

Past JETRO Client

Shire Poised to Capture Opportunities in the Japanese Pharmaceutical Market

Shire's Japan office playing a key role in taking advantage of regulatory changes and the government network

Shire plc (Shire), a biopharmaceutical company with corporate headquarters in Ireland, has been providing treatments in Neuroscience, Rare Diseases, Gastrointestinal, Internal Medicine, and Regenerative Medicine since its founding in 1986. True to their brand message, “To be as brave as the people we help”, the company has served patients with extremely rare and life threatening diseases in over fifty countries. Shire now has businesses in 29 countries including Europe, South America, North America, and Asia.



In 2008, Shire decided to open its representative office in Japan. In 2012, the company incorporated in Japan, and in February 2013, opened its new office in Shinjuku, Tokyo, welcoming Steve Engen as Vice President and Representative Director. In Japan, four of Shire's products are currently licensed and sold through its corporate partners: Replagal® for Fabry disease, Elaprase® for Hunter syndrome, Fosrenol® for end-stage renal disease, and Reminyl® for Alzheimer disease.

In September 2013, Mr. Engen shared his observations of the Japanese market with JETRO, expressing his opinions of how recent trends in the Japanese biopharmaceutical industry could benefit Shire's business.

Benefit 1. Improving Clinical Development Environment

Mr. Engen sees positive signs in the Japanese pharmaceutical industry even with the recent economic downturn. This is due to Japan's ever changing clinical and regulatory environment. He mentioned that compared to 5-10 years ago, drug development, or the regulatory pathway, has become more efficient in Japan. In the past, many drug makers worked to get their products approved in Japan through studies intended as a “bridge” to western data, a process that is complex and difficult to successfully execute. Companies are now able (and encouraged) to include Japan in a global study, a clinical trial conducted under the same protocol in a number of countries. This results in an increased probability for a drug to be approved simultaneously in all regions, including Japan, thereby significantly reducing cost and time to market.

Benefit 2. Improving Reimbursement System

A notable advantage in Japan is that drugs that are approved will be included on the national reimbursement list within three months of approval. The Japanese government serves as one single payer, significantly more streamlined than the complicated processes that companies need to go through in other countries. In Europe, for example, reimbursement and pricing have to be navigated in a complex web of different governments and countries. In the U.S., reimbursement is managed by a multitude of privately-owned healthcare insurance providers.

In addition, the Japanese government started a pilot program in 2010 incentivizing creation of innovative new drugs and promotion of unapproved drug development. Previously, prices of newly approved drugs in Japan were typically reduced every two years based on a review of actual market prices. Under the pilot program, new drugs can continue to maintain their original price if certain conditions are met. In addition, drugs with orphan drug designation in Japan receive a market exclusivity period of ten years. Such programs incentivize innovation of new drugs by allowing pharmaceutical companies to more quickly recapture clinical development costs.

Shire believes that recent changes made to the Japanese reimbursement system provide a sense of security that helps biopharmaceutical companies make the decision to invest in developing treatments in Japan to address unmet needs.

Benefit 3. M&A Opportunities

Shire is one of the fastest growing pharmaceutical companies. The company has achieved much of this growth through a number of strategic acquisitions made over the past 20 years. The year 2013 has been no exception, as Shire has already acquired three companies. These acquisitions will allow Shire to broaden their pipeline of drugs while also accelerating industry innovation.

After joining Shire, Mr. Engen gained a higher appreciation of the breadth of the pipeline and the innovation cycle that the Shire acquisition model would bring. He is confident that based on Shire's successful track record, an increasing number of emerging biopharmaceutical companies both inside and outside Japan will contact Shire to discuss acquisition opportunities.

Benefit 4. Staying in Japan is Essential to Building Relationships with Government Groups

Having a local presence in Japan is essential for building a network with key players and stakeholders involved in healthcare.

In Japan, each pharmaceutical company must maintain strong relationships with two groups: the Pharmaceuticals and the Medical Devices Agency (PMDA) and the Ministry of Health, Labour and Welfare (MHLW). Having effective interactions with the PMDA is critical for a pharmaceutical company in Japan, as the PMDA oversees clinical trial consultations as well as the product approval process. Shire Japan has dedicated specialists to interact with the PMDA to ensure the company appropriately presents clinical and safety data of Shire Japan's drugs.

From a policy standpoint, it is critical for pharmaceutical companies to be part of pricing discussions among the MHLW, patient groups and industry associations such as the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the Japan Pharmaceutical Manufacturers Association (JPMA). An example of the importance of being connected to such organizations is how Shire's local Japanese office is preparing to proactively participate in future policy discussions concerning the impact of Japan's aging society on future market access of new innovative drugs.

Strategies Ahead: Commercialize Well and Quickly Develop Pipeline

Mr. Engen described Shire Japan's business as being built on "three pillars". The first pillar comprises the long-standing partnerships Shire has with local companies in Japan who distribute and promote four of Shire's products. The second pillar represents a collaboration with Shionogi & Co., Ltd. to co-develop and jointly promote in Japan two of Shire's drugs for Attention-Deficit Hyperactivity Disorder (ADHD). Finally, the third pillar represents the key strategy for Shire moving forward: establishing its own commercial presence to directly commercialize Shire's new products in the Japanese market. For Shire, establishing and executing the most effective commercial operation is vital for success in Japan.

In parallel, another important mission for Shire is to quickly develop its pipeline in Japan. Mr. Engen stated, "One of my goals is making sure we include Japan in global studies of our new pipeline products so that such new products can be launched in Japan and the West simultaneously." He continued, "If you are not here (in Japan), it's very difficult to do that."

Demystify Japan

Opportunities in the Japanese pharmaceutical market sound very promising. Yet many foreign companies do not know how to enter the Japanese market. Japan still remains far from Western countries and is filled with mysteries. The country is perceived as an expensive place to do business; corporate tax rates are high, clinical trials are costly, and labor is expensive. The language barrier and differences in business culture may make it hard to fully understand each other. Mr. Engen emphasized

that establishing business in Japan is still possible if a company has knowledge and support. “JETRO’s role would be to ‘demystify Japan’ and assist entry of foreign companies,” he said.

That is what JETRO was able to offer to Shire. Back in 2011, JETRO met with Shire USA, one of Shire’s major operation sites, and since then JETRO has provided consultations, office registration information and information about Japanese industry organizations. JETRO also introduced Shire to the MHLW, the key Japanese government organization in the industry.



Steve Engen, Vice President and Representative Director, Shire Japan

Mr. Engen made one more unique point to be successful in Japan. He suggests bringing in someone who is multi-cultural to lead a new organization will help companies establish a Japan presence more quickly and effectively. Especially in the earlier stage when communication between Japan and headquarters is critical, someone like Mr. Engen who understands relevant markets and cultures can be a powerful asset to the company’s smooth launch.

Asia represents a strategically important area for Shire. The Japanese pharmaceutical market is large, and the business environment surrounding highly innovative drugs, including orphan drugs, provides opportunities for companies like Shire. Mr. Engen is fully confident of Shire’s future success because of its team of specialists, and their extensive knowledge and experience in the key therapeutic areas where Shire will build its presence in Japan.

Japan Company Profile

Japan Company:	Shire Japan, K.K.
Established:	2012
Employees:	18
Business:	Treatments in Neuroscience, Rare Diseases, Gastrointestinal, Internal Medicine, and Regenerative Medecine.
Location:	Shinjuku-ku, Tokyo, Japan
URL:	www.shire.co.jp
Headquarters:	Shire Plc (Ireland/www.shire.com)

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