Market Healthcare Products in Japan?

For products regulated under the PMD Act, two key requirements need to be met: business licenses based on the type of business (e.g., marketing, manufacturing), and approval or notification for each specific product.
The exact types of approvals and licenses required vary depending on the regulatory category of each product, so it is important to confirm these requirements when starting a business.

The details will be explained in later posts on this blog.

1-11. What Are the Regulatory Authorities for Healthcare Products in Japan?

The MHLW is the regulatory authority that oversees and implements the regulations under the PMD Act.
The Pharmaceuticals and Medical Devices Agency (the PMDA) is the regulatory agency that works in collaboration with the MHLW, such as to conduct scientific reviews of marketing authorization applications for products. In addition to these reviews, the PMDA also provides various consultation services, including pre-application consultations, which are practically essential and highly beneficial for companies seeking to conduct clinical trials or obtain regulatory approval.

For veterinary pharmaceuticals, the Ministry of Agriculture, Forestry and Fisheries (the MAFF) is the responsible regulatory authority.

1-12. What Should You Consider When Expanding Your Healthcare Business into Japan?

Entering the Japanese healthcare market involves several key considerations, including:

- **Regulatory Compliance** – Securing the necessary approvals and licenses based on your product category and ensuring compliance with applicable laws are essential. For certain products - especially innovative ones - the regulatory classification may be unclear, requiring a detailed legal analysis or consultation with authorities.
- **Company Incorporation or M&A** – If you plan to establish a presence in Japan, considerations such as company incorporation, potential M&A processes, due diligence, and hiring strategies will be important.
- **Intellectual Property (IP) Protection** – Developing a robust IP strategy is crucial for maintaining market exclusivity and competitiveness. This may include patent and trademark filings, as well as freedom-to-operate (FTO) investigations.
- **Healthcare Data Protection and Privacy** – Handling healthcare-related data requires strict compliance with Japan's data protection laws, including the Act on the Protection of Personal Information (the APPI). Companies must implement appropriate measures to manage sensitive health data securely, ensure proper patient consent, and navigate cross-border data transfers where applicable.
- **Contracts and Agreements** – Negotiating and drafting key contracts, such as licensing agreements, joint research agreements, distribution agreements, and employment contracts, is critical to securing a strong business foundation.

1-13. What Services Does TMI Associates Offer to Clients Entering Healthcare Business in Japan?

Our Healthcare Practice Group is composed of both attorneys-at-law and patent attorneys, each bringing diverse expertise and backgrounds.
Our attorneys-at-law include practicing physicians, a licensed pharmacist, PhD holders in life sciences, and current/former secondees to the MHLW. Our team's expertise is comprehensive and spans a wide range of legal fields, including but not limited to, those outlined above.

Our patent attorneys also come from a wide range of technical backgrounds, including biotechnology, engineering, medical devices, and other advanced technologies. TMI Associates has trademark attorneys as well.

This multidisciplinary team of professionals supports every aspect of our clients' healthcare businesses in Japan - from building IP portfolios and navigating complex regulatory landscapes to handling high-stakes litigation - ensuring their success in this dynamic industry.

You may find more information at: Sector | Our Services | TMI Associates

What's Next?

In our next post, we will provide a detailed overview of the regulations regarding "Pharmaceuticals." Stay tuned!

More to Explore

Here are some recent articles on healthcare topics, authored by TMI members and available in English:

- Drug & Medical Device Litigation Japan 2025 (ICLG)
- The Legal 500: Pharmaceutical Advertising Comparative Guide (the 6th Edition)
- Psychedelic Medicines 2024 – Japan | Global Practice Guides | Chambers and Partners
- Digital Healthcare 2024 - Japan | Global Practice Guides | Chambers and Partners
- Healthcare: Medical Devices 2024 - Japan | Global Practice Guides | Chambers and Partners
- The Latest Grand Panel Decision of the IP High Court: Discussion on Patentability and Article 69(3) Exemption for a Breast Augmentation Composition Patent (TMI NEWSLETTER Issue 30)
- Recent IP High Court Decision regarding the Patent Linkage System in Japan (TMI NEWSLETTER Issue 27)
- When Does a Generic Entry Become Possible? - patent protections and pharmaceutical regulations in Japan (TMI NEWSLETTER Issue 17)

DISCLAIMER: This blog is for general informational purposes only. It offers a general overview of relevant laws and regulations but does not address specific cases and may not cover all conditions, requirements, or exceptions. For detailed guidance or case-specific analysis, please feel free to contact us for a consultation.

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About TMI Associates

https://www.tmi.gr.jp/

Organizational Structure

TMI has a total of more than 1,300 employees worldwide, including over 700 IP/Legal professionals, comprised of 614 attorneys (Bengoshi), 101 patent/trademark attorneys (Benrishi), and 65 foreign law professionals.

Attorneys-at-law (Bengoshi)	611
Patent/Trademark Attorneys (Benrishi)	101
Tax Accountant	2
Advisors	21
Foreign Law Counsel / Foreign Attorneys / Special Foreign Counsel	64
Senior Manager, Management Officers	4
Paralegals	90
Patent Engineers, Patent/Trademark Paralegals	128
Translators	18
Secretaries, Librarians, and other Staff	274
Total	**1,313**

(As of September 1, 2025)

Our Healthcare Practice Group

Our Healthcare Practice Group includes attorneys-at-law and patent attorneys with diverse expertise: physicians, a licensed pharmacist, life sciences PhD holders, and current and former MHLW secondees. We cover a wide range of legal and technical fields, offering comprehensive support in regulatory matters, corporate law, IP, litigation, etc. to help clients succeed in Japan's healthcare sector.

Locations

Japan Tokyo | Nagoya | STATION Ai (Nagoya) | Osaka | Kyoto | Kobe | Fukuoka

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