

Sawai Pharmaceutical Co. Ltd.

Playing a bellwether role in the generic drug industry in Japan

www.sawai.co.jp

Sawai Pharmaceutical Co. Ltd. 2-30 Miyahara 5-chome Yodogawa-ku, Osaka 532-0003 JAPAN	Founded in No. of employees State of Ownership Primary stock exchange	1948 834 Public TSE:4555
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June 2010: Sawai Pharmaceutical, the successor to Sawai Pharmacy founded in 1929, was incorporated in 1948. When the universal health insurance program was implemented in 1961 in Japan, the company changed its main business from OTC (Over The Counter) drug to prescription pharmaceutical manufacturer. Japan's generic drug industry has been encouraged by the government measures. Sawai is a leader in this industry. Venture Valuation (VV) interviewed Mr. Juichi Riku, Director, Research and Development Division, and Chair of the International Affairs Committee at the Japan Generic Medicines Association (JGA)¹.



VV: **Would you please describe your business?**

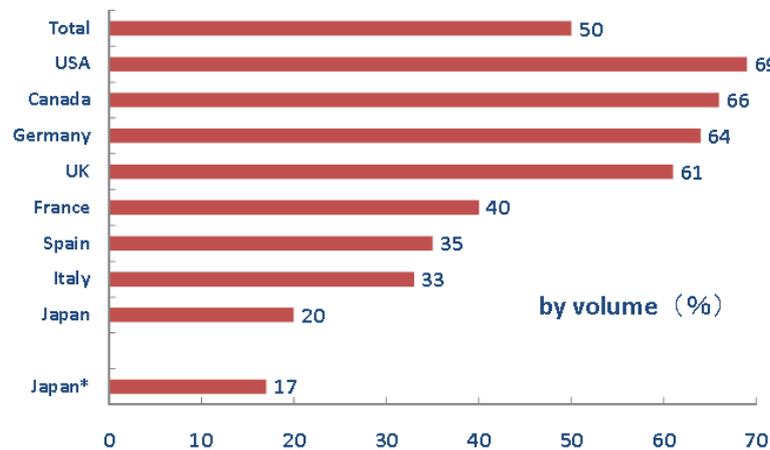
Riku: Sawai Pharmaceutical is a major generic drug company in Japan and preeminent in drug development capacity. Last year we had 63 new products including new strengths approved, the biggest number in the industry. In total we are marketing more than 500 generic products. We invest 8% of sales in research and development, the highest ratio among our major domestic competitors such as Nichi-Iko, Towa, and Taiyo. For the fiscal year ended March 31st 2010, our sales were 50 billion JPY (approx. 549 million USD).

At present we are focusing only on the domestic market where growth is expected at an average annual rate of 8%. It is commonly said that Japan's generic drug industry is 25 years behind the U.S. Generics represent 20% by volume of the total pharmaceuticals market. That is significantly lower than other industrialized countries, for instance, 69% in the U.S., 66% in Canada, 64% in Germany, 61% in the U.K. (see the chart in next page).

As the population is aging, healthcare costs are increasing year after year. By encouraging the use of generic drugs which are cheaper than branded medicines, the Japanese government initiated a plan to increase the use of generic drugs to 30% of the pharmaceuticals market by the fiscal year ended March 31st 2013. In this circumstance, we have a great opportunity to further develop our business.

¹ JGA, established in 1968, is composed of 44 member companies. The current president is Sawai's Chairman.

Generic Share (2008)



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Source: IMS Health MIDAS Market Segmentation, Rx only, Dec 2008. Based on ex-factory

Japan※ : Japan Generic Medicines Association FY 2007

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VV: What are your strengths?

Riku: First of all, our strong drug development capacity is a major asset. We continue to offer a broader line up of high quality and value-added drugs than the competitors.

Second, we leverage a wide range of distribution channels with nationwide wholesalers and local sales agencies. They are well connected with dispensing pharmacies² and hospitals³, particularly those implementing DPC (Diagnosis Procedure Combination)⁴ system. Since the government's measures are targeted on DPC hospitals and dispensing pharmacies, these two segments are prime generators of market growth.

DPC system is open to large and well established hospitals. At present, there are 1,283 DPC hospitals out of all 9,000 hospitals with their bed number accounting for around as many as 50% of the total beds. We expect that the number of DPC hospitals will increase yearly.

Our customer service is another strength. 24-hour service and timely delivery gain trust and credibility with customers. Our well trained MRs (Medical Representative) are aware of the customers' concerns and

² In Japan there are also pharmacies that do not handle prescriptions.

³ According to the statistics published by the Japan Pharmaceutical Association, the pharmacies dispense around 60% of the total prescriptions in August 2009. "After World War II, the Pharmaceutical Affairs Law and other related laws (the so-called *bungyo* law concerning separation of dispensing from medical practice) was promulgated in 1954 and brought into force in 1956. However, this law also failed to popularize *bungyo* because the Medical Law included a provision that physician is allowed to dispense drugs of the patient he/she diagnosed, and patients were accustomed to receiving drugs from physicians." (The 2008-2009 Annual Report of the Japan Pharmaceutical Association)

⁴ DPC is a Japanese version of diagnosis-related group started in April 2003. It consists of the flat-sum reimbursement system based on daily rate and the fee-for-service reimbursement for such as surgery, anesthesia and some tests and treatments. Hospitals without DPC system provide only fee-for-service payment system. This means the more treatment they provide, the more costly healthcare is.



questions about the use of generic drugs. Contrary to Europe and the U.S. where MR does not exist in the generic drug market, they are playing a significant customer service role in Japan since physicians and pharmacists still rely on them in various ways.

VV: What are your current objectives?

Riku: We have to think seriously about how to develop our biosimilar products⁵ business. Global generic drug companies such as Teva, Sandoz, and Hospira are already providing some biosimilar products in Europe. The market for biosimilars will grow significantly in 5 to 10 years. We think that it would be inevitable to seek ways of M&A or business alliance opportunities with Japanese and/or non-Japanese companies in the future.

VV: What opportunities are you exploring in the market?

Riku: The Japanese government's efforts to promote the use of generic products create a great opportunity to begin reshaping the healthcare system. We are trying to keep medical professionals, particularly dispensing pharmacies, informed about generic products. They have been concerned about quality, efficacy, stable supply and provision of information on generic products. According to the Ministry of Health, Labor and Welfare survey in September 2009, 68.5% of the total prescriptions showed "Substitutable with generics". Of 68.5%, only in 5.5% were generic drugs actually dispensed by pharmacists. In total, the percentage of prescriptions that included generic dispensing actually ended up a mere 3.8% (68.5% x 5.5%).

On April 1st this year the government's new generic incentive plan started with the purpose of rewarding dispensing pharmacies, under which they are conferred 60 JPY (approx. 0.66 USD) each prescription for over 20%, 130 JPY (approx. 1.43 USD) for over 25% and 170 JPY (approx. 1.87 USD) for over 30% of total dispensing drugs by volume when they dispense generics. We are hoping that the new plan will improve the use of generics.

VV: How do you differentiate from your competitors and position your company?

Riku: We keep strengthening our customer base and product line to solidify our top position ahead of new comers.

The Japanese generic market is immature. It is attractive for global generic drug players, branded drug manufacturers, and even companies from different industries to enter the market. For instance, Israel's Teva Pharmaceutical Industries, the world's biggest manufacturer of generic drugs, will start sales via a joint venture. Daiichi Sankyo bought a large stake in Indian generics company Ranbaxy Laboratories. Fuji Film, a major Japanese film manufacturer, is entering the generic medicine industry.

We expect fierce competition. However, these new entrants require at least five years to build up a significant product line and to establish close relationships with pharmacists, physicians, and hospital administrators. Although foreign-affiliated companies are successful outside Japan, few

⁵ "Biosimilar or Follow-on Biologic refer to products that are marketed after expiration of patents, which are claimed to have similar properties to existing biologic products." (www.genentech.com)



medical doctors are familiar with their products. Branded drug manufacturers have realized that the generic drug business is very different from theirs. They generally establish a generic business subsidiary which also takes several years to be operational.

VV:

VV Comments after the interview:

Due to intense global competition, the market price of generic medicines abroad is said to be roughly one third as low as in Japan. Sawai's strategy to focus on the domestic market with high future growth potential is a competitive advantage in the current fluid environment.

The top four companies, Sawai, Nichi-Iko, Towa, Taiyo cover one third of the market amounted to 400 billion JPY (approx. 4.4 billion USD). Market observers predict that, in the future, merger and acquisition may be inevitable among domestic companies to consolidate the industry.

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