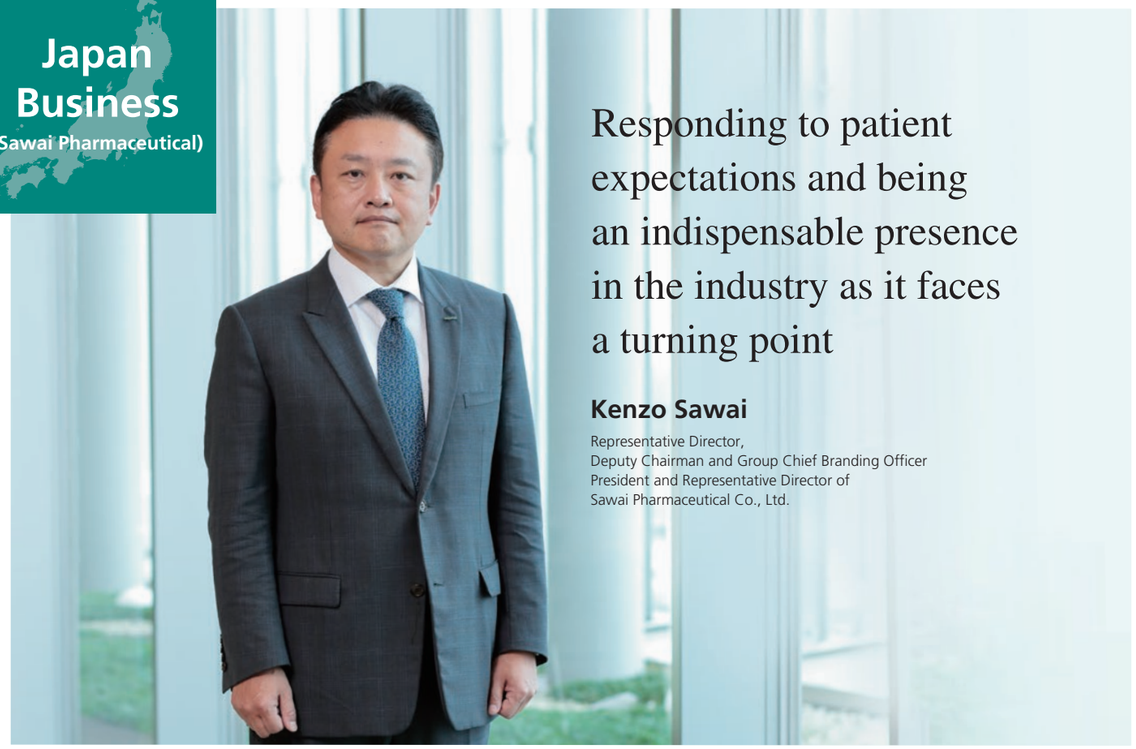
Japan Business (Sawai Pharmaceutical)



Responding to patient expectations and being an indispensable presence in the industry as it faces a turning point

Kenzo Sawai
Representative Director,
Deputy Chairman and Group Chief Branding Officer
President and Representative Director of
Sawai Pharmaceutical Co., Ltd.

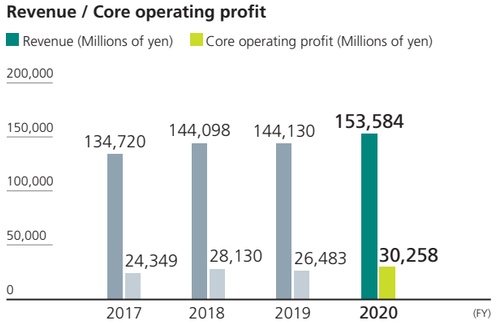
Through new products, we achieved profit targets; in fiscal 2021, will meet quality and supply expectations

The domestic generic drugs market in fiscal 2020 weathered impacts from two drug price revisions, in addition to reticence toward medical visits due to the COVID-19 pandemic. In June and December, we had successful market launches of new products either independently or with few competitors, which greatly contributed to sales and profit. As a result, although revenue of ¥153,584 million (up 6.6% YoY) fell below our target, operating profit reached ¥26,284 million (up 7.7% YoY) and met our target. This year of adversity was an occasion for me to recognize anew the capabilities of our employees and the importance of continuing to bring new products to market.

In fiscal 2021, I think that the most important challenge will be to meet patient expectations by stably supplying high-quality generic drugs and by eliminating market concerns sparked by quality issues with generic drugs. Since bolstering our supply capabilities is an urgent issue in order to meet these demands while growing our market share, we must immediately clarify the direction to take toward expanding our production framework.

For generic drugs, the drug volume share of the domestic pharmaceuticals market is approaching 80% and I expect growth of the overall share to slow going forward.

Revenue / Core operating profit



However, there is a definite number of new drugs every year from patent expirations and we see the market for these new drugs to be approximately ¥700-800 billion over the next three years as original drug patents expire. If we assume that 70-80% of that market will be replaced with generics, there is plenty of room left for growth for Sawai. At present, generic drugs are facing a headwind due to reliability issues; however, Sawai can meet the expectations of a great number of patients by winning even more trust in this environment.

Expanding sales through new products and dedicating ourselves to new product development and stable supply

This year, we formulated our new Medium-Term Business Plan START 2024, which lasts through fiscal 2023. One of the priority strategies of the plan is "expanding share in the Japanese generics market." Growing sales of new products is a key element of this strategy and we plan to launch 85 or more new products in the next three years.

Focus strategy 1 **Strengthen new product development**

Increase products with low competition / few competitors

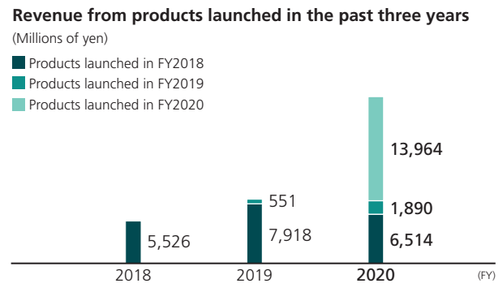
With generic drugs, the switchover to a new generic product happens quickly once the product is approved, after which it is quite difficult to challenge that product's market share. In other words, if we develop new products before our competitors, we can quickly gain market share and reap long-term sales. Consequently, being the first to market after the patent expiration of an originator drug leads to competitive superiority.

A recent trend for many pharmaceutical companies has been toward joint development of products, leading to simultaneous launches of generics, which fractionates market share. It is necessary for Sawai to grow our market share while, as much as possible, increasing the ratio of products with low competition, which can be achieved by bringing more challenging products to market and independently launching products ahead of other companies. In particular, considering the annual drug price revisions, it is essential to increase high value-added products in order to ensure stable operations.

In the last three years, we have actually launched 89 new products, which put our performance ahead of other companies in terms of the number of products and their unit sales volume. What has enabled such performance is our comprehensive strength from many years of accumulated expertise in the generics business. Sawai's R&D human resources are vastly ahead of other generic drug manufacturers and we have a wealth of professionals intimately familiar with surveys and analysis for protecting and leveraging intellectual property, as well as understanding the characteristics of active pharmaceutical ingredients and formulation technology. Thanks to this comprehensive strength, we are able to identify blind spots in patents and generate ideas for leveraging our intellectual property.

The conventional, and arguably passive, process of generic drug development has been to receive approval as

Revenue from products launched in the past three years



Numbers of products launched in the past three years and major products

Total number of released products: 89

	FY2018	FY2019	FY2020
Number of products*	33(3)	14(7)	42(9)
Major products released (generic name)	• Capecitabine • Oseltamivir	• Micafungin sodium (for IV infusion) • Tadalafil CI • Aprepitant	• Eldecalcitol • Bazedoxifene • Fexofenadine hydrochloride / Hydrochloride pseudoephedrine (Pusofeki combination tablets) • Repaglinide • Vardenafil

* Numbers in parentheses are for products that are the first generic drugs to market, or are strongly competitive.

New product launch plan for the next three years

Number of products to be released: over 85

	FY2021	FY2022	FY2023
Number of ingredients	13	11	14
Number of products	32	27	26
Original drug market (billions of yen)	250.7	288.0	274.4

Original drugs for first-listed Generic drugs Cymbalta capsule / Patanol ophthalmic solution / Samsca OD tablets / Nexium capsules / Azilva tablets

quickly as possible after a patent expires, but cleaving to this approach would likely make survival difficult going forward. We will take a stance toward patents that is more aggressive and challenging, and that other companies do not consider, such as ideas that avoid the patents of new drug manufacturers, as well as testing whether patents themselves could be invalid. Certainly, there is the risk of ending in failure, but I think the sizable merits outweigh the risks.

Focus strategy 2 **Strengthen stable supply capabilities**

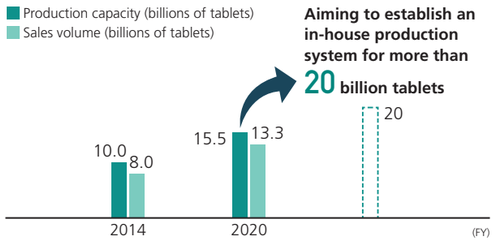
Build production that can supply 20 billion tablets

Another key element for acquiring market share is strengthening our supply capabilities. In order to meet market demands, we must first fully utilize our current production capacity and quickly reach the ability to supply an annual volume of 15.5 billion tablets. Furthermore, we will aim, as quickly as possible, for a supply structure that can handle 20 billion tablets a year.

While there are various approaches to improving production capacity, I would like to build a structure that fully utilizes our capabilities. First off, this means bolstering our work force, then expanding and enhancing facilities at our existing factories. Simultaneously, we will consider a variety of options, such as new capital expenditures, and alliances with and acquisitions of other companies, as we build out our supply capabilities.

An important point that must not be forgotten in this process is maintaining systems that will steadfastly assure quality as we expand supply capabilities. Even if we create rules and procedures that loudly proclaim the importance of quality, it is people who must implement them. The most important thing is putting further effort into training in order to maintain and improve a mindset focused on quality.

Strengthening stable supply capabilities



Striving to grow market share on the reliability and brands we have fostered

Starting a few decades ago when Japan had no generic drugs market, Sawai has been developing, producing, and marketing generics, while being a pioneer nurturing the growth of this market. In doing so, we have placed particular emphasis on quality, on training the employees who ensure that quality, and on continuous improvement activities in our work tasks. We have cultivated this approach over many years so that it is now deeply rooted as our corporate philosophy. With this as a strong foundation, Sawai has for over 50 years built the number one brand in the industry and the reliability that gives that brand its strength.

Going forward, we will ensure close coordination among divisions, including the R&D and Manufacturing Divisions, and the Marketing and Production Control Divisions. As we do so, we will strive to maintain high quality products and stable supply so that the Sawai brand and its reliability are never compromised, while also striving for greater market share.

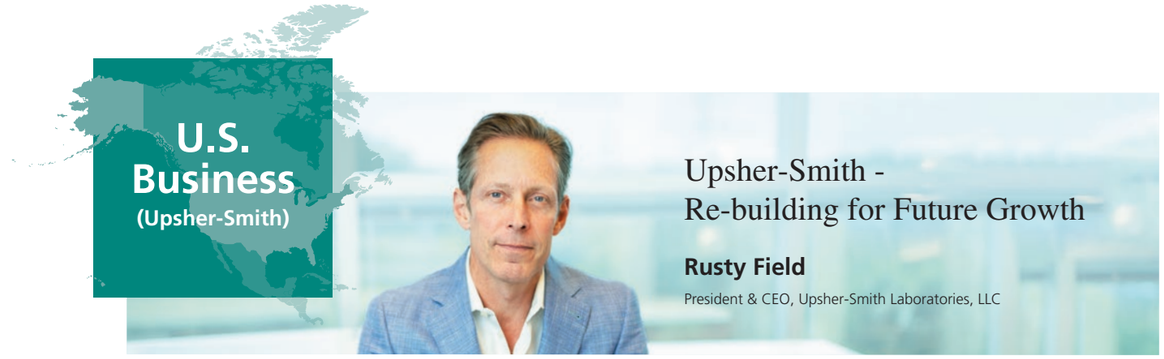
Strengths that form our business foundation

- Track record of approvals of around 800 items
- Abundant experience in patent invalidation trials, patent Ainfringement proceedings, etc.
- Close collaboration with external experts, including intellectual property lawyers
- Personnel structure for achieving a wide range of first launches
- Developing proprietary technologies

- Approximately 100 of around 450 API manufacturing plants are audited annually, including written and on-site audits
- In accordance with GQP, products manufactured by our factories and factories contracted are audited to conform to the approval standards of the Ministry of Health, Labour and Welfare, and provide quality improvement guidance as necessary
- Single-lot samplings each year for all 800 products based on PIC/S, conducting long-term stability tests
- Compliance with ICH Q3D & PIC/S and revisions of the PMD Act

- Information provision system that promptly and accurately conveys product information for approximately 800 items
- Abundant materials and content for patients and medical professionals
- Information gathering structure for side effects and safety, designed to further improve products
- Responding to demand changes through cross-division cooperation

- Procurement structure capable of rapidly responding to fluctuating demand for raw materials
- Manufacturing skills capable of highmix, large-lot production
- Responding to demand changes through cross-division cooperation
- Ensuring proper inventories



Upsher-Smith - Re-building for Future Growth

Rusty Field

President & CEO, Upsher-Smith Laboratories, LLC

Upsher-Smith's Fiscal Year ending March 2021 was a challenging year. Extreme competition in the U.S. generic market drove prices much lower in key generic products and COVID-19 slowed brand product growth. COVID-19 effects on patient behavior and physician access thwarted the Tosymra™ product launch and led to a significant impairment on that product, further impacting our net income performance. In addition, management underestimated the impact of the 3 novel CGRP products launched between October 2019 and March 2020. These impacts on our brand strategy expansion delayed a key effort to offset the risks in our generic business. While the nature of the competitive U.S. generic market was known at the beginning of the FY18-FY20 mid-term plan, the degree and duration of price impact could not be foreseeable at that time.

Throughout these great challenges, we maintained our "best in industry" supply to our customer and kept expenses well below plan. In March 2021 we completed a restructuring to better align our operating structure and expenses with our revenue base.

The next mid-term plan will be focused on repositioning Upsher-Smith for growth beyond FY24 and beyond. There are four critical strategies to accomplish this. First, we will drive growth from our brand portfolio and add new brand products. After deep analysis and evaluation of lessons learned, we implemented changes in August 2020 in key brand distribution strategies doubled Tosymra™ unit growth between October 2020 and March 2021. In April 2021, we implemented strategies to improve Tosymra™'s Average Selling Price (ASP). In addition to these strategies, new Direct-to-Consumer (DTC) strategies will be added Q1-Q2 FY21 to further enhance performance and drive to recoup some of the impairment losses. Second, we will reconstruct our organic pipeline portfolio to focus on commercially complex generic products and 505(b)(2)* small brands. The changes in R&D structure and talent 2019-2020 position us well to accomplish this. Commercially complex products include unique and challenging patient services. Third, we will complete consolidation of manufacturing to drive efficiency and quality for the future. Finally, we will further restructure the business to ensure our capabilities align with these strategies and lower operating costs to better position cash flow and operating profit into the future.

Our leadership and employees are deeply committed to doubling Upsher-Smith's business by 2030 in line with the Sawai Group Holdings long range plan. The near term will be challenging and strategies to mitigate these challenges and position the company for longer term growth are underway. The partnership with Sawai Group Holdings leaders is stronger than ever and the depth of understanding and involvement in our business strategies will enhance our performance into the future.

* 505(b)(2) : A regulatory pathway that allows a sponsor to reference previous studies and information, e.g. safety studies, efficacy studies, literature and other information to seek FDA approval for the development of enhancements to an already approved molecule. These enhancements generally include new routes of administration or new formulations.

Revenue / Core operating profit