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The Health Pod

Japan Pharmaceuticals Market - Regulatory Landscape Episode Guide

This episode outlines the primary distinguishing features of the regulatory landscape of the Japanese pharmaceutical industry, including the regulatory license framework, high level implications of licenses in M&A transactions and other regulatory topics concerning the pharmaceuticals market.

1. Pharmaceuticals and Medical Devices Act (PMD Act)

- The primary law aimed at securing the quality, efficacy and safety of pharmaceuticals and medical devices in Japan. In addition to products, the PMD Act also regulates PMD manufacturers and distributors of pharmaceuticals and medical devices (PMD).

2. Regulatory Bodies

- The Ministry of Health, Labour and Welfare (MHLW) is the governmental regulatory authority which has the authority to issue licenses relating to the manufacture and onward commercialization of PMD products and to instruct and supervise PMD companies to secure product safety.
- The Pharmaceuticals and Medical Devices Agency (PMDA) is the regulatory agency working together with the MHLW to protect public health by assuring safety, efficacy and quality of PMD products. It conducts scientific reviews of marketing authorization applications for PMD products and monitors their post-marketing safety. The PMDA is also responsible for providing compensation for patients suffering from adverse drug reactions and infections caused by pharmaceutical or biological products.

3. Regulatory Frameworks

- A unique feature of Japan's PMD regulatory landscape is the requirement of two separate license frameworks. In order to sell PMD products, the seller first needs to undergo a review that determines whether it has established a system for selling PMD and obtain a license for selling such products. Product efficacy and safety is reviewed separately.

4. PMD Licensing

- There are three major license categories for companies handling PMD products in Japan.
- A Marketing Authorization License must be obtained to sell pharmaceutical products in the Japanese market. This applies to both locally manufactured and imported products, and those manufactured directly, or via third party manufacturers. The marketing authorization holder is responsible for implementing quality control and post-marketing safety control.
- A Manufacturing License allows a company to manufacture a PMD product.
- A Sales License is required to sell the product.

5. Drug Approval

- Marketing authorization is granted for each product after a review of data related to the results of nonclinical and clinical studies, ingredients and quantities, dosage and administration, indications, adverse reactions, etc. of the proposed product.
- Product approval has historically been a long process in Japan, however in recent years the MHLW has been working to shorten the process. Drug authorizations are currently granted in approximately one year from receipt of application.
- Further, the MHLW has introduced an expedited process for especially important and innovative drugs comprising three separate systems.
- The **Special Approval System** for products required to prevent the spread of diseases that may seriously affect public health, such as COVID-19. They are intended to be used in limited circumstances in which there are no other appropriate treatment methods and in cases where the product has been approved for use in certain foreign countries.
- The **Preliminary Examination and Designation System** shortens the approval review process leading to commercialization (from 12 months to six months), for innovative pharmaceutical products, medical devices and regenerative medicine developed in Japan and identified as expected to have remarkable efficacy based on the results obtained in early-stage clinical studies.
- The **Conditional Approval System** expedites the approval process for products that treat certain serious illnesses with limited effective treatment options and for products for which it is difficult to conduct clinical trials due to the limited number of patients.

6. **Regulation of Clinical Trials**
   - Clinical trials are conducted to collect the study results required for the application for marketing authorization of pharmaceutical products.
7. **Ongoing Regulation of Approved PMD Products**
   - There are three systems for maintaining and investigating the safety of pharmaceutical products once they are available in the market:
   - The **Adverse Reaction/Infectious Disease Reporting System** is employed when serious adverse reactions or infections occur.
   - The **Re-examination System** is used on new pharmaceutical products once a certain period of time has elapsed since marketing authorization was obtained.
   - The **Re-evaluation System** evaluates whether existing pharmaceutical products available in the market for long periods remain effective in light of current science and technology.
8. **Regulatory Considerations for International Investors in Japanese PMD market**
   - The Foreign Exchange and Foreign Trade Act requires a foreign investor acquiring a stake in a Japanese pharma company to notify in advance as an inward direct investment if that target company manufactures biological products.
   - In the pharmaceutical industry, the manufacturing of pharmaceuticals, pharmaceutical intermediates, and highly controlled medical devices such as artificial respirators for pathogenic organisms are classified as belonging to the core industry and are subject to stricter requirements for exemption.
9. **Considerations on Licensing and Marketing Authorizations During Restructuring or in an M&A Context**
   - With increasing costs in R&D, many pharmaceutical companies are actively engaging in global reorganization and M&A activities in order to expand their scale.
   - One must consider whether or not such activities will result in changes to the organization of a targeted company. When no organizational change occurs, such in the case of a share transfer, changes are not required to the licenses held by a marketing authorization holder. When there is a change in the organization of the target company, as in the case of a merger, company split (demerger), or a business transfer, licenses held by a marketing authorization holder cannot be succeeded.
   - The licenses held by the disappearing company in a merger or the splitting company in a company split may need to be re-obtained if the surviving company or the succeeding company does not hold the requisite licenses.
   - On the other hand, for marketing authorizations, a company that continues to exist after the merger, a company established after the merger, or a company that has succeeded the data related to the pharmaceutical product succeeds the status of the marketing authorization holder for that pharmaceutical product. Likewise, in the case of a business transfer, the company that succeeded the materials and data related to a pharmaceutical product succeeds the status of the marketing authorization holder for that pharmaceutical product.

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