Tackle Social Challenges

Drug Loss

Japan does not have access to certain drugs used in other countries. How can we make these drugs available in Japan?

Eri Sekine

Executive Vice President　CMIC Co., Ltd.

The terms "drug loss/lag" refers to drugs that are developed outside of Japan not being approved in Japan. However, CMIC Group's unique Pharmaceutical Value Creator (PVC) business model, which fully supports the value chain of pharmaceutical companies, helps address these social issues and assists the entry of foreign pharmaceutical companies and biotech companies into the Japanese market. Executive Vice President Eri Sekine talks about our past, present, and future initiatives.

Japan, a country renowned for its high standard of medical care, experiences drug loss and drug lag which greatly impacts patients with rare diseases and pediatric patients.

Medical care in Japan is among the best in the world because its health insurance system enables patients to receive treatments with the latest medical equipment. However, can they truly receive the newest treatments? The answer is yes and, in some cases, no. This is because of drug loss and drug lag, a situation that Japan faces where drugs approved overseas are either not approved in Japan or to be approved much later than other regions. Data released in 2023 by the Ministry of Health, Labour and Welfare (MHLW) showed that 143 drugs had not been approved in Japan. Of those, only 57 were in the process of being developed, including undergoing clinical trials, for use in Japan. Of the other 86 drugs, 40 were for treating rare diseases and 32 for pediatric patients. This shows the great impact that drug loss and drug lag have on patients with rare diseases and sick children. Regulatory authorities, including the MHLW, are carefully examining the situation, which in recent years has come to be publicly recognized as a social issue.

◆Facts About Drug Lag / Loss

The Current Situation of Drug Lag / Loss in Japan, Europe, and the U.S.

	Approved	Total Number of Unapproved Drugs	The Number of Unapproved Drugs	
			Under Development	**Development not yet started**
U.S.	136	7	3	4
Europe	86	57	26	31
Japan	0	**143**	57	**86** (Drugs)

Breakdown →

A Breakdown of Drugs Not Under Development in Japan

Drugs for Children	**Drugs for Rare Diseases (Orphans)**	**Drugs Developed by Biotech**
32 Drugs (37%)	**40** Drugs (47%)	**48** Drugs (56%)

※Note: Of the 86 drugs that were not approved, 14 (16%) were not for pediatric patients, orphan drugs, or drugs developed by startups.

Source: MHLW's website: "The Report by the Expert Panel on Comprehensive Measures to Achieve a Rapid and Stable Supply of Pharmaceuticals", translated by CMIC.

Supporting foreign pharmaceutical and biotech companies in their early entry into the Japanese market and facilitating the approval of drugs that are needed in Japan.

The pharmaceutical market in Japan, the third largest after the U.S. and China, is attractive, and it welcomes innovative drugs. New drugs are listed on the NHI price listing in Japan just 60 days after approval, and the universal healthcare system enables patients to receive expensive care if necessary, at an affordable cost. However, many foreign biotech are not familiar with the Japanese market, nor are they well-informed about the recent improvements to clinical trials in Japan. Also, biotech often have limited resources, making development in Japan a lower priority. CMIC Group offers seamless solutions covering the entire process, from drug discovery, non-clinical and clinical study, and New Drug Application filing to manufacturing, marketing and distribution, and post-marketing services. We provide extensive support not only to major pharmaceutical companies but also to biotech that want to enter the Japanese market. For companies that do not have an affiliate in Japan, we can serve as an In-Country Clinical Caretaker (ICCC) to conduct clinical trials in Japan. Furthermore, we assist our clients in creating business and development strategies that are focused on obtaining approval for the manufacture and distribution of drugs, including consultations with the Pharmaceuticals and Medical Devices Agency (PMDA). This helps them rapidly recover their investments. By improving quality and speed and reducing costs, we have created an eco-system for clinical trials that enables drugs to be delivered quickly to the patients in Japan who need them.

Together with our stakeholders, we are committed to sharing information and promoting communications to accelerate global drug development.

Since simultaneous global development and approval is the ideal way to market a new drug in multiple major markets, Japan would greatly benefit by playing a part in from the early stages of global drug development. CMIC takes pride in its extensive knowledge and experience in global drug development and its close relationships with key opinion leaders in various disease areas. We are also dedicated to establishing an environment where the safety and efficacy of drugs can be easily assessed through digital transformation and the effective utilization of existing data. Furthermore, we hold seminars and sessions at academic meetings and conferences to share information with foreign pharmaceutical companies and biotech about the state of clinical development in Japan and the attractions of the Japanese market. At the DIA Global Meeting held in San Diego in the U.S. in June 2024, we invited speakers from both Japanese and foreign pharmaceutical companies to discuss about “Global Development Strategies: For the patients around the world, including Japan, to have speedy access to innovative drugs.” The session focused on how to advance developments not just in the U.S. but also in multiple regions countries. We also share information at conferences inside and outside Japan as well as in webinars.

Together with our stakeholders, CMIC Group will continue to solve social issues through promoting information sharing and communication.

At a session from “DIA Global Annual Meeting 2024”