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Japan Pharmaceuticals Market – Compliance Episode Guide

Overview of compliance issues in Japan

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Compliance is a key factor in running a sustainable business in the pharmaceutical industry in Japan. Pharmaceutical companies are subject to strict regulations and compliance with laws and regulations is indispensable to ensure the safety of patients. However, historically there have been some material violations of laws by pharmaceutical companies and accordingly, Japanese regulatory bodies have been focused on monitoring compliance issues in this industry.

1. Requirements for compliance system
   - The Pharmaceuticals and Medical Devices Act ("PMD Act") provides strict rules concerning the supply of drugs in Japan, which includes, for example, rules which require companies to manufacture drugs strictly pursuant to the approved method and safety reporting requirements. However, material violations have occurred in the past and the regulatory authorities strongly require all pharmaceutical companies to establish a comprehensive and robust compliance system.
   - On August 1, 2021, the PMD Act was amended to require pharmaceutical companies to have a robust compliance system which prevents the violation of relevant laws and regulations.
   - MHLW issued a Compliance Guidance which provides specific guidelines for pharmaceutical companies to establish an adequate compliance program. This guideline is the first official guideline published by the authority in this area and is aimed at facilitating compliance by pharmaceutical companies.
2. Drug promotion
   - Drug promotion is one of the key compliance issues which any pharmaceutical company doing business in Japan should be aware of. Material violations have occurred in connection with drug promotion, including cases where pharmaceutical companies carried out problematic promotion based on false or misleading information.
   - Any misleading or false drug promotion is prohibited by the PMD Act. To prevent any violations, pharmaceutical companies are required to have a robust governance system in compliance with the MHLW's guidelines. Amongst others, the guidelines allows pharmaceutical companies to provide off-label information only upon unsolicited request from HCPs.
3. Anti-corruption
   - Pharmaceutical companies interact with HCPs and healthcare institutions in various circumstances and close attention should be paid to anti-corruption issues.
   - Interaction with public HCPs may give rise to bribery issues, which result in criminal liabilities and extraterritorial enforcement (FCPA and UK Bribery Act etc.). Further, irrespective of whether the HCP is a public official, pharmaceutical companies are generally prohibited from providing any benefits to HCPs or hospitals as a means of unjustifiably inducing drug sales. Companies should comply with detailed industry codes, which provides rules concerning interaction with HCPs.
   - Donations, fee-for-services arrangements and business courtesy practices (e.g. meals) in particular are considered as high risk areas.

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