ACCESSING THE JAPANESE GENERIC PHARMACEUTICAL MARKET

CHALLENGES, STRATEGIES, AND TOOLS FOR COMPANIES ENTERING THE JAPANESE GENERIC PHARMACEUTICAL MARKET

SITUATION

The Japanese government has identified growth of the nation’s generic drug market as imperative to Japan’s long-term economic health. Japan has one of the most acute needs to reduce the drug spend component of its growing healthcare costs, and unlike its G8 peers falls far short of the successes that other countries have had in using generic drugs as a tool to accomplish this strategic goal.

As a result, the growth and development of the Japanese generic market and the companies that make up the industry also lag well behind that of peer countries. In 2012, the U.S. generic market was worth $87 billion in sales, with each of the top five U.S. generic companies generating more than $3 billion in revenue.

By contrast, the Japanese generic market rose to just U.S. $10.6 billion in value, and although many top Japanese generic companies saw their revenue increase from previous years, none have seen over U.S. $1 billion in sales.

Source: IMS & Japan Generic Medicine Association
Note: change in calculation method in 2012

The Japanese government, recognizing the country’s growing, aging population as well as rising costs of branded medicines, has begun instituting healthcare policy changes to cut their expenditures on medical costs. Substitution of low-cost generic drugs for innovator products has been identified as a strategy where major savings are possible. In April 2013, the Japanese government introduced an initiative for increasing generic usage that aims to increase generic share by volume to over 60 percent by the end of FY2017 (March 2018). To help achieve this goal, the Japanese government has revised its drug pricing scheme effective April 2014. The new scheme proposes to lower generic starting prices to 50 percent of the current price of the innovator drug, and also proposes a tiered, biennial price reduction for long-listed innovator products which are currently seeing less than 60 percent generic substitution. This brings a particular set of challenges and opportunities for established domestic players, as well as foreign companies looking to expand into Japan.

Active pharmaceutical ingredient (API) and generic finished dose suppliers who recognize this growth potential and understand the specific needs and challenges unique to the Japanese market stand to see significant earnings in this region over the coming years.

CHALLENGE

Previous government initiatives with the goal of increasing generic substitution have resulted in only modest success due to a long-standing Japanese cultural skepticism of generic medicines. The mistrust of generics by the older generation of Japanese physicians, pharmacists and patients stems not only from a cultural preference for familiar, local products but also from concerns that generic medicines may not undergo the same efficacy and safety tests as innovator products.

Additionally, the reliability and stability of generic supplies has been an issue in Japan as manufacturers frequently withdraw older products from the market in response to reduced sales and lower reimbursement fees. With half of the active ingredients found in drugs on the Japanese market of domestic origin, there is also a strong incentive for manufacturers to seek lower cost sources from overseas without sacrificing the quality or reliability of supplies.

Companies supplying generic medicines to the Japanese market need access to high-quality, low cost APIs from reliable, reputable sources.

Government policy initiatives have prioritized education and incentivization for physicians and pharmacists dispensing generic medications, and a new generation of consumers understands that generic medicines are equivalent to innovator products. Generic companies operating in Japan have had to approach their businesses in ways that are different from U.S. or European companies.

Pharmaceutical companies in the business of producing generics know their strategy must directly address market challenges.
The Japanese pharmaceutical market is the second largest in the world, and the government is taking every step necessary to assure that the percentage of that market represented by generics more than doubles over the next half-decade. The company that makes informed decisions about the product portfolio they bring to this market can not only ride this wave of growth, but position themselves as a trusted face of generic medicine for Japan’s next generation. In order to successfully execute this distinctly different mission, how have generic manufacturers incorporated high-quality, timely generics intelligence in their business to solve some of these needs?

**QUESTION**

The Japanese pharmaceutical market is the second largest in the world, and the government is taking every step necessary to assure that the percentage of that market represented by generics more than doubles over the next half-decade. The company that makes informed decisions about the product portfolio they bring to this market can not only ride this wave of growth, but position themselves as a trusted face of generic medicine for Japan’s next generation. In order to successfully execute this distinctly different mission, how have generic manufacturers incorporated high-quality, timely generics intelligence in their business to solve some of these needs?

**CASE EXAMPLE**

A top three Japanese generic manufacturer, acutely aware of these market pressures, has successfully deployed Thomson Reuters Newport to address many of these challenges, and has continued to enjoy significant revenue growth.

Unique to the Newport solution and of critical importance to the company was the combination of worldwide industry content from patents and pricing to regulatory filings and chemical synthesis, with the availability of active ingredient manufacturing intelligence. This delivers three significant benefits to their business, enabling them to:

- Accurately and reliability target new product launch opportunities long into the future
- Secure those launches by locating early, potentially exclusive sources of supply
- Find cheaper sources of supply to lower costs without sacrificing product quality, for its older portfolio of products

The company has also integrated Newport into other important business processes, using the solution to monitor competitive threats, identify and analyze potential new business partners or acquisitions of interest, and assess its opportunities to open new markets outside of Japan.

**MANUFACTURING LOCATION OF GENERIC APIs (share in value)**

**Source:** Mitsubishi UFJ Research and Consulting (2013)