



**Mitsuo Sawai**

Representative Director,  
Chairman and President  
(Group Chief Executive Officer and  
Group Chief Operating Officer)

## Fulfilling our mission as a healthcare corporate group with an eye toward the future of the generic drug industry

### Goal of the new system

#### Navigating the harsh environment of the generic drug business with a new system that makes quick decision-making possible

In April 2021, the Group transitioned to a holding company structure by establishing Sawai Group Holdings Co., Ltd. (hereinafter, “the Company”), and the three representative directors were tasked with managing the Group based on a division of duties. I was the Chief Executive Office of the overall group, Deputy Chairman and Sawai Pharmaceutical President Kenzo Sawai was responsible for the generic drug business, our core business, and President Kazuhiko Sueyoshi was in charge of overall management of the Group’s management departments and new and overseas businesses.

Taking into consideration the results of these measures and the business environment, we integrated management in June 2023 by having me serve as both the Chairman (Group CEO) and President (Group COO). At the same time, Kenzo Sawai resigned as both an officer of the Company and Sawai Pharmaceutical President. Furthermore, Kazuhiko Sueyoshi resigned as President of the Company but was then appointed Deputy Group CEO in charge of both special missions and ESG.

After transitioning to a holding company structure, it was necessary to eliminate disparities in risk management, compliance, information security, and sustainability within the Group and make governance more effective, and these efforts have firmly taken root over the last two years. For the U.S. business, too, bold revisions were made to the R&D system, which made it possible to return the business to profitability. Therefore, Kazuhiko Sueyoshi, who was responsible for both fields, resigned and was placed in charge of ESG (environment, society, and governance), which are remaining issues.

On the other hand, for the generic drug business, our core business, it was possible to establish a system that generates a certain level of profit even while competitors struggle by having each senior vice president think for themselves and fulfill their responsibilities and mission under President Kenzo Sawai. However, we are confronting a situation in which it is impossible to see future growth and expansion through a single company’s efforts unless there are changes to systems and environment in the industry, such as annual drug price revisions.

In response to this situation, Kenzo Sawai decided to step back from management and focus on industry-related activities based on his strong resolve and awareness that he “wants to undertake activities to maintain business for the overall industry by leveraging his experience, knowledge of systems, and other skills.”

Kenzo Sawai was succeeded by Motohiko Kimura, who had served as the Senior Vice President of the Manufacturing Division at Sawai Pharmaceutical and will take control of the generic drug business. He was extremely successful in contributing to higher quality and an increase in GMP level based on his experience and knowledge acquired at a new drug manufacturer, and I expect that he will make further contributions to quality and the stable



\*1 An abbreviation for Good Manufacturing Practices, international standards related to pharmaceutical manufacturing and quality control.

supply required of Sawai Pharmaceutical. Furthermore, Shoji Yokota, who was responsible for R&D at Sawai Pharmaceutical, was appointed a Director of the Company. His duty will be to provide overall supervision and management for future R&D, including that related to new business development.

At the same time, the Tokyo Stock Exchange's Corporate Governance Code requires that companies listed on the Prime Market install external directors who possess management experience at other companies. To meet this demand, Dr. Masayuki Mitsuka, who served six years as the President of Mitsubishi Tanabe Pharma, took up the position of external director and will be responsible for strengthening the Group's governance. I consider it extremely significant that we have a person with knowledge of management at overseas companies and with expertise in the laws and regulations related to the Group's business, such as the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and GMP,\*1 serving as an external director.

Because of these personnel changes, we have transitioned to a system with a single Representative Director that makes quick decision-making possible. In addition, we have reinforced our governance system by having half of our six directors as external directors.

### Business environment for the Japan generic drug industry

#### A period of transformation in old systems, necessary to provide a stable supply of high quality generic drugs and contribute to a reduction in government spending on healthcare

For the generic drug business, our core business, Sawai Pharmaceutical is committed to patients and strives to develop and provide products under the corporate philosophy of "always putting patients first." However, we are facing difficult conditions when we will no longer be able to fulfill our corporate mission of offering a stable supply of high quality generic drugs.

Until now, the use of generic drugs has spread because of government policies that promoted their use, which also resulted in growth for our business. Because of quality-related problems with products of some drug manufacturers that gave insufficient consideration to quality and possessed insufficient related systems required of drug manufacturers, shipments of almost 40% of generic drugs in 2022 were suspended or limited, resulting in supply shortages. Furthermore, in recent years authorized generic (AG) drugs have captured a larger share of the market, and generic drug manufacturers are fighting among themselves for the remaining market share.

Generic drugs produced through high-mix, low-volume production have a cost ratio of about 70%, which is more than twice that for general new drugs. Around 60% of our products are priced at ¥10 or less, and because of annual drug price revisions, many products are priced below cost, making 30% of our products unprofitable. However, despite being unprofitable, we cannot stop producing and supplying certain drugs because of their importance for the lives and health of people in Japan. Even though we have implemented more measures than other companies, such

as reforming management and increasing production efficiency, we recorded a decline in profit for fiscal 2022 for various reasons, including higher energy costs.

Furthermore, in April 2024, fees for three medical services will be revised (medical service fees, nursing fees, and fees for disability welfare services), resulting in a "triple revision." Because of increases in the cost of goods and personnel expenses, there are demands for an increase in compensation for each of these services, but major increases in the budget for social security expenses are out of the question. In 2025, all members of the baby boomer generation will be at least 75, and social security expenses will continue to grow. Having launched an expert working group regarding quick, stable supply of drugs, the Ministry of Health, Labour and Welfare is conducting in-depth deliberations on various topics, including the structure of businesses in the industry.

Under the current drug price system, the price of generic drugs is set at the weighted average of three price ranges.\*2 However, this mechanism does not reflect the efforts of individual companies. Sawai Pharmaceutical conducts formulation development in order to create products that are easy for patients to take and easy for healthcare professionals to use. It is our opinion that the system of drug prices should revert back to one that pays different manufacturers different prices in order to reward the efforts of companies that provide a stable supply of quality generic drugs.

In response to increases in costs, Sawai Pharmaceutical was forced to raise the invoice price\*3 of some of its products in 2022. Although some wholesalers protested, it was only because of these conditions, that we were able to communicate to society our strong determination to provide a stable supply. Generic drugs account for a larger percentage of the market than the 80% target set by the Ministry of Health, Labour and Welfare, indicating that GE promotion measures implemented so far have achieved some of the objectives. We are likely approaching a period of transformation in old systems, and one example of this transformation is moving toward a system in which drug manufacturers receive proper compensation for drugs that physicians consider absolutely necessary, and discontinue drugs that are not.

Generic drugs contribute to about ¥1.7 trillion in healthcare cost savings annually, and Sawai Pharmaceutical accounts for ¥280.9 billion of that. If generic drugs were replaced with originator drugs, healthcare costs would increase a corresponding amount. Raising the price of inexpensive generic drugs in order to ensure an appropriate return and creating a system that offers a stable supply of generic drugs would be beneficial to both the Japanese people and the government. If we can properly communicate correct information on the problems the industry faces and generic drugs to the Ministry of Health, Labour and Welfare, healthcare organizations, insurers, politicians, and the people in Japan and transform the structure of the industry, I am confident that the generic drug industry will surely grow.

\*2 The rule is that the price of listed generic drugs is placed in one of three price ranges ("less than 30% of highest drug price," "between 30% and up to but not including 50% of highest drug price, and "50% or more of the highest drug price") based on the weighted average market price at the time of the drug price revision.

\*3 Invoice price: the price manufacturers sell to wholesalers.

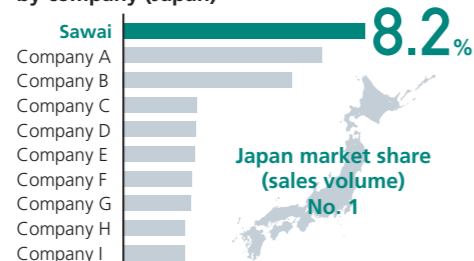
### Recovering trust for the overall industry

#### Taking the lead in eliminating supply shortages and restoring trust as the industry leading company

Turning to the production of generic drugs, it is difficult to rapidly increase production because there are intricate production plans for each production facility. Under these conditions, Sawai Pharmaceutical has worked to release and ship as much inventory as possible, but because of overall supply shortages, there have been times when we have caused problems, particularly for existing business partners, and have been dressed down when making sales calls.

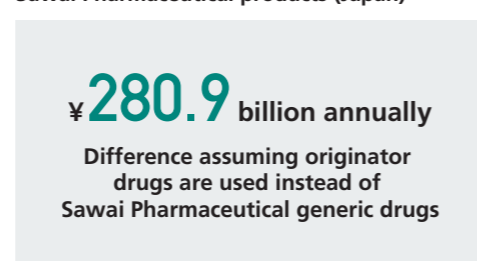
However, we were able to produce 16.6 billion tablets, more than 10% more tablets than the actual production for the previous fiscal year, as a result of all employees, including those at partner companies, working together to strengthen the system for increased production. Inventory levels have almost returned to their original level, and there has been a dramatic decline in limited shipments since April 2022. But, the Group is not the only company to face supply shortages.

Prescription drug sales (tablets) by company (Japan)



Japan market share (sales volume) No. 1

Amount of medical expense savings due to Sawai Pharmaceutical products (Japan)



Through industry organizations, including new drug manufacturers, and in collaboration with the Ministry of Health, Labour and Welfare, Sawai Pharmaceutical has taken the lead in moving forward with such efforts as making public information on supply conditions for all drugs.

As for the issue of generic drug quality, we have promoted not only efforts to restore trust in generic drugs through the Japan Generic Medicines Association but also general checks of whether all drug Manufacturing and Marketing Approvals held by each company are reflected in actual production.<sup>\*4</sup> Although the goal has yet to be reached, the association is working to restore trust in the overall industry by fully releasing information. Third-party audits have begun, and Sawai Pharmaceutical underwent its audit before other companies. It will be impossible to convince people to use generic drugs with peace of mind unless we restore trust in the overall industry, not simply tell people that there are no problems with the Sawai Group's quality. As the leading company in the industry, I consider it our mission to restore trust in generic drugs.

<sup>\*4</sup> See "Association's Efforts to Restore Trust in Generic Drugs," issued by the Japan Generic Medicines Association. <https://www.jga.gr.jp/english.html>

### Rebuilding the U.S. business

#### Becoming profitable by revising the research system Expectations for product launches developed at low cost

Turning to the business strategy for the U.S., while we acquired Upsher-Smith based on a strong evaluation of its judgment regarding products for development, its R&D system was revised as business has grown slightly more difficult. This led to a review of the cost structure and improved operating profit. Chairman and CEO Taku Nakaoka, who took up the position in 2022, provided the guidelines for the cost structure review, and the American President and COO Rich Fisher was responsible for providing practical instructions.

At the new factory built in Minnesota, production was launched in January 2023, and starting in fiscal 2024, costs are expected to fall between \$4.00 million to \$6.00 million as a result of merging factories and bringing production of commissioned products in house. In addition, the Company is examining increasing factory utilization rates and developing new revenue sources by expanding into the commissioned production business.

As for products, we will not only launch new ones but also include Sawai Pharmaceutical Paragraph 4 products. By product launches developed at low cost under new leadership, it may be possible to achieve the vision of generating sustainable growth in the long term as a specialty drug company.

### Monetizing new businesses

#### Fields relatively immune from the impact of drug price revisions will stabilize earnings

In addition to activity making investments in growth opportunities outside the generic drug field, we are taking on the challenge of new businesses in four fields that leverage the strengths we have acquired in existing businesses in order to achieve the government's goal of a society with healthy longevity.

In the "digital medical devices" field, one of these fields, we applied for approval for the non-invasive neuromodulation device SWD001, which is used to treat migraines in the acute stage, in December 2022. In the field of NASH,<sup>\*5</sup> too, we have made progress with the business, which has included concluding a treatment app joint-development and marketing license with CureApp, Inc. in August 2022. As there is no established drug therapy for NASH, treatment is centered on dietetic therapy, and there are hopes that this will be a promising method if it is possible to control diet with digital technology. The focus of both of these products and services

<sup>\*5</sup> NASH  
Non-alcoholic  
steatohepatitis

<b>Medical devices business</b>	<p><b>SWD001 (non-invasive neuromodulation device)</b></p> <ul style="list-style-type: none"> <li>Acute-phase migraine treatment: Applied for approval to manufacture and market in December 2022 and preparing to release</li> <li>Depression: Plan to examine applying after trials in US completed</li> </ul> <p><b>SWD002 (treatment app for NASH indications)</b></p> <ul style="list-style-type: none"> <li>Preparing phase 3 trial for treatment app that a joint development and sales license with CureApp Inc. was concluded. Expect to launch in FY2023.</li> </ul>
<b>Digital business</b>	<p><b>SaluDi (PHR<sup>*6</sup> management app)</b></p> <ul style="list-style-type: none"> <li>Selected for Yabu City Digital Health Aging Project (Yabu City, Hyogo Prefecture), and will be introduced in FY2023</li> <li>Selected for Nagasaki's official PHR app Aijisai Net and working to link with EHR<sup>*7</sup> and PHR</li> </ul>
<b>Health food business</b>	<p><b>Triple Seikatsu-Shukan (products with functional claims)</b></p> <ul style="list-style-type: none"> <li>Completed test marketing in November 2022</li> <li>Evaluated business feasibility based on test marketing results and will launch the business from this fiscal year</li> </ul>
<b>New drug business (Orphan diseases)</b>	<p><b>Drugs for rare diseases (orphan drugs)</b></p> <ul style="list-style-type: none"> <li>Reinforce in-house evaluation system and continue to examine pipeline expansion</li> </ul>

<sup>\*6</sup> Personal health record (PHR)

<sup>\*7</sup> Electronic health record (EHR)

has received high praise from physicians.

As for "health foods," we are looking at expanding our lineup of products with a focus on the field of pre-symptomatic approaches and preventive measures. With a sense of excitement that only Sawai Pharmaceutical can provide, I want to develop and commercialize unique health foods.

On the other hand, there are about 7,000 rare diseases in the world, and for orphan drugs, treatments for these rare diseases, a single product does not make a business; therefore, we are examining the pipeline of products in this field from a long-term perspective.

One of the new businesses is the "health foods" business, and for this business, the selling price can be set to match demand and value added unlike for the generic drug business, our core business. Furthermore, it is expected that the "digital medical devices" business will be one whose profits reflect our efforts as it is relatively immune from drug price revisions.

### Medium- to long-term growth strategy

#### Steadily achieving Sawai Group Vision 2030 targets and meeting the expectations of shareholders

In fiscal 2022, the Group's revenue surpassed ¥200.0 billion for the first time. The Group Strategy Council firmly deliberates on the future growth strategy to achieve the numerical targets appearing in Sawai Group Vision 2030. For growth-oriented investments, even individual small investments, we impose governance on and manage them by having them examined by the Group Investment Committee and referring them to the Group Strategy Council.

In particular, investments will be focused on R&D in the future. Because R&D is important not only for the generic drug business but also the new businesses, I would like to fully discuss the issue and make investments from which we can "reap" revenue in the future. Until now we have limited investments, including capital expenditures, so that we could fund them from operating cash flows, but because we will now need to use large amounts of funds, we plan to raise funds primarily through bank loans. While keeping in mind ROE, we will examine making use of leverage through loans and bonds.

What I have learned through dialogue with investors is that there are great expectations for the Group in terms of "Sawai being the only company that can support generic drugs, part of Japan's healthcare infrastructure." It is well known that even if a company takes the lead



Sawai Group Vision 2030 Targets and Prerequisite Values

	FY2022 actual	FY2030 targets
Japan business revenue	¥163.7 billion	¥260.0 billion
New business revenue	—	¥80.0 billion
U.S. business revenue	¥36.6 billion	¥60.0 billion
Total revenue	¥200.3 billion	¥400.0 billion
ROE	6.5%	10% or more

in making capital expenditures, it is difficult to benefit from this because of annual drug price revisions; therefore, there is agreement that “without changes to the system, this infrastructure will be lost.”

Unless we are able to maintain the sustainability of the generic drug business, healthcare costs for people in Japan will continue to increase. Furthermore, if the business is unsustainable for domestic manufacturers and Japan ends up relying on overseas manufacturers, money will flow overseas. In terms of health and safety security—that is, protecting the health and safety of people—we must meet the expectations that generic drugs used in Japan should be ones produced in Japan.

As for the return for shareholders who support us, I want to conduct business so that we can be sure to achieve and maintain a stable dividend with a target payout ratio of 30%.

Sawai Group’s reason for existing and corporate philosophy

Maintaining efforts to embody the corporate philosophy of “always putting healthier lives first” and “always putting patients first” and meeting expectations

Our corporate philosophy of “always putting healthier lives first” embodies our desire to contribute to the health of even more people as a healthcare corporate group that is centered on the generic drug business and continues to develop with society. Thoroughly adopting this philosophy and vision in business activities will lead to unshakeable trust. The Group’s most important responsibility and the reason for its existence is to create the conditions so that through the generic drug business, our core business, we can provide the necessary volume of quality generic drugs when necessary.

The many employees who joined the Company because they were attracted by our corporate philosophy of “always putting healthier lives first” and Sawai Pharmaceutical’s corporate philosophy of “always putting patients first” give shape to the Group’s corporate culture. I will work so I can declare that one of the Group’s strengths is that new people who join the Group fully adopt this philosophy. This is a never-ending issue. By marshaling the power of all employees to embody the corporate philosophy and being persistent in our efforts, we will continue to take on challenges in order to meet the expectations of all stakeholders.

*M. Sawai* Representative Director, Chairman and President  
(Group Chief Executive Officer and Group Chief Operating Officer)



Message from the newly appointed external director

Navigating a harsh business environment and transforming the Company into one that contributes to people’s health in the long term

Masayuki Mitsuka, Ph.D. External Director



Despite being indispensable for the people in Japan, there are clearly issues with generic drugs

For Japan’s pharmaceutical industry, the government has set the target of generic drugs accounting for 80% of the market on a volume basis, and the distinction between generic drugs and new drugs has rapidly grown clearer. This is necessary to ensure the sustainability of Japan’s health insurance system. The use of generic drugs is recommended because they lessen the financial burden on patients, and thus, generic drugs have not only become indispensable for all people in Japan but also contribute to promoting SDGs for the whole of Japan on various fronts.

On the other hand, two major issues have come to light. One is concerns about the quality of generic drugs as a result of incidents at several companies that have shaken trust in generic drugs. The other issue is the sustainability of the business for the overall generic drug industry because of annual drug price revisions that have a greater impact on generic drugs than new drugs.

Amid this difficult business environment, I received an opportunity to participate in Sawai Group Holdings’ management as an outside party. The Company is one that will navigate this difficult business environment from various perspectives, including market share, product track record, and financial soundness, and possesses the potential to contribute to people’s health while growing in the long term.

Issue of quality provides a chance to transform the industry

The industry must overcome the issues of quality concerns, excessive number of manufacturers and retailers, and, as a result of these, the downward pressure on drug prices. Of these issues, quality concerns could provide an opportunity for the overall industry to move to the next stage. While the various companies in the industry are promoting measures to reinforce the system that places the greatest priority on compliance, governance, and

quality, it is also important to focus on whether management has set unrealistic targets for workplaces regarding production volume, deadline for obtaining approval, and similar activities, and whether sufficient human capital support is provided. As an external director, I consider it important to check whether workplace governance is effective and whether there are sound management targets that match the actual capabilities of the Company.

Focus on investing in people, the key to survival

Overall prescription drug sales in Japan hit a record high of ¥10.9 trillion in fiscal 2022, but considering the trend since 2015, sales growth is flat, having grown only from ¥10.5 trillion to ¥11.0 trillion, and this trend will continue into the future. I expect that as sales and the market share of expensive new drugs grows, generic drug manufacturers will be weeded out before new drug manufacturers. There are two keys to surviving this. The first is ensuring a production volume that guarantees one’s presence in the market, and the second is possessing both strong cost competitiveness and quick development capabilities for drugs whose patents have expired.

In the pharmaceutical industry, “investing in people,” an important element for innovation, and “diversity of human resources” are more critical than in other industries. In the new drug business, new drug discovery and development require the skills of highly specialized individuals, but in the generic drug business, a different type of continual innovation, one that simultaneously increases production volume, quality from a patient perspective, and cost competitiveness, is required. As an external director, I want to focus on investing in human capital that management needs, particularly the securing of highly specialized people, and diversity.