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Japan on the Move: Pharmaceuticals and Medical Devices (PMD) Act Amendment Demands Proper Compliance Foundation for Entry into Japan

Japan has long been an attractive market for big pharmaceutical companies, especially for those with a robust portfolio of innovative products. Japan's strong fundamentals, including sizable underlying patient populations; competitive pricing based on a predictable and transparent pricing method; an established health care delivery system; a streamlined supply chain; a generally solid awareness of new health technologies; and supporting infrastructure for disease diagnosis, treatment, and management, make it an attractive market to establish a direct corporate presence. While some emerging biotechnology companies in the United States and in Europe grow by having their licensing or partnership deals cover the Asia region, including Japan, those companies have shown a continued interest in having their own direct presence in Japan, rather than relying entirely on partners to capitalize on the return on their innovative products.

Pharmaceutical and biotech companies face new structural challenges and considerations, explored in this GT Advisory, for entry into the Japanese market. These challenges, if not appropriately and expeditiously addressed, could result in a lack of bandwidth that hampers corporate growth in Japan.

- The Amendment to the Act on Securing the Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices is the most comprehensive regulatory scheme reform for pharmaceuticals in past decade;

- Organizational failure to address noncompliance in the pharmaceutical industry in Japan is the underlying reason for the Amendment;
- A robust legal compliance system cannot be established without the proper level of investment, the right organizational structure, and a stronger supervisory mechanism;
- Full-time, dedicated compliance personnel within the business organization is critical after a product launch in this new landscape;
- Active monitoring and auditing of illegal marketing and advertising practices can facilitate voluntary reporting of such improper practices and reduce the enforcement penalty or surcharge;
- Companies contemplating entry into Japan or that recently have started doing business in Japan should consider developing a holistic legal and compliance roadmap to ensure their business undertakings are in line with the updated regulatory framework.

Japan's Fundamental Statute Governing Pharmaceutical and Medical Device Industry Sees Largest Reform of the Past Decade

On Dec. 4, 2019, the "Act on Securing the Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices" (the "Act") was amended ("Revised Act"). Certain articles of the Revised Act took effect April 1, 2020, Sept. 1, 2020, and Aug. 1, 2021, while other articles will take effect Dec. 1, 2022. Among other things, the Revised Act provides a blueprint to progressively roll out the whole scheme, including the below statutory changes related to pharmaceutical or life sciences businesses:

1. An expedited approval procedure for innovative pharmaceuticals and medical devices (so-called Sakigake Review System) (effective Sept. 1, 2020);
2. A conditional approval system for pharmaceuticals and medical devices that require a long clinical trial period (so-called Conditional Early Approval System) (effective Sept. 1, 2020);
3. Introduction of an approval review system for high-tech medical devices (e.g., medical devices using artificial intelligence (AI)) without the need for obtaining authorization from the regulator, Ministry of Health, Labour and Welfare (MHLW) for individual improvements (effective Sept. 1, 2020);
4. Establishment of an MHLW official committee for the evaluation and monitoring of health care products (effective Sept. 1, 2020);
5. Relaxation of statutory restrictions on blood drawing (effective Sept. 1, 2020);
6. Introduction of a notification procedure for a change in manufacturing methods pursuant to a post-approval change-management protocol (effective Aug. 1, 2021);
7. Provision of electronic package inserts (effective Aug. 1, 2021);
8. Obligation for marketing authorization holder (those engaged in the manufacture, sale, and distribution of pharmaceuticals, medical devices, cosmetics, etc.) to establish a legal compliance system (effective Aug. 1, 2021);
9. Introduction of new penalties for false or misleading advertising (effective Aug. 1, 2021);
10. Bar code display on pharmaceutical product packaging (effective Dec. 1, 2022).

The Revised Act incorporates a substantial amount of changes. Here, we highlight No. 8 and No. 9 above, both of which portend a profound impact on the business practices of established pharmaceutical companies in Japan, as well as on companies building or contemplating a presence in the country.

Addressing the Emerging Need for a Robust Compliance Practice

While pharmaceutical company operations in Japan historically have had a relatively low legal risk, the landscape over the past decade has evolved toward increased regulatory scrutiny. The industry's self-governed approach continues in large part, but more proactive involvement of the regulator and enforcement agencies has become the norm.

Recent cases have led to higher demand for a stronger legal compliance system. For example, when an improvement order was issued to a major pharmaceutical company by MHLW in March 2017, it took a considerable period of time for the violation to be reported by the company itself, and the adverse event failed to be reported within the time limit. In addition, when a suspension order was issued to a pharmaceutical research institute in January 2016, the institute systematically hid the violation from the MHLW's inspection and failed to appropriately comply with MHLW's reporting order, even submitting false records to the on-site investigation.

Given these cases, Japanese regulators have serious concerns about pharmaceutical and medical device companies and their officers having a low awareness of and/or low investment in a legal compliance system. Some specific types of violations include those in which the officers (i) are aware of the illegal situation but fail to improve it and continue to engage in the illegal activities without due consideration, and (ii) are unable to prevent, detect, or improve the illegal activities due to the lack of an appropriate business operation system or management and supervision system.

Under the Revised Act, the marketing authorization holder must take the following measures:

- Specify the authority held by marketing directors of pharmaceutical companies, etc.;
- Establish a necessary compliance system to ensure the appropriateness of the operations of the marketing authorization holder;
- Comply with the Good Quality Practice Ordinance.

On Jan. 29, 2021, MHLW further stipulated the "Guideline for Compliance with Laws and Regulations by Manufacturers and Distributors" (link in Japanese).

Under the Guideline, the marketing authorization holder is advised to establish the system

- Formulating the proper standards to be observed by officers and employees;
- Providing education, training, and regular evaluation of officers and employees;
- Preparing, managing, and storing business records;
- Building a supervision system for the work of officers and employees.

The Revised Act sets the responsibility for establishment of the compliance system not only on the Representative Directors but also on the so-called Responsible Officers. Responsible Officers for operations related to pharmaceutical affairs under the Revised Act are in a position to assume responsibility for compliance with laws and regulations, and for the establishment and operation of a

compliance system. Responsible Officers are assumed to be directors under the Companies Act (in the case of a membership company such as limited liability company (GK or *Godo Kaisha*), Responsible Officers are assumed to be members (*shain*)). An individual officer whose responsibility includes pharmaceutical affairs will be a Responsible Officer by statutory definition, regardless of whether such officer lives overseas or domestically.

The Revised Act does not necessarily require the creation of new internal regulations or the establishment of a new business supervision system. However, it will be important to assess whether or not the existing system is sufficient to ensure compliance with laws and regulations related to pharmaceutical affairs; and if not, the companies will consider how to improve. In general, a supervision system is required to be developed, and its development should take into account the size of the business, the nature of the business, and the risk of violation. For a company that recently has built up its presence or has operated its business in Japan for only for few years, it is possible to utilize the internal audit function of a foreign affiliate, so long as it is effective.

The establishment of the above measures in accordance with the Revised Act and guidelines is crucial not merely for meeting the requirements of the Revised Act but also for preventing future violations of the law.

In addition, as a general trend, MHLW has become focused on compliance issues in pharmaceutical industries and strongly encourages pharmaceutical companies to establish and maintain a robust compliance system, including appointment of the Responsible Officer, as discussed above. Once a business in Japan is expanding after local marketing authorization has been granted, the responsible compliance officer in Japan will be considered acceptable only if such individual can successfully raise his or her opinion to the company's leadership in Japan, and can be empowered with proper resources to attend to the local compliance issues in a timely and proper fashion. In some cases, regulators reach out to companies for direct communication with the responsible compliance personnel and expect to have an in-person meeting with such personnel to resolve any compliance concerns. Companies should consider appointing full-time compliance employee in the Japanese business organization once the company starts to launch its product in Japan.

New Surcharge for False or Exaggerated Advertising

Introduction of the surcharge system aims to ensure the effectiveness of the current false and exaggerated advertising regulations given many cases of violation in recent years. For example, charges of falsification of data in clinical research data concerning the effects of a drug for hypertension has led the regulator to believe the existing law does not create a desired level of deterrence.

In Japan, administrative penalties for false and exaggerated pharmaceutical advertising include revocation of licenses and orders to suspend operations, or criminal penalties (i.e., fines). However, such penalties have not had a sufficient deterrent effect, especially when considering the potentially large profits of a violator company or a product distributor operating without the proper license or marketing authorization.

- The surcharge covers false or exaggerated advertising (including internet marketing) regarding the name, manufacturing method, efficacy, effectiveness or performance of drugs, medical devices, etc. In principle, the surcharge amount is 4.5% of the total sale amount of the subject product during the violation period. However, the new system introduces several new features.

- The surcharge may overlap with the surcharge under the Act against Unjustifiable Premiums and Misleading Representations ("Act against UPMR"). If there is a surcharge payment imposed under the Act against UPMR for the same case, the surcharge amount rate will be reduced from 4.5% to 1.5%.
- The amount of the surcharge can be reduced if a violator voluntarily reports the violation, and the surcharge amount can be reduced by 50%.
- There will be exemptions when (a) five years have passed since the company ceased its false or misleading advertising or (b) the total product sale amount of the violator's whole product portfolio is less than JPY 50 million.

Proactive Compliance Practice After Starting a Business in Japan

The Revised Act shows the regulator's intention to adopt a step-by-step approach to enforcement, so that companies have sufficient time to meet the desired level of the compliance in accordance with new mandates. Established companies may consider taking advantage of this opportunity to assess their current practice's readiness to meet the regulator expectations. At the same time, companies entering the Japanese market or developing products should consider developing a roadmap for its investment in legal and compliance infrastructure, including policies, procedures, a local compliance team in Japan in line with all requirements stipulated in the Revised Act and applicable guidelines.

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