

sawai



Always putting  
healthier lives first

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Integrated Report 2024

## Sawai Group corporate philosophy

# Always putting healthier lives first

The Sawai Group corporate philosophy of “always putting healthier lives first” embodies our desire to contribute to the health of as many people as possible as a healthcare corporate group which develops sustainably alongside society, with the generic drugs business as our core business. We will mobilize the strengths of all Group employees to pursue the challenge of meeting the expectations of all stakeholders.

### Sawai Group Mind



The Sawai Group will serve every stakeholder wholeheartedly.

The Sawai Group will continue the challenge to improve access to healthcare for more people.

The Sawai Group aspires to play a pivotal role in healthcare through its contribution to society.

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## Editorial policy

This report references the International Financial Reporting Standards Foundation's International Integrated Report Framework and includes information that could impact our medium- to long-term corporate value creation and that is connected with information about the Company's strategies, performance, and future projections, as well as non-financial information concerning the environment, society, and governance. The contents herein have been assigned priority internally based on their nature and quantity, risks, opportunities, and dialogues with stakeholders, and have been deemed to be of particular importance.

This report has been prepared by the Group Sustainability Committee, which is supervised by the President, and with the support of the committee's administrative office.

### Reporting period:

April 1, 2023 to March 31, 2024  
(some information herein falls outside of this period)

### Abbreviations used:

In this report, "generic drugs" are abbreviated as either "GE drugs" or "GE."

### A caution concerning forward-looking statements:

This report contains forward-looking statements regarding the Company's plans, outlook, strategies, and results for the future. All forward-looking statements are based on judgments derived from the information available to the Company at the time of publication. Accordingly, please be aware that the impact of certain risks and uncertainties could cause the Company's actual results to differ materially from any projections presented in this report.

### Reporting scope:

Sawai Group Holdings and its consolidated subsidiaries

## Group history

Not only “always putting patients first”  
but also striving to succeed in  
“always putting healthier lives first”  
for all people



1929

Sawai Pharmacy, the predecessor of Sawai Pharmaceutical Co., Ltd., was founded in Asahi-ku, Osaka City.

1948

Sawai Pharmaceutical Co., Ltd. was incorporated in Asahi-ku, Osaka City.

1965

Shifted from making OTC drugs to ethical pharmaceuticals.

1930

1940

1950

1960

1970

1929–

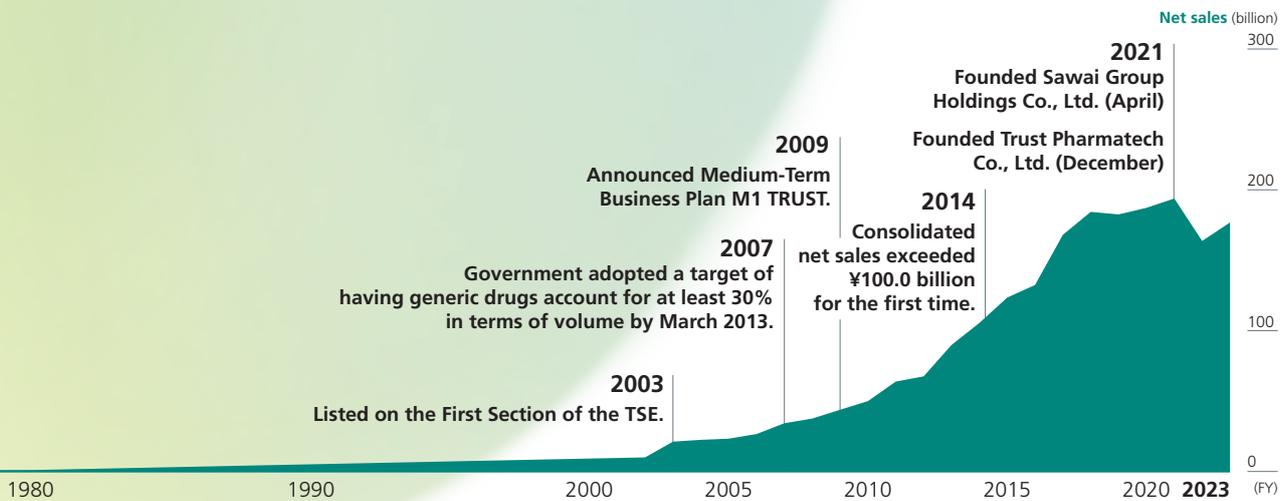
### Sawai Pharmacy founded in Asahi-ku Osaka as local pharmacy

Sawai Pharmaceutical's history starts almost 90 years ago. Hanpei Sawai and Noyo Sawai (a pharmacist) established Sawai Pharmacy, Sawai Pharmaceutical's predecessor. At that time, there were few pharmacies, and Sawai Pharmacy supported the health of residents by providing drugs as a local pharmacy.

1965–

### Transformed into manufacturer of prescription medications and then into a leading GE company

In response to changes in the drug market due to the introduction of a universal medical care insurance system, Sawai transformed itself from a manufacturer of over-the-counter medications into a manufacturer of prescription medications. By supplying one product after another that meet the needs of healthcare professionals, we have built a foundation to grow into a leading company in the generic drug industry.



### 2003–

#### Contributed to spreading and expanding GE as a company listed on the First Section of the Tokyo Stock Exchange

In line with the basic policies of expanding market share, further strengthening the management structure, and building a solid Sawai brand, Sawai continued to grow, boosted by the tail wind of government policies to promote the use of generic drugs. We also strengthened our production and development capabilities, which included construction of the Kanto and Sanda Nishi factories and a new development center.

### 2021–

#### Transformed into GE manufacturer that continues to be selected with an eye toward industry reorganization

Sawai transitioned to a holding company structure in 2021 in order to strengthen its existing businesses and foster new businesses that meet the needs of the time. In fiscal 2022, revenue exceeded ¥200.0 billion (including discontinued operations), as the Company worked to provide a stable supply of inexpensive, high-quality generic drug as social infrastructure.



### Value created by The Sawai Group

## Leading the way in the promotion of generic drugs as an industry pioneer

Sales volume

Approx.  
**15.7**  
billion tablets

Sawai Pharmaceutical

Share of Japan's prescription drug market (volume)

Approx.  
**8.4%**

Sawai estimate

Amount of reduction in healthcare costs

Approx.  
**¥293.9**  
billion

Japan business

Number of products on sale

Approx.  
**770**

Production system

**8**  
facilities  
throughout Japan

## Group vision

# Pursuing all people's health from all perspectives as a general healthcare company

## Sawai Group Vision 2030

### The World We Want to Build

A world where more people can receive healthcare services and live a full life with peace of mind among society

### Our Ideal State

A company with a strong presence that continues to contribute to people's health by providing a multifaceted mix of products and services that meet individual needs based on scientific evidence

## Medium-Term Business Plan "Beyond 2027" → P. 27

Giving top priority to establishing a trusted corporate foundation, and setting key themes for business strategy and business foundation

### Key themes for business strategy

- 1 Achieving steady growth in the generics market
- 2 Establishing sustainability of the generics business
- 3 Continuing investment in growth areas

### Key business foundation themes

- 1 Creating talent that underpins sustainable growth
- 2 Working on sustainability initiatives
- 3 Improving capital efficiency





**Mitsuo Sawai**

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

# Continuing to fulfill our mission as a healthcare corporate group trusted by society to provide a stable supply of generic drugs

## Overview of an inappropriate test incident and recurrence prevention measures

### Working to prevent recurrences and regain trust, which is my responsibility

First, I would like to express my heartfelt apology for the incident regarding inappropriate testing by our main subsidiary, Sawai Pharmaceutical, that came to light in April 2023. It was determined that there was inappropriate stability monitoring dissolution testing of Teprenone Capsules 50mg "Sawai" at Sawai Pharmaceutical's Kyushu Factory. Regrettably, this incident occurred even though we said that "our mission is to provide a stable supply of high-quality drugs" and we have earned the trust of customers that "Sawai is associated with high quality." As a result, we have caused problems for healthcare professionals, patients and many other stakeholders who use Sawai drugs because they trust them.

After this came to light, Sawai Pharmaceutical requested that a special committee made up of external Good Manufacturing Practice (GMP) experts and attorneys investigate the incident. To take responsibility for this incident, on October 23, 2023, three days after receiving the investigation report, we announced the results without waiting for the national government to issue a business improvement order. In response to the recommendations from the committee on recurrence prevention measures, we have been steadily implementing such measures in related departments, including launching the Corporate Culture Reform Project, which is directly under the supervision of President Kimura.\*1

However, as a member of management, I take full responsibility for this incident. Since 2008, when I took up the position of Sawai Pharmaceutical president, I have visited all our factories each quarter and thought that I had communicated to workplaces what it means to manufacture quality drugs, which is included in the corporate philosophy "always putting patients first." Knowing that human beings make mistakes, we should have created a system to detect when mistakes are occurring to prevent inappropriate work from being carried out, but we failed to create such a system.

To clearly show that this was a management responsibility, the five Directors from Sawai Pharmaceutical, including myself, repaid part of our remuneration in response to the government's business improvement order issued December 22, 2023. Starting this year, we designated December 22 as the day we resolve not to let such incidents occur again.

It is now my responsibility as CEO to build this type of system. Furthermore, we will work to regain people's trust by not only implementing various overlapping measures, such as exchanging opinions with employees in production through activities that include townhall meetings held by President Kimura and reinforcing the whistleblower system, but also thoroughly implementing recurrence prevention measures.

\*1

Recurrence prevention measures related to inappropriate testing at our subsidiaries

- 1) Corporate Culture Reform Project
- 2) Reassessing the existing products from manufacturing and quality perspectives, and implementing corrective measures
- 3) Implementing recurrence prevention measures at Sawai Pharmaceutical's Manufacturing Division
- 4) Implementing recurrence prevention measures at Sawai Pharmaceutical's Kyushu Factory
- 5) Implementing recurrence prevention measures at Sawai Pharmaceutical's Reliability Assurance Division

Details of various initiatives and information on the progress are available on the Sawai Pharmaceutical's website and will be regularly updated. (see the following URL for details)  
[https://www.sawai.co.jp/important\\_news/detail/17](https://www.sawai.co.jp/important_news/detail/17)  
 (Available only in Japanese)

### Changes in the business environment and our approach

#### Thoroughly implementing pricing policy introduced in fiscal 2023 and building a system that enable a stable supply of generic drugs in the long term

The details of 2024 drug pricing system reforms, which will have a major impact on our generic drug business, have been announced.\*2 They include measures to ensure a stable supply of drugs, such as company scoring systems that identify companies capable of providing a stable supply of generic drugs and make it easier for medical institutions to select those company's drugs, which we regard as having a positive impact on our business.

These company scoring systems are advantageous for Sawai Pharmaceutical in two ways. First, we expect to possess an additional production capacity of 6.5 billion tablets within three years as a result of Sawai Pharmaceutical's investments to expand its production capacity.

Another advantage is that both for items whose cost of production has dramatically increased and for unprofitable items, Sawai Pharmaceutical began implementing in fiscal 2023 a pricing policy to have them purchased at nearly the National Health Insurance (NHI) drug price without excessive discounts. A 2023 drug price survey reveals that the average difference rate for all drugs, which is the difference between the NHI drug price and market drug price, is about 6.0%. With products for which the drug price has already been revised as a result of being unprofitable, we need to sell under a 7.0% price difference from the NHI drug price in order to obtain good scores in the company scoring system. However, Sawai Pharmaceutical, which has already implemented its pricing policy, can easily sell its products in this range.

Even so, the business environment will remain harsh as long as this drug pricing system is in place. For other products like foods, higher raw material prices are generally reflected in the selling price. However, drugs are capped by the NHI drug price and it is difficult to pass on the price. Furthermore, the NHI drug price has recently been lowered every year. If this situation continues, we will have to take on new challenges to survive and grow. With this in mind, we are implementing an unprecedented pricing policy through negotiations with various stakeholders.

In response to this movement, the current drug pricing system reforms include an expanded system to support prices, such as repricing of unprofitable products being applied as an exception to products requested by companies according to sudden jumps in costs and supply issues. This allowed us to finally generate a profit on previously unprofitable drugs.

We are evaluating if selling drugs at a lower price is really beneficial for the industry and patients. We believe that it is important to create a system that makes it possible to provide a stable supply into the future by passing on increases in the cost of sales.

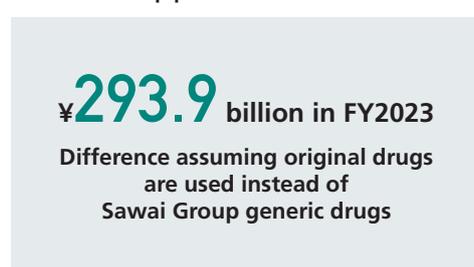


\*2  
For details, see the Japan Generic Medicines Association's website.  
<https://www.jga.gr.jp/jgapedia/deals/2403.html>  
(Available only in Japanese)

Prescription drug sales (tablets) by company (Japan)



Reduction in healthcare costs due to Sawai Group products



## Business portfolio and capital policy

### **Withdrawing from the U.S. business, concentrating business resources in the Japan generic drug business, and transitioning to management that is conscientious of cost of capital and stock price**

At the Board of Directors meeting held in January 2024, it was decided to revise our business portfolio and capital policy so that we could improve management to better meet shareholders' expectations by further increasing return on capital.

One element of this policy was the claims decision to withdraw from the U.S. business. The U.S. business had deteriorated to a point where a return to profitability was unlikely, as profit continued to decline year by year amid fiercer competition due to the entry of rival companies and Indian companies into the market.

One path forward at that time was to invest in R&D and generate greater sales through new brand drugs. Management decided, however, that from a capital strategy perspective, it would be better to invest capital into the Japan business, which claims relatively high profitability, and not the U.S. business, which offers narrow profit margins. It was determined that concentrating business resources in Japan's generic drug market, which continues to be plagued by unstable supply, would offer growth opportunity that could lead to strong profit.

At the same time that withdrawal from the U.S. business was being considered, we also considered revising our capital policy. We have long been aware of demands from the Tokyo Stock Exchange to adopt management that is conscientious of cost of capital and stock price. Until now, business results were primarily evaluated based on the profit and loss statement, which management focused on. But we now undertake management that is conscientious of return on equity (ROE) and return on invested capital (ROIC), which are indicators from a shareholder perspective.

## New Medium-Term Business Plan to achieve long-term vision

### **Revising numerical targets in response to greater opportunities in Japan's generic drug market Working to strengthen production capacity and reinforce human capital to eliminate supply shortages**

Touting three initiatives in the Medium-Term Business Plan START 2024 (FY2021–FY2023): "expand share in the Japanese generics market," "expand the U.S. business," and "cultivate new growth areas through new business," we moved forward with various initiatives to achieve the long-term vision of Sawai Group Vision 2030.

Meanwhile, we withdrew from the U.S. business and started to take on the challenge of new business development. Even so, our Japan generic drug business increased its market share by 1%, which made strong contributions to revenue. In particular, in the final year, we achieved a major success by taking on the challenge of implementing a pricing policy for generic drugs. Numerically, although overall group revenue and core operating profit declined due to the withdrawal from the U.S. business, we recorded an improvement in both earnings per share (EPS) (¥281.80 → ¥312.67) and ROE (5.8% → 6.6%) in this challenging environment.

One issue that must be addressed to achieve our long-term vision is establishing a business model that makes it possible to promptly respond to changes in the market, which includes creating a compliance and governance structure. With the withdrawal from the U.S. business and greater business opportunities for the Japan generic drug business, we also revised the quantitative targets in the Sawai Group Vision 2030 in June 2024.

Having revised upward our forecasts made when the Vision was initially formulated, we are aiming to generate revenue of ¥300.0 billion from the generic drug business by fiscal 2030.

Furthermore, we set a new ROE target of 13% or more and ROIC target of 10% or more as we transition to management that places a greater emphasis on capital efficiency. Through these plans, we will contribute to the resolution of social issues by providing products and services, including those in the disease prevention and diagnosis fields, and fulfill our central role of offering a stable supply of generic drugs as part of the social infrastructure.

The three years of the new Medium-Term Business Plan “Beyond 2027,” which was announced along with revisions to the long-term vision, have been positioned as an important period to develop this foundation (see P. 28 Medium-Term Business Plan). While the supply shortage of generic drugs is expected to continue for the next several years, Sawai Pharmaceutical will build a system for increased production of about 6.5 billion tablets, which is expected to eliminate the shortage. This will be a major driving force for moving the Group forward.

To fulfil our responsibility to quickly eliminate drug shortages, we will not only focus on expanding production capacity, reinforcing our cost competitiveness, and improving capital efficiency but also promote collaboration and cooperation among generic drug companies. Most importantly, we are committed to address the priority issue of strengthening human capital, the source of value creation.

### Initiatives for sustainability

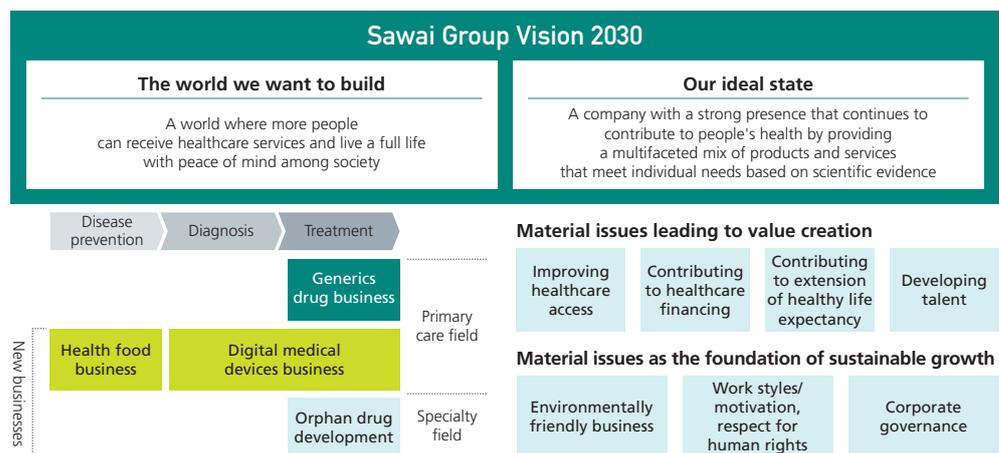
#### Furthering our efforts on promoting diversity, reinforcing governance structure, and addressing climate change

We are aware that initiatives for sustainability are also important management issues in order to achieve our long-term vision and implement the new Medium-Term Business Plan. Based on the idea that it is our employees who support Sawai, we established the ID&E Promotion Office\*<sup>3</sup> in October 2023 to promote diversity, which is stated in our long-term vision. We actively promote initiatives to encourage the active participation of driven people regardless of gender, which is primarily being undertaken by the office. Currently, the ratio of women in management positions is less than 10%, but we believe that raising this to 20% or more is an important goal. Therefore, we will quickly introduce various systems including working from home. The origin of Sawai Pharmaceutical can be traced back to a pharmacy set up by a pioneering Japanese female pharmacist almost 90 years ago. In this sense, too, I want female employees to play an active role.

On the other hand, we have significantly enhanced the governance structure. The ratio of external directors has increased to 3 out of 5. In addition, because one person with extensive management experience at pharmaceutical companies has been added as a director, the Board of

\*<sup>3</sup>  
Inclusion, Diversity, and  
Equity Promotion Office

#### “Sawai Group Vision 2030” and material issues for sustainability



Directors has become more lively, and numerous insightful comments have raised our collective awareness. For example, when pursuing a return on investments, we are asked to provide detailed explanations of why we chose that investment and how we evaluated it before approving it. This is also true of measures to prevent recurrences of inappropriate testing. However, there is still only one female director, and we need to improve this number.

We will also further reinforce our initiatives for the environment, as the impact of climate change is becoming more severe. It is important to view climate change as a business risk, and the view of investors and consumers has become more critical. Having taken on the difficult challenge of strengthening production capacity while also reducing CO<sub>2</sub> emissions, we will strive to reduce CO<sub>2</sub> emissions while expanding both environmental-friendly production and use of renewable energy.

In April 2024, we issued social bonds in Japan. We recognized this as proof that it is our business to resolve the social issue of a shortage of generic drugs and thus contribute to achieving SDGs and a sustainable society.

### Message to stakeholders

## Uniting the capabilities of all our employees to realize our corporate philosophy and continue to take on challenges to meet expectations

Not only is the shortage of generic drugs expected to continue, but the generic drug market is also projected to grow due to the increase in the elderly population. In this environment, we think that the Japan generic drug business will be facing an unprecedented opportunity, as there are high expectations for Sawai Pharmaceutical's production capacity. In addition to aiming to quickly move to the next growth stage by steadily capturing these current growth opportunities, as a leading generic drug company, we will establish a business model that serves as social infrastructure to ensure a stable supply of high-quality, inexpensive generic drugs in the long term. Furthermore, we will continue to take on new business fields and contribute to an extension of healthy life expectancy.

To establish a trusted corporate foundation on which all of our activities exist, and embody "always putting healthier lives first," the Group corporate philosophy, we will unite the capabilities of all our employees and continue to take on challenges to meet the needs of all stakeholders.

*M. Sawai*

### Mitsuo Sawai

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



# Inappropriate testing investigation results and recurrence prevention measures

## Summary of inappropriate testing incident

Teprenone Capsules 50mg “Sawai” produced at Sawai Pharmaceutical’s Kyushu Factory always undergoes dissolution tests as part of stability monitoring to continually check and guarantee post-approval quality. The same type of tests conducted in April 2023 revealed that previous testing had been conducted inappropriately.

The products, drugs to improve acute gastric mucosal lesions during the acute exacerbation phase of acute and chronic gastritis and to treat gastric ulcers, can be used for up to three years after production. The dissolution test uses the paddle method, in which the formulation is added to a specific test solution, mixed, and then the volume of dissolved drug is measured. As a general rule, the test is conducted one year, two years, three years, and four years after production. The passing standard is a dissolution rate of 70% or more, and a result of less than 70% is out of specification (OOS).

In the improper tests, the granules were removed from the capsule and placed in a different capsule, and then the refilled specimen was subject to a dissolution test to determine whether it passed or failed. Capsule aging is the reason for the decline in dissolvability. Therefore, refilling new capsules with the content of old capsules would not result in the decline in dissolvability and make it possible to avoid a non-compliant test result.

After the misconduct was discovered, an internal investigation was quickly launched and a special investigation committee, which included independent experts in GMP and attorneys, was established. An investigation of facts related to the inappropriate testing was conducted between July 20 and October 17, 2023, and the special investigation committee submitted their report on October 20 of the same year.

## Investigation results

The investigation by the Special Investigation Committee included (i) a detailed review and examination of relevant documents, (ii) interviews with a total of 56 people involved, (iii) access to the testing facilities, (iv) a digital forensic examination of high-performance liquid chromatography data and internal email data related to the dissolution tests of this product, and (v) a questionnaire survey.

As a result, it was found that the inappropriate testing was conducted following an out-of-specification (OOS) result in a dissolution test during stability monitoring conducted in 2013.

In response to the OOS results, the senior management of the Kyushu Factory at the time ordered the capsule content to be transferred to new capsules and tested to examine the cause of the decline in dissolvability. However, they did not issue an internal report, examine the cause, and take corrective measures in accordance with GMP.

After that, test staff thought that senior management had provided instructions to handle the situation by using specification results based on tests of the replaced capsules, which resulted in this inappropriate testing continuing.

Although it was not found that senior management

had directed or implicitly approved the inappropriate testing, due to inadequate supervision, inappropriate testing practices were not detected and continued for many years. It was found that at least since the third-year dissolution test of this product in 2017, there had been inappropriate testing conducted for all lots, and that for those falling outside of specification results in the dissolution tests from 2010 to 2014, proper deviation management based on GMP had never been carried out until the inappropriate testing was discovered.

The investigation notes the following human factors for why this situation continued: (1) the widespread tendency to underrate the importance of stability monitoring, (2) the tendency not to question but simply follow superiors’ instructions, and (3) lack of understanding of GMP among those involved in the testing. In addition, there were several physical factors for the incident (1) defects in the effective supervising system in terms of quality control and quality assurance, (2) insufficient management of test records, and (3) excessive workload and shortage of members of the Quality Control Department, which is responsible for the test.



Details of the latest initiatives related to recurrence prevention measures can also be found on the Sawai Pharmaceutical website, under "Progress with the Corporate Culture Reform Project." [https://www.sawai.co.jp/important\\_news/detail/17](https://www.sawai.co.jp/important_news/detail/17)(Available only in Japanese)

## Main recurrence prevention measures

### Corporate Culture Reform Project

Main topics	Initiatives	Implementation status and frequency
Thoroughly spread a spirit of legal compliance and general compliance through retraining and routine notices	Designate a legal compliance week (in general, third week of each month) and provide all employees, including directors, with compliance education on the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and the GMP basics	Once a month (legal compliance week)
Strengthen promotion of the whistleblowing systems	Improve understanding of the whistleblower system, such as thoroughly educating employees that such items as GMP violations can also be reported using the system	As needed
Create a venue for direct dialogue between the president and employees and promote dialogue between management and employees by regularly issuing the messages from the president	Create venues for direct dialogue between employees and responsible directors, including the president, which involves holding town hall meetings	At least once a month (as needed)

### Manufacturing Division

Main topics	Initiatives	Implementation status and frequency
Reconduct and continue to conduct GMP education for all employees	Hold group discussions at each workplace (educate employees about this incident and uncover issues for each department they work in) Obtain the opinion of all employees regarding discussion items in order to rebuild a quality culture	Work to resolve the following issues taking into consideration employee opinions
Secure human resources for the factory Quality Control Department and Quality Assurance Department from either inside or outside the company	Redefine the number of staff required, strengthen recruiting activities, conduct job rotation of experienced employees	Plan to add about 105 employees by fiscal 2026
Introduce a system to ensure data integrity	Quickly introduce MES and LIMS into all factories (already introduced: Kashima, Kanto, Sanda Nishi [MES], TP Seima, TP Yachi [LIMS])	Introduce into the new building of Daini Kyushu Factory in June 2024

### Kyushu Factory

Main topic	Initiatives	Implementation status and frequency
Create a system to allocate necessary resources to the Production Department and Quality Management Departments	(1) Undertake a planned increase in number of employees* (2) Ensure integrated data management and data integrity by introducing chromatography data systems (CDS)	(1) Plan to add 18 employees by the end of fiscal 2024 (2) Completed introduction by June 2024
Continue to conduct legal compliance education and training	(1) Offer all employees a total of 40 GMP educational (e-learning) courses (2) Repeatedly provide employees with GMP education (30 basic classes) for the term of their employment	(1) Completed May 2024 (2) 10 classes/year, one cycle every three years

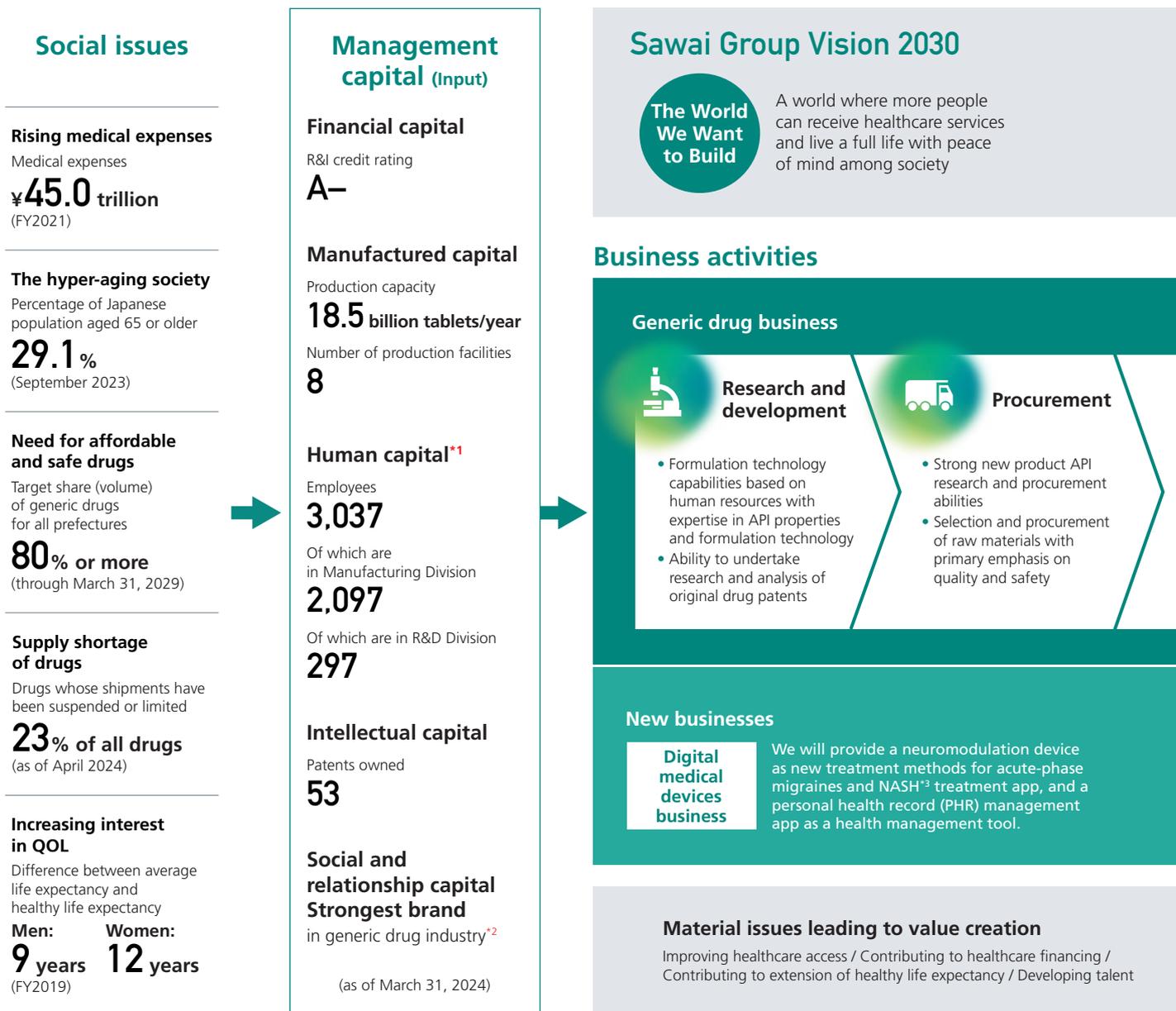
\* The reference rate based on the Approach Toward Securing Workers for Manufacturing Sites set by the Federation of Pharmaceutical Manufacturers' Association of Japan's Quality Committee has already been met

### Reliability Assurance Division

Main topic	Initiatives	Implementation status and frequency
Obtain quality event information in a timely manner from manufacturing sites by digitalizing information and ensuring data integrity	(1) Introduce a quality event management system (QMS) (jointly with the Manufacturing Division) (2) Introduce MES and LIMS (jointly with the Manufacturing Division)	April 2025: Launch deviation and CAPA operations by QMS
Construct a verification system based on legal compliance by third parties regarding decisions of the responsible director and Marketing Director of the Pharmaceuticals	(1) Have Audit & Supervisory Board members attend monthly meetings when the Marketing Director of the Pharmaceuticals (2) Have outside experts attend meetings when the responsible director reports to the Compliance Committee	(1) Once a month (2) Monthly

# Providing high-quality healthcare services to even more people

As the leading generic drug company, we strive to provide a stable supply of high-quality generic drugs and support the healthy lives of people. We are also taking on the challenge of evolving into a general healthcare company by developing new businesses.



<sup>\*1</sup> Total for Sawai Group Holdings, Sawai Pharmaceutical, Medisa Shinyaku, Kaken Shoyaku, and Trust Pharmatech  
<sup>\*2</sup> 14th consecutive year ranked top in approval rating among generic drug companies favored by pharmacists (Research by Nikkei Drug Information)  
<sup>\*3</sup> Non-alcoholic steatohepatitis

### Our Ideal State

A company with a strong presence that continues to contribute to people's health by providing a multifaceted mix of products and services that meet individual needs based on scientific evidence



#### Production and reliability assurance

- Manufacturing know-how for high-mix, low-volume production
- Stringent quality management
- Establishment of a trusted corporate foundation



#### Sales and market

- Provision of accurate information
- Extensive product lineup

#### Health food business

By expanding our business to the pre-symptomatic illness and prevention fields, we will provide products that support longer healthy lives.

#### New drugs business

By making the most of our formulation technology capabilities, we will provide new treatment opportunities, such as those for rare diseases (orphan drugs).

#### Material issues as the foundation of sustainable growth

Environmentally friendly business / Work styles, motivation, and respect for human rights / Corporate governance

### Business results (Output)

Revenue

¥176.9 billion

Operating profit

¥18.6 billion

ROE ROIC

6.6% 4.8%

#### Japan generic drug business

Production volume

15.9 billion tablets

New products

10 products

Patent applications

30

#### New businesses

**Obtained marketing and manufacturing approval**

for the non-invasive neuromodulation device Relivion®

**(first in Japan)**

**Launched phase 3**

clinical trial for NASH<sup>3</sup> treatment app

(FY2023 results)

### Value provided to society (Outcome)

**Improving healthcare access**

Sales volume

**15.7 billion tablets**  
(Sawai Pharmaceutical)

**Contributing to healthcare financing**

Amount of reduction in healthcare costs

**¥293.9 billion**

**Contributing to extension of healthy life expectancy**

Personal health record (PHR) management app

Used by more than

**1,300**  
medical institutions

**Developing talent**

Employee education and training expenses

**¥92.23 million**

# Sawai Group's strengths



## Research and development

R&D expenses

¥ **12.2** billion

Sawai Pharmaceutical

Number of patents held

**53**

Sawai Pharmaceutical

### Strength 1 Formulation technology capabilities based on human assets with expertise in API properties and formulation technology

One of our Group's major strengths is our formulation technology capabilities, one aspect of which is collecting the latest information related to APIs and formulation from throughout the world, and this makes it possible to conduct development in line with ICH Guidelines. Furthermore, we actively take on research that will lead to future development themes and work to accumulate and expand our formulation technology. We also strive to provide drugs that meet the needs of healthcare professionals and patients using SAWAI HARMOTECH®, a series of formulation technologies born from this research.

### Strength 2 Ability to research and analyze patents of original drugs

By utilizing both human assets with extensive experience in patent invalidation trials and proceedings and internal and external patent databases, we implement an extremely advanced patent strategy. We develop the best patent strategy for new issues in collaboration with attorneys who specialize in intellectual property.

In recent years, we have also been keeping an eye on intellectual property trends in the U.S. and Europe and leveraging those trends for our intellectual property strategy in Japan.

#### Initiatives

- Apply SAWAI HARMOTECH® technology to newly developed products
- Conduct joint research on bioequivalence prediction technology with independent research institutes
- Use digital technology to increase operational efficiency
- Increase quality of evaluation technology and test-method development



## Procurement

Suppliers

Procure a wide range of raw materials from around

**500** companies in **30** countries

throughout the world

### Strength 1 Strong new product API research and procurement abilities

As for APIs used in new development, we undertake various activities such as searching for APIs throughout the world and examining production facilities and quality. We also conduct analysis and trial production of pharmaceuticals using samples of these APIs. We use APIs that meet our own standards, which are even higher than those of the Ministry of Health, Labour and Welfare. The API Sourcing Group, whose members have experience at new drug manufacturers and API trading companies as well as knowledge of formulation, provides support for research and procurement as specialists in purchasing.

### Strength 2 Selection and procurement of raw materials with primary emphasis on quality and safety

We confirm that quality management systems meet Sawai standards by inspecting API manufacturer factories and checking that manufacturing is carried out in an appropriate environment and there is appropriate analysis of quality controls. We also release information on the country and factory where APIs are manufactured to provide healthcare professionals with peace of mind. In addition, we actively undertake multisourcing of API in order to ensure stable procurement.

#### Initiatives

- Expand application and screening processes and undertake multisourcing for new application items
- Continue to work to reduce costs in response to rising prices of raw materials, other materials, etc.
- Conduct GMP audits of API manufacturers and manufacturing subcontractors



## Production and reliability assurance

**Production capacity**  
**18.5 billion tablets**  
 Sawai Pharmaceutical

**Number of products approved to manufacture**  
 Approx. **710**  
 Sawai Pharmaceutical

### Strength 1 Manufacturing know-how for high-mix, low-volume production

To produce various types of generic drugs using the same machinery, it is vital to possess the know-how to prevent the mixing of principal ingredients. For tablet presses that form granules into tablets, it takes almost an entire day to switch between products, and Sawai ensures quality by validating each cleaning procedure. This know-how related to specifically validating generic drug production processes and managing production makes it possible to conduct high-mix, low-volume production while ensuring consistent quality.

### Strength 2 Working to become a trusted company

We are working to foster a culture that values legal compliance and quality by designating the third week of each month legal compliance week and providing all employees, including officers of the various Sawai Group companies, with opportunities to continue their study of such topics as the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (PMD Act), GQP/GMP ministerial ordinances, production controls, and quality controls.

We are aiming to become a trusted company by realizing an open, honest organizational culture through compliance education and similar activities.

#### Initiatives

- Increase production to eliminate limits on shipments
- Ensure the construction of new facilities and launch and transfer of production
- Work to improve yields through by scaling up
- Strengthen quality control through systems
- Improve retention rate through aggressive recruiting and expanded education and training



## Sales and marketing

**Number of MRs**  
 Approx. **370**  
 Sawai Pharmaceutical

**Number of products on sale**  
 Approx. **770**  
 Sawai Pharmaceutical

### Strength 1 Provision of accurate information

We provide information to patients and healthcare professionals through the following channels; approximately 370 medical representatives (MRs); the Medical Information Center, an inquiry desk open 24 hours a day, 365 days a year; and a website. As well as providing accurate information to all healthcare professionals, MRs are also responsible for collecting information on the side-effects and safety of drugs and providing feedback to the medical community.

### Strength 2 Extensive product lineup

The lineup of products offered by our Group companies extends to about 770 products. Our ability to not only collect and provide information on various diseases, and in a wide range of fields, but also to broadly meet the treatment policies and needs of healthcare professionals, which is possible because we market numerous products, is another strength of the Sawai Group.

Because of our continuing training for MRs that covers various products, MRs acquire extensive knowledge. Furthermore, it is precisely because of our wide lineup of products that we can propose multiple drugs to treat the same diseases and more concomitant drugs.

#### Initiatives

- Improve the efficiency of visits by promoting area marketing
- Conduct promotion activities for healthcare professionals using a wide range of information provision tools
- Restore and improve trust through sincere, meticulous sales activities
- Build a foundation for stable supply by maintaining product value

## Message from responsible officers

We are implementing numerous ingenious mechanisms to deliver high-quality generic drugs to patients through collaboration among various departments and divisions, including those involved in R&D, intellectual property, reliability assurance, manufacturing, and sales/marketing. Through these initiatives, we will contribute to a stable supply of generic drugs, part of the social infrastructure for an aging society.



### Research & Development Division

#### Aiming to develop high value-added formulations selected by patients and healthcare professionals

In the R&D Division, we are moving forward with creating proprietary formulation and analysis technologies based on the latest science and technology knowledge, with the aim of developing high value-added formulations that are selected by patients and healthcare professionals. Along with reducing development costs through various measures, such as creating formulation evaluation technologies in collaboration with independent research institutes both in Japan and overseas and increasing research efficiency through digitalization, we are promoting the development of formulations suited for stable production with an eye on product life cycle.

The new knowledge and technology obtained from product development leads to more patents. It is also linked to the growth of both researchers themselves and the Company through proactive endeavors such as presenting reports at academic conferences and obtaining academic degrees, as well as through the increased recognition of Sawai's proprietary technology achieved by bringing SAWAI HARMOTECH® and other technologies under one brand.



**Shoji Yokota, Ph.D.**

Director,  
Senior Managing  
Executive Officer,  
Group Chief Research  
& Development Officer



### Intellectual Property Division

#### Adding new technology to Sawai's proprietary formulation technology SAWAI HARMOTECH®

Some time ago, most of the formulation methods for particular GE drugs were patented in line with the management strategy of that time. In recent years, however, there has been a substantial increase in patents for general purpose formulation technology that can be applied to various drugs. We are moving forward with branding this general purpose formulation technology as SAWAI HARMOTECH®, and in fiscal 2023, new tablet printing technology, OD tablet evaluation methods, and other technologies were added to the brand. We are also developing proprietary technology for nitrosamines, a recent hot topic, and have already applied for several patents.

This technology is cutting edge for the times, and we are not only making use of it within our company but also considering collaboration with other companies. I would like to maximize the value of Sawai's intangible assets in this way. Therefore, there is an urgent need to develop human resources who can move these measures forward, and we are working with other divisions to address this issue.



**Nobuko Sugimoto**

Senior Executive Officer,  
Group Chief Intellectual  
Property Officer



### Reliability Assurance Division

#### Working to retrain employees in response to inappropriate testing

Taking the inappropriate testing at the Kyushu Factory seriously, the Reliability Assurance Division is working to provide training on the PMD Act, drug production controls, and quality controls throughout the Company in order to once again raise awareness of laws, ordinances, and the GMP compliance spirit. Furthermore, head office staff discuss the sharing of issues at workplaces and countermeasures during their monthly visits to factories in order to reinforce collaboration between the head office Quality Assurance Department and factories.

At the same time, we are revising our audit methods, such as adding independent GMP/GQP experts to auditors to regain and improve trust in Sawai's overall production process, including API and formulation subcontractors. In addition, we are introducing a system of such activities as event controls, including ones related to deviations and recurrence prevention, and responding to inquiries from healthcare professionals.



**Toshiomi Nakate, Ph.D.**

Executive Officer  
Group Chief Quality & Safety Officer



### Manufacturing Division

#### Expanding and reinforcing facilities to achieve a production capacity of 25.0 billion tablets or more

We are working to reinforce facilities, particularly at the Sawai Pharmaceutical's Daini Kyushu Factory and Trust Pharmatech, in order to achieve the production capacity of at least 25.0 billion tablets stated in our long-term vision. To operate the expanded production facilities under proper quality management, we plan to add more than 100 new workers in fiscal 2024 through new graduate and mid-career hires. We will lower costs and increase production efficiency through such initiatives as introducing quality and production-related systems, improving quality in collaboration with other divisions, and introducing multisourcing for main raw materials.

Through these initiatives, we will construct a system to eliminate generic drug instability and achieve a stable supply of high-quality products, which is one of our major social missions.



**Toshiya Hasuo**

Senior Executive Officer  
Group Chief  
Production Officer



### Marketing Division

#### Working to regain the trust of medical facilities, wholesalers, and retailers

In light of the announcement of inappropriate testing and related administrative sanctions in fiscal 2023, the Sales Division worked to regain trust by apologizing to medical institutions and sincerely explaining our countermeasures.

At the current time when the drug supply remains unstable, there are high expectations for the Company, and we will not only properly communicate our various initiatives to offer a stable supply while maintaining product value but also aim to win high praise as the generic drug manufacturer that makes the greatest contributions to healthcare. To win the trust of medical facilities, wholesalers, and retailers, we will reinforce meticulous sales activities and area marketing and continue to evolve as both a generic drug manufacturer that can make contributions that meet diverse needs and the manufacturer with the top supply of prescription drugs.



**Seiji Nishimura**

Senior Executive Officer  
Group Chief  
Marketing Officer

# Aiming to become a corporate group trusted by stakeholders

## Message from Group Sustainability Committee Chair

Promoting sustainability management that embodies our corporate culture and contributing to the realization of a sustainable society

**Taku Nakaoka** Group Chief Sustainability Officer (Chairman of the Group Sustainability Committee)



We will promote sustainability management that further embodies the corporate culture that has been handed down over the past 90 years, and contribute to the realization of a sustainable society.

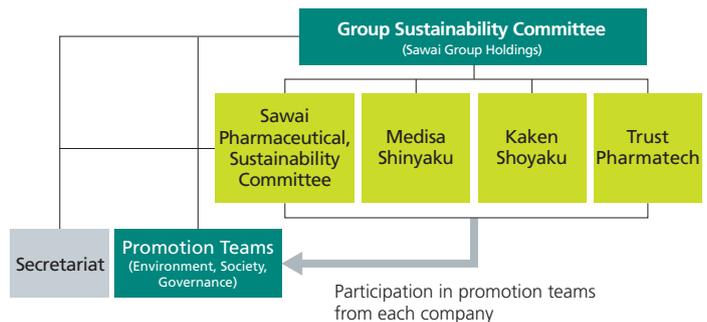
Sawai Pharmaceutical, which has a 90-year history, upholds the corporate philosophy of “Always Putting Patients First.” Sawai Group Holdings, established through a share transfer of Sawai Pharmaceutical, also embraces the philosophy of “Always Putting Healthier Lives First,” with a commitment to improving patients’ health primarily through its generic drug business, and contributing to the healthy lives of families and society as a whole. These corporate philosophies reflect our desire to contribute to the health of many people as a healthcare corporate group that develops sustainably together with society through our daily activities.

With the establishment of Sawai Group Holdings in 2021, we renamed the CSR Committee to the Group Sustainability Committee and established the Group Sustainability Management Office to serve as the committee’s secretariat, leading activities that previously spanned multiple organizations. Under the supervision of the Board of Directors, the Group Sustainability Committee consists of members selected from our company and each group company, and discusses and carries out various related activities, including the unique initiatives of each group company. Specialized teams like the Global Environment Team, Social Contribution Team, and Governance Team, which consist of members from across the company’s organizations, also support these efforts.

Moving forward, we will continue to leverage the collective wisdom and strength of our Group to promote sustainability management that further embodies our corporate philosophy, striving to realize a sustainable society together with our stakeholders.

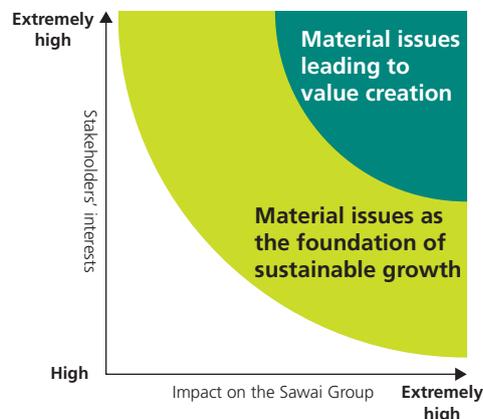
## Sustainability promotion structure

We are promoting initiatives through deliberations of the Group Sustainability Committee, which is composed of representatives of each group company and supervised by the Board of Directors. To undertake practical initiatives, three promotion teams, the Environment (E) Team, Society (S) Team, and Governance (G) Team, subordinate bodies under the committee, were created to conduct related activities. The Secretariat is responsible for assisting the committee, communicating information on sustainability, and supporting the promotion team.



## Process for identifying material issues

The Sawai Group identified its material issues by referring to international guidelines and norms, dialogue with internal and external stakeholders, and the results of external evaluation. These material issues in our sustainability initiatives have been identified and prioritized from two perspectives: stakeholders' interests and the impact on the Sawai Group. In order to update its initiatives to keep them in line with changes in the business environment and emerging social issues, the Sawai Group will check the appropriateness of these material issues through regular review to confirm changes in their impacts and adapt its business activities to those changes.



### Step 1 Creating lists of candidate issues

We held employee workshops, each of which focused on “E”(environmental), “S”(social), or “G”(governance), where the participants created a list of management issues that were considered closely related to the Sawai Group’s medium- to long-term corporate value in line with standards and goals established by international initiatives, including the Sustainability Accounting Standards Board (SASB) Standards, the Global Reporting Initiative (GRI) Standards, and the Sustainable Development Goals (SDGs), as well as the Sawai Group Corporate Philosophy, the Code of Conduct, the Sawai Group Vision, and the status of the business environment.

### Step 2 Identifying issues and assessing their impacts

The candidates for material issues listed in Step 1 were mapped from the two perspectives of stakeholders’ interests and the impact on the Sawai Group, and the issues in each relevant area on the map were categorized into two groups: material issues leading to value creation and material issues as the foundation of sustainable growth.

### Step 3 Verifying appropriateness

Targets, initiatives, and monitoring indicators were defined for each of the identified material issues, and their appropriateness was verified by the Group Sustainability Committee. Subsequently, the Board of Directors discussed and reviewed those issues and granted the final approval for them.

## Topics

### Group Sustainability Committee initiatives when formulating Medium-Term Business Plan Beyond 2027

For the Medium-Term Business Plan, the first year of which is fiscal 2024, the Group Sustainability Committee deliberated for more than six months in order to make sustainability promotion a key pillar. Starting in August 2023, teams responsible for environment, society, and governance were formed and worked to formulate concrete targets. When selecting team members, consideration was given to avoiding any bias in terms of areas of operational responsibility diversity, division, or business location.

As for setting initiative targets, deliberations carefully moved forward, taking into consideration such factors as the opinions of stakeholders inside and outside the company, and targets were set to also reflect the opinions of Group

Sustainability Committee members. There was a focus on setting concrete numerical targets, taking into consideration that the numerical targets in the previous Medium-Term Business Plan were insufficient.

In February 2024, the Group Sustainability Committee approved proposals that brought together all ESG fields, and the Board of Directors incorporated those into part of the Medium-Term Business Plan. The targets, which were deliberated on from various perspectives, are the foundation for promoting sustainability throughout the Company. This fiscal year’s Group Sustainability Committee will also firmly manage progress in implementing these initiatives and continue to work to reach those targets.

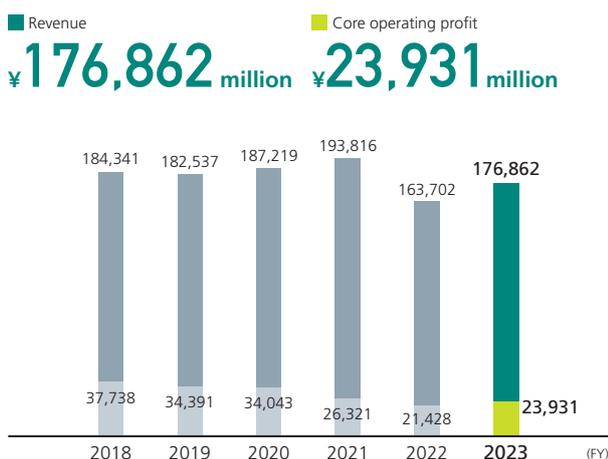
**Material issues and KPI List**

Material issues		Reason for identifying these issues	Our ideal state in 2030
Improving healthcare access	Product quality and safety	Supplying high-quality, safe products based on our corporate philosophy, the goal of which is to achieve healthy lives, is an important responsibility as a pharmaceutical company.	Being highly trusted for the quality and safety of the Group's products because of our control systems and preventive measures.
	Maintaining a stable supply	A stable supply of medicines and, consequently, constant access to medicines for healthcare professionals and patients is the important responsibility of pharmaceutical companies.	Leading the industry by continuing to provide a stable supply of high-quality GE drugs.
Contributing to healthcare financing	Development of high value-added generic drugs	The Company's reason for existence is to contribute to making healthcare financing sustainable through the early launch of high value-added generic drugs.	Being able to launch generic drugs, even those that are difficult to manufacture, ahead of its competitors and deliver those to patients.
Contributing to extension of healthy life expectancy	Expanding business to a wider range of healthcare domains, including pre-symptomatic illness and prevention	We want to achieve sustainable growth by leveraging the strengths acquired through the generic drug business and contributing to solutions to social issues in related fields.	Having a strong presence that continues to contribute to people's health by providing a multifaceted mix of products and services that meet individual needs based on scientific evidence.
Developing talent	Securing production, quality, and R&D talent	Medium- and long-term growth will be achieved by securing and developing talent, which is most important for our business, as the labor force shrinks.	Possessing the talent necessary for sustainable growth and an environment in which anyone can take the initiative to develop their careers, which makes it possible for each individual to make the most of their capabilities and the business to grow.
Environmentally friendly business	Responding to climate change	Limiting climate change is the most important issue humanity faces because of its severity and seriousness.	Holding a position as a leading company in the industry in regard to our initiatives related to climate change and decarbonization.
	Promotion of recycling and the reduction of energy use and waste	To build a sustainable future, we consider it necessary to contribute to the realization of a circular society and make effective use of and recycle resources.	Spreading and implementing the idea of a circular economy within the Group.
	Water use reduction	The use of water, which is indispensable for life, is one of the main environmental burdens caused by our business activities, and there is a need to reduce it.	Continually reducing water usage through such initiatives as introducing water-saving equipment and improving operation procedures.
	Conservation of biodiversity	Recognizing that biodiversity provides various benefits, we consider promoting nature-positive initiatives important for business continuity.	Possessing an awareness of biodiversity preservation throughout the Group with employees actively taking part in related initiatives.
Work styles, motivation, respect for human rights	Promoting inclusion, diversity and equity (ID&E)	We consider fostering a corporate culture in which various values and backgrounds are accepted as an important element for the growth of the company and the individual.	Possessing a workplace environment in which diversity is respected and employees can energetically contribute.
	Improving employee engagement	Under our human resources philosophy, we value the individuality and creativity of each employee and strive to enhance employee engagement.	Maintaining high engagement with employees and having all employees satisfied with both work and the company.
	Working on human rights due diligence	As a healthcare company deeply linked to life, we believe that giving consideration to the human rights of all stakeholders is an important responsibility.	Continuing to not violate human rights throughout the supply chain, including our own company.
Corporate governance	Enhancing risk management and compliance	As a company that handles drugs, which are products linked to life, we must ensure high ethics and business continuity.	Promoting business activities in which all officers and employees have a strong sense of ethics and responsibility and maintaining zero compliance violations.
	Enhancing supply chain management	We consider it important to share ESG-related social issues with business partners and jointly tackle those issues.	Having firmly rooted sustainability activities carried out in collaboration with business partners.
	Strengthening information security	It is important to build a system to fully protect and manage information related to our company and stakeholders.	Continuing to have zero incidents as a result of having constructed a security system that eliminates information leaks and cyberattacks.
	Ensuring the reliability of non-financial information	We consider ensuring the reliability of both financial and non-financial information indispensable for enhancing our corporate value.	Having all disclosed non-financial information certified by a third party.

	Main issues and objectives for FY2023	Indicators and FY2023 results	Medium-Term Management targets (end of fiscal 2026)
	<ul style="list-style-type: none"> <li>Have the Quality Assurance Department conduct GMP audits of API and formulation manufacturers</li> <li>Build a quality management system for medical devices</li> </ul>	<ul style="list-style-type: none"> <li>Number of audits of API and formulation manufacturers: 92</li> <li>Created medical device procedure manual and conducted QMS education</li> <li>Established GMP Audit Office within the Quality Assurance Department in January 2024</li> </ul>	<ul style="list-style-type: none"> <li>Introduce a system and fortify the personnel structure to establish reliability assurance system</li> <li>Complete introduction of Quality Event Management System (QMS) no later than fiscal 2024</li> </ul>
	<ul style="list-style-type: none"> <li>Aim to soon establish an in-house production system with a production capacity of 20.0 billion tablets or more</li> <li>Construct solid dosage form at facility at Daini Kyushu Factory</li> <li>Move forward with introducing multisourcing and procurement from multiple manufacturers</li> </ul>	<ul style="list-style-type: none"> <li>Company production capacity: 18.5 billion tablets</li> <li>Sales volume: 15.7 billion tablets (17.1% share of the Japan GE market)</li> <li>Capital expenditures to raise production capacity: ¥18.6 billion</li> </ul>	<ul style="list-style-type: none"> <li>Update top-level production capacity equipment in Japan</li> <li>Company production capacity: 22.0 billion tablets or more (increase Daini Kyushu Factory's solid dosage form capacity to 3.5 billion tablets)</li> </ul>
	<ul style="list-style-type: none"> <li>Be the first to launch products and solely market products through an advanced patent strategy and formulation technology capabilities</li> </ul>	<ul style="list-style-type: none"> <li>R&amp;D expenses: ¥12.2 billion</li> <li>Launched three ingredients and 10 items, including two competitive ones</li> </ul>	<ul style="list-style-type: none"> <li>Continue to make top-tier R&amp;D investments in the generics industry (for the development of new products and the improvement of existing products)</li> <li>Planning to launch 44 or more new products over three years</li> </ul>
	<ul style="list-style-type: none"> <li>Obtain manufacturing and marketing approval for the neuromodulation device</li> <li>NASH treatment app: Conduct phase 3 clinical trial</li> <li>PHR management app: Encourage its adoption as part of initiatives targeting corporate health insurers, municipalities, and regional healthcare networks</li> </ul>	<ul style="list-style-type: none"> <li>Obtained manufacturing and marketing approval for Relivion® in December 2023</li> <li>Launched phase 3 clinical trial for NASH in January 2024</li> <li>Adopted by multiple municipalities and regional healthcare networks (adopted by 1,340 medical facilities as of April 30, 2024)</li> </ul>	<ul style="list-style-type: none"> <li>Having digital medical devices (neuromodulation device and NASH treatment application) and PHR management application begin to contribute to earnings</li> </ul>
	<ul style="list-style-type: none"> <li>Conduct aggressive hiring to secure production and quality control talent, an urgent issue</li> <li>Develop workplace environments and improve work conditions</li> </ul>	<ul style="list-style-type: none"> <li>New graduate and mid-career hires: 227</li> <li>Introduced in-house recruitment and in-house dual job system and established career consulting desk</li> </ul>	<ul style="list-style-type: none"> <li>Strengthening capability to recruit new graduates and mid-career workers</li> <li>Establishing attractive working conditions that are mindful of the work environment</li> <li>Appointing and utilizing diverse talent such as women and the elderly</li> </ul>
	<ul style="list-style-type: none"> <li>Consider introducing solar power equipment at each factory</li> <li>Have environmental data such as CO<sub>2</sub> emissions verified by a third party and formulate calculation rules</li> </ul>	<ul style="list-style-type: none"> <li>CO<sub>2</sub> emissions: 69,752 t-CO<sub>2</sub></li> <li>Completed third-party verification of fiscal 2022 data</li> <li>Expanded TCFD recommendations to Trust Pharmatech</li> </ul>	<ul style="list-style-type: none"> <li>Compared to FY2013+α level, 46% reduction of total emissions volume (FY2030)</li> </ul>
	<ul style="list-style-type: none"> <li>Separate each material that consists of PTP sheet waste material and start to recycle said material</li> <li>Disclose waste plastic reduction plan</li> </ul>	<ul style="list-style-type: none"> <li>Recycled 11.1 t of PTP sheet waste material, reducing CO<sub>2</sub> emissions to 28.13 t/CO<sub>2</sub>t</li> </ul>	<ul style="list-style-type: none"> <li>Waste plastic recycling rate of 65% or more (FY2030)</li> </ul>
	<ul style="list-style-type: none"> <li>Set water usage reduction targets</li> <li>Reduce factory water usage by at least 1% year on year in terms of intensity-per-unit-production</li> </ul>	<ul style="list-style-type: none"> <li>Water usage intensity: 14.4</li> </ul>	<ul style="list-style-type: none"> <li>3% reduction of water usage intensity (compared to FY2023)</li> </ul>
	<ul style="list-style-type: none"> <li>Agree to the Declaration of Support for Osaka Biodiversity</li> <li>Participate in conservation activities targeting "Itasenpara" bitterling, a Yodo River endangered species</li> </ul>	<ul style="list-style-type: none"> <li>Participants in Yodo River "Itasenpara" bitterling conservation activities: 27</li> </ul>	<ul style="list-style-type: none"> <li>Consideration and start of content on TNFD-related initiatives</li> </ul>
	<ul style="list-style-type: none"> <li>Establish the ID&amp;E Promotion Office</li> <li>Provide management team members with training in the promotion of women's active engagement.</li> </ul>	<ul style="list-style-type: none"> <li>Ratio of women in managerial positions: 8.33%</li> <li>Men's utilization of childcare leave: 37.3%</li> <li>Percentage of employees with disabilities: 2.60%</li> </ul>	<ul style="list-style-type: none"> <li>Ratio of women in managerial positions: 15% or more</li> <li>Men's utilization of childcare leave: 100%</li> <li>Percentage of employees with disabilities: 2.85%</li> </ul>
	<ul style="list-style-type: none"> <li>Set employee engagement targets</li> <li>Introduce a permanent work-from-home system to enable diverse workstyles</li> </ul>	<ul style="list-style-type: none"> <li>Employee engagement indicator score: 4.17 (FY2022)</li> </ul>	<ul style="list-style-type: none"> <li>Employee engagement indicator score: 4.50</li> </ul>
	<ul style="list-style-type: none"> <li>Provide e-learning training to all employees to prevent harassment, which is a human rights risk</li> </ul>	<ul style="list-style-type: none"> <li>Considered future initiatives related to respecting human rights</li> </ul>	<ul style="list-style-type: none"> <li>Reinforcing human rights due diligence at business partners</li> <li>Initiatives to spread awareness of the importance of respecting human rights within the company</li> </ul>
	<ul style="list-style-type: none"> <li>Hold Group Compliance Committee meetings</li> <li>Provide compliance training through e-learning</li> </ul>	<ul style="list-style-type: none"> <li>Number of Group Compliance Committee meetings: 9</li> <li>Number of compliance-related e-learning sessions offered: 4 (There were also five classes on GMP and PMD Act during the second half)</li> </ul>	<ul style="list-style-type: none"> <li>Reinforcing the Risk Management Committee and the Compliance Committee</li> </ul>
	<ul style="list-style-type: none"> <li>Consider ways to collaborate with all members of the supply chain and understand their current state</li> </ul>	<ul style="list-style-type: none"> <li>Prepared for understanding the current state of ESG activities at business partners through our business partner questionnaire</li> </ul>	<ul style="list-style-type: none"> <li>Enhancing supply chain management</li> </ul>
	<ul style="list-style-type: none"> <li>Provide information security managers and staff with training by external experts</li> </ul>	<ul style="list-style-type: none"> <li>Introduced a quarantine system to detect and quarantine unauthorized terminals, which started operating in December 2023</li> </ul>	<ul style="list-style-type: none"> <li>Expanding SAWAI CSIRT system</li> <li>Reinforcing cyber risk countermeasures</li> <li>Automating incident response</li> </ul>
	<ul style="list-style-type: none"> <li>Conduct third-party verification of environmental data</li> </ul>	<ul style="list-style-type: none"> <li>Number of offices where onsite verifications were made: 3 (Sanda Factory, Head Office, and Research lab)</li> </ul>	<ul style="list-style-type: none"> <li>Document the calculation process for non-financial information and conduct risk assessment</li> </ul>

# Financial highlights

## Revenue / Core operating profit

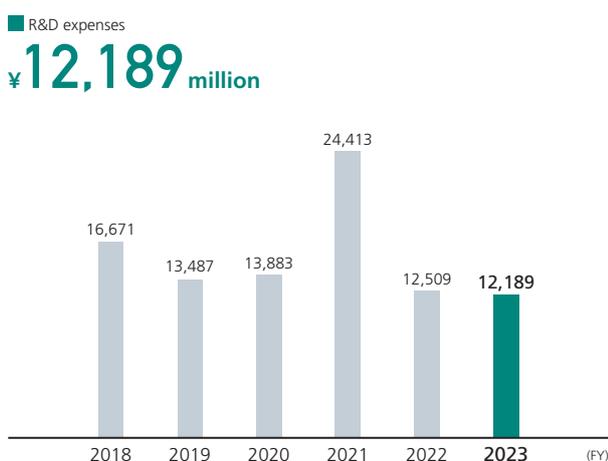


**Revenue:** Revenue rose 8.0% year on year because of an increase in sales of products launched in fiscal 2022 or later and cost pass-throughs, particularly for low-priced drugs.

**Core operating profit:** Core operating profit rose 11.7% year on year as a result of increased revenue and revised distribution pricing policy despite greater costs.

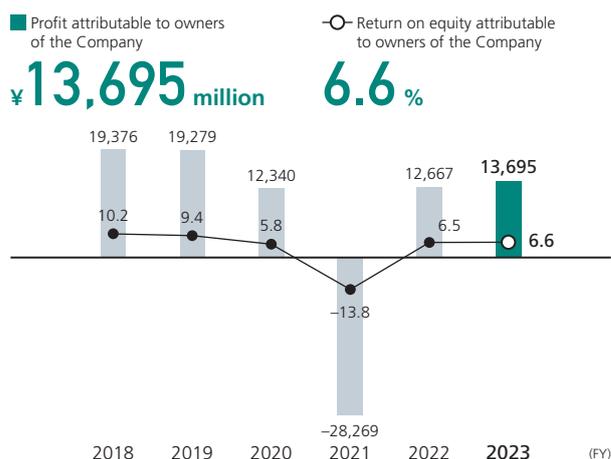
Note: Fiscal 2022 and fiscal 2023 figures are for continuing businesses, excluding discontinued business

## R&D expenses



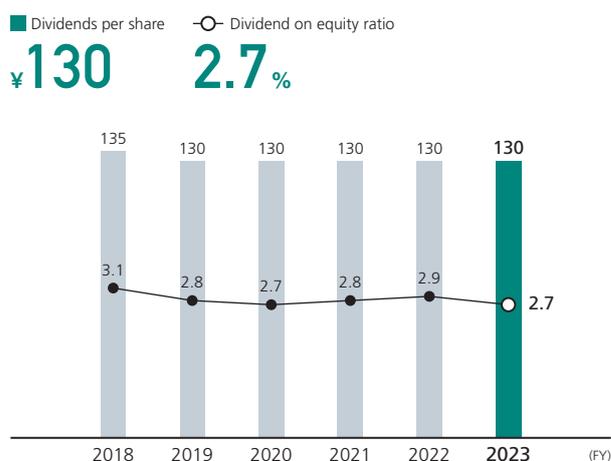
The Sawai Group continued to invest aggressively in research and development in order to be first to market with new products that will differentiate us from our competitors to achieve future growth.

## Profit attributable to owners of the Company / Return on equity attributable to owners of the Company



Both operating profit and profit attributable to owners of the Company rose as a result of increased revenue from the Japan business and our efforts to maintain our cost ratio due to pricing policies. Contributions to profit from the discontinued US business were about the same as those for the previous fiscal year.

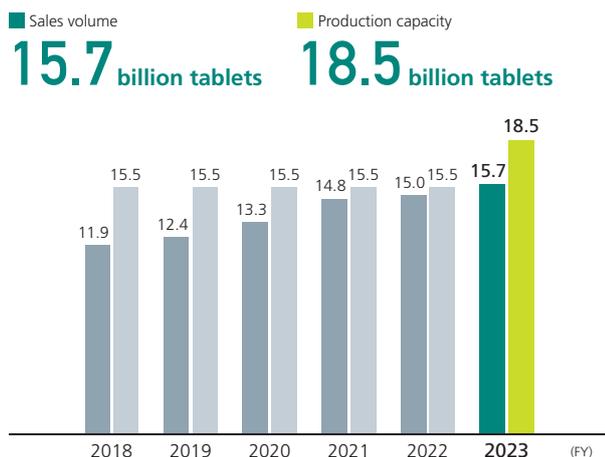
## Dividends per share / Dividend on equity ratio



In the new Medium-Term Business Plan announced in June 2024, we set forth the policy of providing stable and continuous dividends, taking into account overall medium- to long-term profit levels, DOE, etc. In fiscal 2023, the Company provided an annual return to shareholders of ¥130 per share.

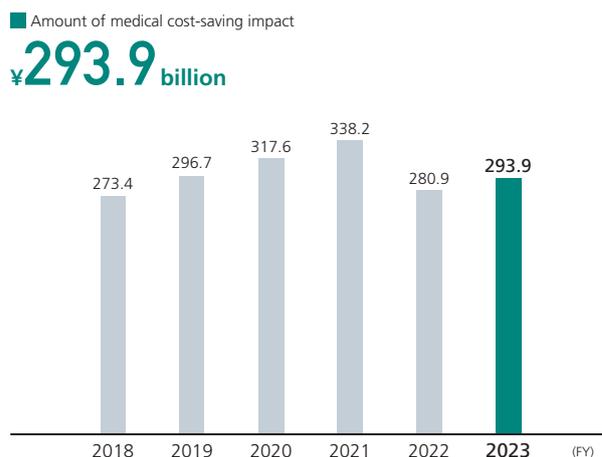
# Non-financial highlights (Scope of data: Sawai Pharmaceutical)

## Sales volume / Production capacity



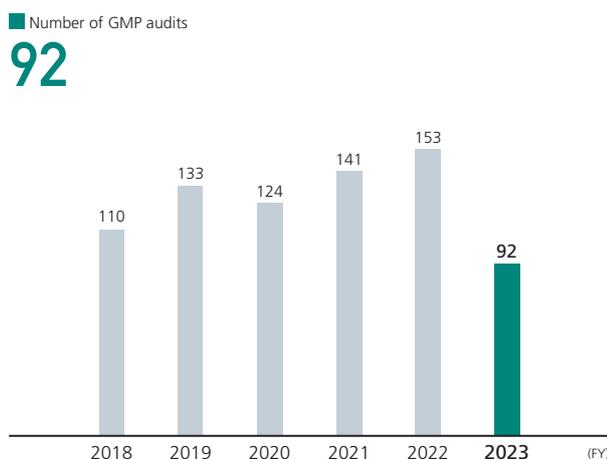
The Group's ability to supply a relatively large number of top quality generic drugs is backed by our industry-leading production capacity. Production capacity increased 3.0 billion tablets year on year as Trust Pharmatech started operations.

## Amount of medical cost-saving impact



The Sawai Group's greatest contribution to society lies in increasing the sustainability of the health insurance system by reducing the burden of medical expenses through the supply of generic drugs. While the difference between the price of long-listed drugs whose patents have expired and that of generic drugs is shrinking, our generic drugs contributed to healthcare cost savings of about ¥290.0 billion, which still substantially exceeds our revenue.

## Number of GMP audits



Sawai Pharmaceutical has formed a dedicated audit team, which performs more than 100 GMP audits a year on average. The number of audits conducted each fiscal year fluctuates within a certain range, as the year for the next audit is determined based on the results of the previous audit. As the number of products manufactured and marketed grows, the number of audits at new manufacturing sites has increased annually, and remote audits and commissioned audits by independent parties have been used to cover the increase.

## CO<sub>2</sub> emissions



Despite our having started to purchase non-fossil CO<sub>2</sub>-free electricity in fiscal 2023, there has been an upward trend for various reasons, including increased operating rates at Group offices.

# Formulating the New Medium-Term Business Plan "Beyond 2027" to Achieve the Sawai Group Vision 2030

## Establishing a trusted corporate foundation and aiming for further growth

The Company announced its new Medium-Term Business Plan in June 2024. In addition to paving a path to achieve our long-term vision based on “establishing a trusted corporate foundation,” we will concentrate management resources on quality assurance and production capacity enhancement in the generics business.

Management Plan Overview	START 2024 FY2021–2023	Medium-Term Business Plan Beyond 2027 FY2024–2026	Sawai Group Vision 2030
	<b>Review</b> <ul style="list-style-type: none"> <li>Expanding share in the Japanese generics market</li> <li>Withdrawing from the U.S. business</li> <li>Cultivating new growth areas</li> </ul>	<b>Plan Summary</b> <ul style="list-style-type: none"> <li>Establishing a position as a trusted company</li> <li>Steadfastly capturing opportunities and establishing sustainability in the generics business</li> <li>Reviewing our business portfolio and capital policy to promote business management focused on related KPIs</li> </ul>	<b>The world we want to build</b> A world where more people can receive healthcare services and live a full life with peace of mind among society  <b>Our ideal state</b> A company with a strong presence that continues to contribute to people's health by providing a multifaceted mix of products and services that meet individual needs based on scientific evidence
<b>Revenue (consolidated)</b> 	176.9 23.9 FY2023 (result)	Revenue ¥220.0 billion Core operating profit ¥33.0 billion FY2026 (target)	310.0 FY2030 (target)*
<b>Revenue (Generics business)</b>	¥176.9 billion	¥219.0 billion	¥300.0 billion
<b>Revenue (New business)</b>	¥0.01 billion	¥1.0 billion	¥10.0 billion
<b>Operating profit</b>	¥18.6 billion	¥31.0 billion	–
<b>Share in the generics market / Sales volume (Generics business)</b>	17.1% / 15.7 billion tablets	20.5% / 19.0 billion tablets	25.0% or above / 24.0 billion tablets
<b>In-house production capacity</b>	18.5 billion tablets	22.0 billion tablets	25.0 billion tablets or more
<b>ROE</b>	6.6%	10% or above	13% or above
<b>ROIC</b>	4.8%	8% or above	10% or above
<b>Net DE ratio</b>	0.27	0.4 or below (benchmark)	–
<b>Shareholders' equity to total assets</b>	55.7%	50% or above (benchmark)	–
<b>DOE</b>	2.7%	3.0% or above	–

\* Revised June 2024

## Overview of previous Medium-Term Business Plan Start 2024

During the first three years of our efforts to realize our long-term vision, we worked to expand our share in the Japanese generics market, make business investments for future growth in the U.S., and cultivate new growth areas.

For the Japanese generics business, there have been both positive and negative developments. Even so, we increased production volume by further reinforcing our production system and succeeded in becoming at times the first and at times the only generic drug company to launch certain generic drugs. Our market share increased by 1 percentage point, and revenue, EPS, ROE, and ROIC also improved. On the other hand, we withdrew from the U.S. business in general. As for new businesses, we launched the challenge of entering fields in which we can leverage the strengths we have acquired in our existing businesses.

### Qualitative review of START 2024

<b>Japanese generics business</b>	<ul style="list-style-type: none"> <li>• Non-compliance with GMP in the stability monitoring of Teprenone Capsules 50mg “Sawai”</li> <li>• Increase in production volume due to the strengthened system for increased production at our existing factories and partner companies</li> <li>• A better outlook for early establishment of our own production system with an annual capacity of 20.0 billion tablets or more</li> <li>• Revised distribution pricing policy to realize a long-term stable supply</li> </ul>
<b>U.S. business</b>	<ul style="list-style-type: none"> <li>• In April 2024, withdrew, in principle, from the U.S. business, for which return on capital has fallen short of the cost of capital, mainly due to large impairment losses recorded in FY2021</li> </ul>
<b>New businesses</b>	<ul style="list-style-type: none"> <li>• Started taking on the challenge of new businesses that leverage the strengths we have acquired in existing businesses in order to achieve the government’s goal of a society with healthy longevity</li> </ul>

## New Medium-Term Business Plan and 2030 Long-term Vision

### Beyond 2027 (FY2024–FY2026) key themes

In the new Medium-Term Business Plan, we have set a total of six key themes, which are grouped into business strategy and business foundation, and positioned “establishing a trusted corporate foundation” as the basis for all we do.

Through the business strategy, we aim to increase new product sales by developing items that offer a competitive advantage using our advanced formulation technology and launching them exclusively. We will continue to strengthen our ability to provide a stable supply. Furthermore, we will work to export Sawai generics to China and ASEAN member countries.

As for business foundation, we will strive to secure and develop diverse human resources, who are essential to the growth strategy, while also reducing our CO<sub>2</sub> emissions and implementing additional reforms to corporate governance. To improve capital efficiency, we will also transition from management focused on profit and loss to management that is conscious of the cost of capital, and we will work to improve management so that we can meet our shareholders’ expectations.

#### Key themes for business strategy

- 1 Achieving steady growth in the generics market
- 2 Establishing sustainability of the generics business
- 3 Continuing investment in growth areas

#### Key themes for business foundation

- 1 Creating talent that underpins sustainable growth
- 2 Working on sustainability initiatives
- 3 Improving capital efficiency

### Establishing a trusted corporate foundation

### Achieving the Sawai Group Vision 2030

To play a leading role in the generic drugs industry into the future, we will work over the next three years to build a system that enables us to respond to potential changes in the structure of the industry, to strengthen our cost competitiveness, and to improve capital efficiency. In addition, we consider reinforcing human capital, the source of value creation, the most important issue for achieving that, and we are implementing related initiatives.

As the generic drug manufacturer with top sales of 24.0 billion tablets, we are an indispensable part of Japan’s social infrastructure and have a social responsibility to fulfill. Furthermore, we will contribute to solutions to social issues and the development of society by providing products and services, including those in the field of disease prevention and diagnosis.

### Initiatives to achieve long-term vision

<b>Japanese generics business</b>	<ul style="list-style-type: none"> <li>• Establishing a sustainable business model</li> <li>• Establishing a reliability assurance system and improving compliance and governance</li> <li>• Increasing the utilization of our production facilities (in which we have already invested) to quickly eliminate drug supply shortage and to further drive our growth, and further expanding our production capabilities</li> <li>• Steadily developing and launching new products to support our growth</li> <li>• Further reducing costs and creating production capacity</li> <li>• Continuously implementing the pricing policy to achieve a long-term stable supply and implementing cost control</li> <li>• Promoting collaboration and cooperation with other companies</li> </ul>
<b>New businesses</b>	<ul style="list-style-type: none"> <li>• Taking ongoing measures to quickly monetize each business</li> </ul>
<b>Financial capital policy</b>	<ul style="list-style-type: none"> <li>• Increasing ROE by improving capital efficiency</li> </ul>
<b>Sustainability efforts</b>	<ul style="list-style-type: none"> <li>• Strengthening human capital, which is a main source of our value creation</li> </ul>

## Japanese generics business



### Motohiko Kimura

Senior Managing Executive Officer  
Representative Director and President of  
Sawai Pharmaceutical Co., Ltd.

## Striving to build a system for achieving both a stable supply of generic drugs and our own sustainable growth

### Review of the first year as president Simultaneously addressing inappropriate testing and strengthening production capacity

I would like to express my deepest apologies to all related parties for the substantial problems caused by the inappropriate stability monitoring dissolution testing of Teprenone Capsules 50mg “Sawai” at Sawai Pharmaceutical’s Kyushu Factory that was discovered in April 2023.

This incident came to light just as I took up the position of president, and since then, I have addressed it through such steps as conducting an in-house investigation, disclosing the results of the investigation outside the Company, providing explanations to business

partners and other parties, and holding dialogues with employees. We are now making steady progress in implementing recurrence prevention measures in order to regain trust as soon as possible.

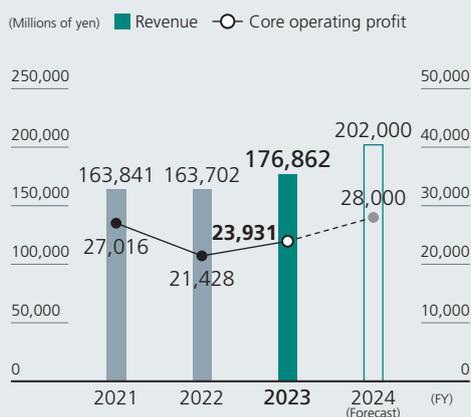
At town hall meetings held as part of recurrence prevention measures, I communicated my honest opinion to employees in the various departments and answered numerous questions. Since moving from Senior Vice President of the Manufacturing Division to President, I have uncovered issues related to conditions at several divisions, including the Reliability Assurance Division, Research & Development Division, and Marketing Division, by gathering information, and I am working to resolve those problems while incorporating ideas from the workplace into management.

At the same time, we worked to enhance production capacity to eliminate the generic drug supply shortage through two initiatives. The first was the launch of Trust Pharmatech, which was planned since I was Senior Vice President of the Manufacturing Division and involved the transfer of Kobayashi Kako production facilities and 400 employees. The second was the construction of a new

### SWOT analysis

<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>• Brand strength as top manufacturer</li> <li>• Stable financial base</li> <li>• Strengthened production capacity following quick investments</li> <li>• Development of capabilities that enabling us to launch products first and exclusively</li> <li>• Growing share of high value-added products</li> </ul>	<p><b>Weaknesses</b></p> <ul style="list-style-type: none"> <li>• Securing and developing talent that can handle growing production capacity</li> <li>• Constraints on productivity due to high-mix, low-volume production</li> </ul>
<p><b>Opportunities</b></p> <ul style="list-style-type: none"> <li>• Chance to reorganize the generic drug industry</li> <li>• Growing demand due to advance of aging society</li> <li>• Growing healthcare and medical needs</li> <li>• Generic drugs as social infrastructure</li> <li>• Company scoring system that promotes sales at reasonable prices</li> </ul>	<p><b>Threats</b></p> <ul style="list-style-type: none"> <li>• Increase in launch of AGs</li> <li>• Lower reliability due to generic drug supply instability</li> <li>• Growing raw material and utility costs</li> <li>• Lower NHI drug prices due to annual drug price revisions</li> <li>• Changes in various systems</li> </ul>

### Revenue / Core operating profit



### Medium- and long-term quantitative targets (Generic drug business)

	FY2023 results	Beyond 2027 targets	Sawai Group Vision 2030 targets*
<b>Revenue</b>	¥176.9 billion	<b>¥ 219.0 billion</b>	¥300.0 billion
<b>Generics market share/Sales volume</b>	17.1% / 15.7 billion tablets	<b>20.5% / 19.0 billion tablets</b>	25.0% or more / 24.0 billion tablets
<b>In-house production capacity</b>	18.5 billion tablets	<b>22.0 billion tablets</b>	25.0 billion tablets or more

\* Revised June 2024

solid dosage form facility at Daini Kyushu Factory. Because both projects progressed as planned, we increased our production capacity by 5.0 billion tablets. However, as of May 13, 2024, there continued to be limited shipments of 249 items, and thus we still have a responsibility to meet the expectations placed on Sawai Pharmaceutical to dramatically improve the situation and provide a stable supply.

### Bright signs as pricing policy and interdepartmental collaboration boost business results

In fiscal 2023, our Japan generic drug business revenue rose 8.0% year on year due to growth in sales of products launched since fiscal 2022. In addition, core operating profit increased 11.7% year on year despite the impact of higher energy and sales costs.

The improved business results are due to increased revenue, the revised distribution pricing policy, and implementation of a pricing policy that reflects increased costs into the wholesale acquisition cost, particularly for low-priced items.

As for the pricing policy, the Marketing Division has spearheaded earnest negotiations to win the understanding

of business partners. On the other hand, even after the inappropriate testing was discovered, the Manufacturing Division not only conducted normal production but also worked hard on future-oriented activities, including collaborating on the launch of Trust Pharmatech and addressing construction of the new solid dosage form facility at the Daini Kyushu Factory. Furthermore, with the 2024 drug pricing reforms, there were special increases in the price of unprofitable drugs\* based on requests by companies for recalculation in response to the sudden rise in raw material prices and stable supply problems. Our head office tenaciously negotiated with government authorities regarding the recalculated prices and the Manufacturing Division compiled and provided the data necessary for those negotiations. In this way, the Marketing Division, Manufacturing Division, and head office departments were able to work together, just like a well performing orchestra, and I think this facilitated the fiscal 2023 business results.

However, one issue that we face is the increase in raw material prices, which is likely to continue for a while. There are limits to the extent that cost increases can be

covered by cost cuts through increased productivity, which means we will have to continue to implement pricing policies. Furthermore, we will work to ensure earnings by increasing production capacity and launching better products at the right time.

\* These are prescription drugs for which the Ministry of Health, Labour and Welfare determines it is appropriate to raise or maintain the current NHI drug price because its price is clearly low despite its importance for healthcare.

### Steadily implementing recurrence prevention measures and focusing on talent and system development to restore trust

It is important to reform our corporate culture to ensure that recurrence prevention measures take root and avoid such incidents as inappropriate testing from occurring again. One such recurrence prevention measure is the Corporate Culture Reform Project, a project directly under the supervision of the President. Project-related information, including its progress, is also available on the Sawai Pharmaceutical website at all times. Furthermore, I explain to all business partners and other stakeholders I meet the progress we have made in implementing recurrence prevention measures.

At town hall meetings, a venue for direct dialogue with employees, I have explained to MRs, who communicate with medical institutions, our progress with production workplace improvements and recurrence prevention measures. MRs use this information to answer questions from medical institutions.

It is necessary to properly develop talent and systems to prevent recurrences. As for system development, the R&D Division is moving forward with optimizing high-mix, low-volume production and further improving quality, starting with high-priority products.

In my opinion, one of the reasons for the inappropriate testing was that work and knowledge depended on particular individuals. Therefore, we are moving forward

with digital transformation both to prevent incidents such as the inappropriate testing from occurring by ensuring work does not become dependent on a particular individual, and to improve production and quality efficiency. For example, in the new facility of the Daini Kyushu Factory, we introduced a system that automatically enters data from analysis equipment and makes necessary calculations, eliminating human involvement as much as possible. We will gradually introduce this system into other factories. At the Kanto factory, where it has already been introduced, this system has eliminated mistakes and improved test efficiency, leading to stable operations. A similar DX is underway in the Quality Assurance Department, and we plan to quickly introduce a quality control system that makes it possible to visualize progress with such operations as deviation management and CAPA in fiscal 2024.

We will only restore trust when our efforts have won the praise of outside stakeholders. As we are now still on the path to restoring trust, we must make our efforts to



Webpage to check progress [https://www.sawai.co.jp/important\\_news/detail/17](https://www.sawai.co.jp/important_news/detail/17) (Available only in Japanese)



Townhall meeting

## Generic drug industry environment

### Social issues

<b>Rising medical expenses</b> Medical expenses <b>¥45.0 trillion</b> (FY2021)	<b>Hyper-aging society</b> Percentage of Japanese population aged 65 or older <b>29.1 %</b> (September 2023)	<b>Need for affordable and safe drugs</b>	<b>Drug shortage</b>
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### Quantitative targets and outline of the drug pricing system reform in April 2024

<b>Quantitative targets</b> <b>Primary</b> — To achieve a volume share of <b>80% or more for generics in all prefectures</b> by the end of FY2029 <b>Secondary</b> — <ul style="list-style-type: none"> <li>To have the number of components replaced over 80% by biosimilars constitute <b>more than 60% of the total components</b> by the end of FY2029</li> <li>To achieve a value share of <b>65% or more</b> for generics by the end of FY2029</li> </ul>	<b>Raising NHI drug prices of unprofitable drugs</b> <b>Repricing of unprofitable products</b> — To raise NHI drug prices of unprofitable products as requested by companies exceptionally in response to soaring costs and supply issues <b>Essential medicines</b> — To relax requirements for eligible products from 25 years to <b>15 years</b> after listing
<b>Company scoring system</b> A system to enhance transparency in companies' supply systems, etc., and to provide preferential treatment in drug pricing to companies with capability and track record	<b>Selective treatment</b> A system under which a patient pays a portion (one-fourth) of the difference in drug price between a generic drug and a long-listed drug when choosing a long-listed drug that is eligible for selective treatment.

continue to firmly implement recurrence prevention measures and communicate those results to parties outside the Company. In an emergency, what you do in normal times will come into play. After returning to normal times, it is important to continue to maintain our determination to prevent such an incident from ever occurring again.

### Taking the lead to establish a trusted corporate foundation and generate business growth

At the start of the Medium-Term Business Plan START 2024 in 2021, the generic drug business was in a precarious position because of annual drug price revisions. Looking back at that time, we made progress with enhancing the production system as planned, and we were able to boost earnings to a certain extent. Furthermore, we saw positive signs for the future in the final year for various reasons, including having introduced pricing policies to achieve a long-term stable supply and having our opinions reflected in price recalculations for unprofitable items.

In the new Medium-Term Business Plan Beyond 2027, which was announced in June 2024, we position the period of the plan as a time to concentrate management resources to ensure quality and expansion of production capacity, and to establish a system for growth in the current Medium-Term Business Plan and great strides in the next. We will make the next round of investments to improve productivity at Trust Pharmatech and respond to further increases in demand at the Daini Kyushu Factory with an eye toward increased production capacity of 3.5 billion tablets, compared to the initially planned 3.0 billion tablets, resulting in overall production capacity of 22.0 billion tablets. It is necessary, however, to enhance production capacity even more in order to increase our share of the Japan generic drug market from the current approximate 17% to our target of 25% or more by fiscal 2030. In addition to our own production, we will likely examine flexibly partnering and collaborating with other generic drug companies.

Another important topic is the steady development and launch of new products. A medium- and long-term



strategy that includes a patent strategy for R&D is critical, as the usage ratio of generic drugs has reached more than 80% and development of new products is becoming more difficult. When it comes to decisions regarding what to develop and launch, rather than having individuals make them, I believe that it is important that we make them systematically by sharing and organizing our development portfolio within the organization.

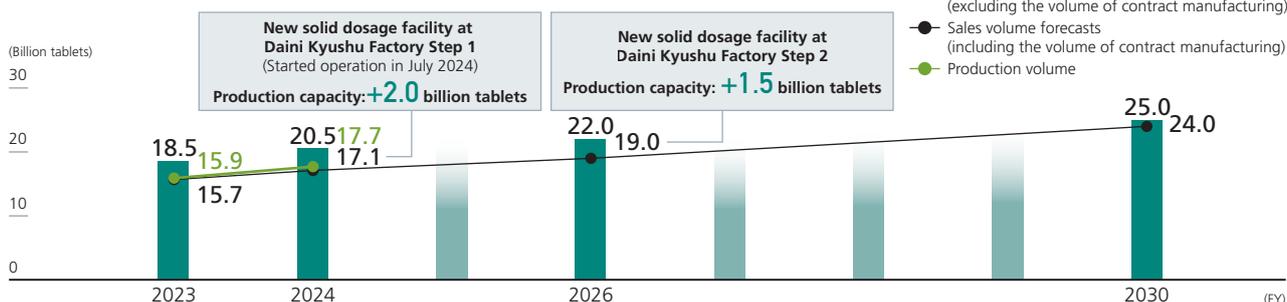
To achieve that, the most important measure is securing and developing talent, and in the new Medium-Term Business Plan, we have positioned “creating talent that supports sustainable growth” as a key theme. We are focusing on securing talent by strengthening recruiting, as well as making efforts to retain employees, including introducing a mentor system and reviewing personnel allocations at factories. To raise the level of young employees, it is important to improve compensation. We must also be thorough about providing education, particularly GMP and compliance education.

The period of the new Medium-Term Business Plan is an important one for putting us on the path to achieve our long-term vision, the Sawai Group Vision 2030. With myself leading the way, we will raise the morale of employees and move forward to both establish a trusted corporate foundation and generate business growth.

### Motoshiko Kimura

Senior Managing Executive Officer  
Representative Director and President  
of Sawai Pharmaceutical Co., Ltd.

### Expanding in-house production capacity toward FY2030



Note: For the current number of items, it is assumed that the machines are kept running in two shifts per day on weekdays for the current number of items. Contract manufacturing is not included.

# New businesses

In addition to the core generic drug business, we are working to develop new businesses such as digital and medical devices with the aim of achieving sustainable growth for the Group. As a general healthcare corporate group that helps ensure healthy lives, we continue to take on the challenge of contributing to people’s health from the field of pre-symptomatic illness and prevention to the field of treatments to expand the range of new options beyond drug therapy.

## 1. Non-invasive neuromodulation device, Relivion®

### First in Japan to obtain marketing and manufacturing approval as a medical device for treatment of migraines during the acute phase

In December 2023, we were the first company in Japan to obtain marketing and manufacturing approval of the non-invasive neuromodulation device Relivion® as a medical device to treat migraines during the acute phase.

Neuromodulation is a treatment method to adjust nerve functions through electric and magnetic stimulation. Relivion® is worn on the head and relieves migraine pain by stimulating the nerves connected to that pain with electrical currents. As the sole distributor in Japan, we are further expanding treatment options for migraines during the acute phase beyond drug therapy.



Non-invasive neuromodulation device, Relivion®



#### Message from responsible officer

#### Expectations that this will lead to new treatments options for patients

Relivion® is the Group’s first medical device business launch, and it drew the whole company together, particularly the Research and Development Division and Reliability Assurance Division, to address new issues, such as consulting with related authorities, applying for PMDA approval, and building a QMS system. More than three years after launching an examination in July 2020, we are truly happy to have obtained approval. Offering a new option for treating migraines, which are now mainly handled using drug therapy, enables us to provide patients suffering from migraines and medical professionals with a lot of value.

Through these initiatives, we have been able to build a system to handle medical devices in addition to the generic drug business. We aim to contribute to the realization of “always putting healthier lives first” and satisfy unmet medical needs by working to provide various treatment options.

#### Toyohiro Sawada, Ph.D.

Executive officer,  
Group Chief Product  
Strategy officer,  
Group Deputy Chief  
Research & Development  
officer, and General Manager  
of Group Product  
Strategy Department





See the following press releases for details.

<https://www.sawai.co.jp/release/detail/625>

<https://www.sawai.co.jp/release/pdf/640>

<https://cureapp.blogspot.com/2024/02/nashcureapp.html>

## 2. PHR management app, SaluDi

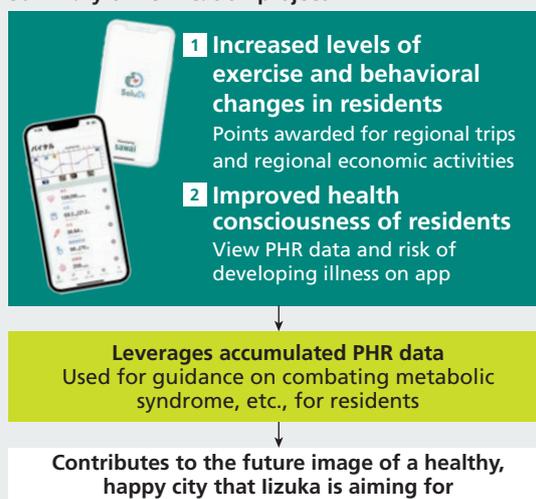
# Providing an app for an inter-industry collaborative verification project related to healthy urban development in Iizuka, Fukuoka

We are providing SaluDi for a verification project regarding healthy urban development that starts with PHR service. The project is being conducted jointly by Iizuka City and Japan Wellbeing Consortium member companies.

This project aims to enhance the health of local residents by capturing those uninterested in health, digitalizing guidance for combating metabolic syndrome, and supporting health and productivity through partnerships with local companies. SaluDi is being used as a health management app that can record and store vital statistics such as blood pressure and weight.

The project revealed that there was an increase in health awareness, as 72.8% of the 190 participating Iizuka City residents responded that “they were more conscious of health.”

### Summary of verification project



## 3. Non-alcoholic steatohepatitis (NASH) treatment app

# Launch phase 3 clinical trial of treatment app that is expected to help treatment through lifestyle guidance



In January 2024, we launched a phase 3 domestic clinical trial of a non-alcoholic steatohepatitis (NASH) treatment app, for which we concluded a development and marketing license agreement with CureApp Inc. Although there is a risk that if NASH progresses it can result in liver cancer, there is no established drug therapy, and it is difficult to maintain effective diet and exercise treatment methods.

This app encourages behavioral changes using learning content for individual patients. Furthermore, the app makes it possible for not only patients themselves but also physicians to manage records, such as changes in the patient’s weight, allowing for optimal treatment and lifestyle guidance. Through the phase 3 clinical trial, which targets patients for whom physicians determined lifestyle guidance could be an effective treatment, we will examine what percentage of participants have seen an improvement 48 weeks later using the app.

## Message from General Manager of Group Human Resource Department

### Promoting efforts to secure & develop the diverse talent indispensable for the Group's growth strategy

**Fumihito Yamakawa**

General Manager of Group Human Resource Department



#### A human asset strategy based on the Medium-Term Business Plan

In June 2024, the Group announced its new Medium-Term Business Plan, which is supposed to be implemented by the end of March 2027. To achieve this plan, the Human Resources Department is likewise implementing various measures based on the human asset strategy. The new Medium-Term Business Plan lays out a path to provide a stable supply of generic drugs through the generic drug business, our core business, by increasing sales volume to 19.0 billion tablets and production capacity to 22.0 billion tablets so that we can capture a market share of 20.5% in the Japanese market.

Of course, delivering high quality, high value-added generic drugs as we do now is a precondition for expanding our scale. Therefore, it is important that we reinforce the systems and expand functions related to quality controls, quality assurance, and R&D. In light of this, the most important elements to achieve our new Medium-Term Business Plan are (1) securing talent and (2) retaining talent, both of which support business growth.

First, we must reinforce new graduate and mid-career recruiting to secure talent (1). Sawai Pharmaceutical, the Group's core subsidiary, plans to conduct large-scale recruiting of more than 400 people in fiscal 2024, twice that for the previous fiscal year. However, the recruiting market is getting tougher every year, with the so-called seller's market continuing. Name recognition and an image of being a major player in the industry will soon no longer be enough to attract workers, and additional measures will be necessary so that potential workers choose us from among the many companies.

Let's now consider retaining talent (2). This is a key management issue for many Japanese companies, not just the Sawai Group, and the result of the unprecedented

seller's market that has spread to the mid-career market. Just like other companies, the Group recorded a larger employee turnover than in the previous year.

Of course, it is a great loss when we lose employees who have spent years gaining experience and growing at the Company. In particular, for a drug manufacturer like the Group, the accumulation of expertise, skills, and knowledge backed by experience is important, and measures to reduce turnover are an issue we must address.

#### Transforming into a dynamic company in which employees work with enthusiasm and fulfillment

We must create an even more attractive company in order to steadily advance in addressing the Group's talent-related issues of securing and retaining talent.

"Attractive company" is a simple term, but it entails numerous elements. For example, two such elements are identification with the company, including its management policy and corporate culture, and agreement with working conditions, such as satisfaction, wages, and benefits. The Group aims to be attractive in terms of all elements, and I think that we need to implement flexible measures that reflect each individual's situation, which is particularly true regarding agreement with working conditions.

For example, young employees focus on treatment, including wages, and future career development, while employees with a family stress balancing work and family life, and older employees want a rich senior life and support for their health. Priority should be given to measures that can win agreement. Of course, attractive remuneration that reflects responsibilities and results is important regardless of the particular situation of the individual.

Regarding this point, the Group's human resources philosophy of "fostering and leveraging the individual"

refers to the idea of valuing each employees' personal individuality and characteristics in an unchanging pillar of our human resources policies. We consider as an attractive company one that values an employee's individuality and personality and provides support for each employee's individual situation, such as age or interests. To illustrate this, in the new Medium-Term Business Plan we use the phrase "a dynamic company in which employees work with enthusiasm."

By introducing the human resources measures described below, we will attract and retain talent by creating a dynamic company in which employees work with enthusiasm.

**Promoting ID&E,\* particularly the active participation of women**

Promoting diversity, particularly encouraging women to play an active role, is one of the important measures for expanding the Group's business.

Japan's labor force is on a one-way decline, and it is said that women working and making active contributions will be a major factor in mitigating the impact of Japan's shrinking labor force.

To secure talent at a time of fierce competition for recruitment, it is important to attract outstanding talent while recognizing various differences, such as gender, race, nationality, and age.

Women now account for around 40% of Group employees, which is relatively high for a drug manufacturer, and around 40% of new hires have been women in recent years. It is expected that the proportion of women will increase in the future.

While promoting the active participation of female employees by introducing a childcare leave system, short-time work systems, and other systems that go beyond legal requirements, the Company is working to further strengthen these measures.

\* An abbreviation for inclusion, diversity, and equity. We stipulate policies that focus on understanding and accepting differences in each person's background (race, nationality, age, etc.) (inclusion), leveraging talent regardless of background (diversity), and treating all employees (equity) impartially.

**Human asset strategy to enhance corporate value**



# Human asset strategy



**Labor Practices**

<https://global.sawaiigroup.holdings/sustainability/social/employee/>

**Diversity**

<https://global.sawaiigroup.holdings/sustainability/social/diversity/>

**Human Rights**

<https://global.sawaiigroup.holdings/sustainability/social/human/>

**Human Resources Development**

<https://global.sawaiigroup.holdings/sustainability/social/development/>

**Occupational Safety and Health Management**

<https://global.sawaiigroup.holdings/sustainability/social/safety/>

## Respecting human rights

Everyone inherently has human rights, or the rights to live a full life as a human being, and every business is responsible for respecting human rights.

We recognize that, as a corporate group that procures the active pharmaceutical ingredients (APIs) and other raw materials it uses for business activities from both Japan and abroad, the Sawai Group must make efforts to protect, respect, and remedy human rights of all people not only within the Group but also throughout its supply chain. Therefore, the Group’s Code of Conduct requires us not only to comply with all laws and regulations related to human rights but also to support and respect the protection of internationally proclaimed human rights, to oppose any form of discrimination on the basis of race, gender, nationality, ethnicity, religion, ideology, political opinion, sexual orientation, disease, or disability, and not to be complicit in human rights abuses. We also request our business partners to formulate their own human rights-related codes of conduct and guidelines and cooperate with us in protecting human rights with the aim of promoting sustainable business based on the harmonious coexistence and co-prosperity of the Sawai Group and its business partners.

As a healthcare corporate group involved deeply in life, the Sawai Group is committed to ensuring that the human rights of not only patients but also various other stakeholders, including employees and business partners both in Japan and abroad, are fully respected. We therefore support the United Nations Bill of Human Rights and the International Labour Organization (ILO) Declaration on Fundamental Principles and Rights at Work and promote initiatives in accordance with the United Nations Guiding Principles on Business and Human Rights.

## Recruiting and developing talent

### (1) Recruiting talent

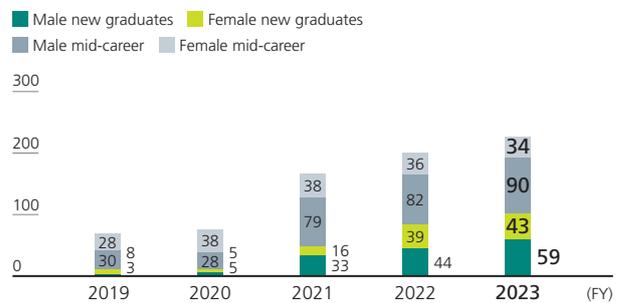
Amidst this unprecedented seller’s market, it is growing more and more difficult to recruit, making it important to set attractive working conditions. Considering this situation, Sawai Pharmaceutical, our core subsidiary, raised its monthly salary approximately 7% in fiscal 2024, which includes regular raises and higher base pay, surpassing the usual level in Japan.

In addition, the starting pay for new graduates was raised to improve our recruiting capabilities.

We will continue to explore setting attractive working conditions while keeping a close eye on recruiting market trends.

### Number of recruits

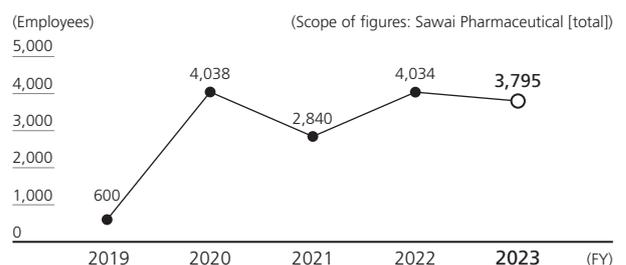
(for Sawai Pharmaceutical)



### (2) Career development

Placing the greatest emphasis on the employee's drive, based on the core HR philosophy of “fostering and leveraging the individual,” we have created an environment in which motivated employees can take the initiative to develop their careers.

### Number of employees trained\*1



\*1 From FY2020 the number of participants in e-learning, is included.



ESG Data  
<https://global.sawaigroup.holdings/sustainability/esg/>

One example of this is the introduction of “the definition of competence requirements” by our core subsidiary Sawai Pharmaceutical. These documents stipulate in detail the skills that the Company wants employees to develop, and they are provided to employees to help them develop their careers and skills.

Furthermore, we have established financial support systems for employees taking Sawai Web School (e-learning), Sawai Open School (outside exchange training), and correspondence courses in order to support employee-driven skill development. These systems aid independent learning by making it possible for individual employees to take courses as many times as they want.

Furthermore, we have created systems that encourage employees to think about their own career path and provide opportunities to conduct work in line with this. These include the in-house recruitment system,<sup>\*2</sup> in-house dual job system,<sup>\*3</sup> and career consultation desk, which were introduced in April 2024.

We will continue to create various systems to support employee-driven career development.

<sup>\*2</sup> In-house recruitment system is a system in which if there is a need for an in-house transfer, related information is made available to employees and employees can instigate the transfer.

<sup>\*3</sup> In-house dual job system: This is a system in which employees do not fully transfer to a new department but hold two positions.

## Promoting inclusion, diversity and equity (ID&E)

### (1) Promoting the active participation of women

At the Group, diverse talent actively contributes under the core HR philosophy of “fostering and leveraging the individual.” Since we have a large number of female employees, we are striving to create a good workplace so that motivated and skilled talent can work with enthusiasm.

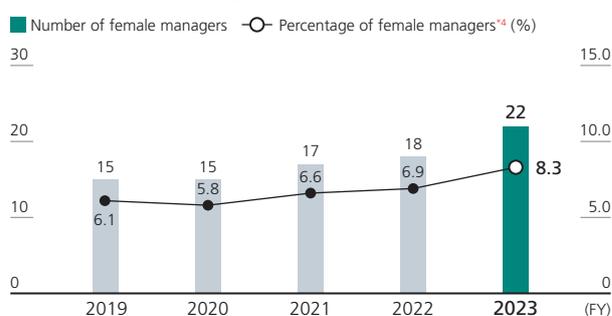
In 2022, we established a company-wide project to promote ID&E mainly by members gathered through internal recruitment. And then, in October 2023, the ID&E Promotion Office was established as a department dedicated to further promotions. In February 2024, we conducted training in the promotion of women’s active engagement for management team members, which ultimately communicated the Company’s determination and resolution to promote the active participation of women. Starting in fiscal 2024, we plan to launch a new training program for female leader candidates.

In the new Medium-Term Business Plan, we set the target of women accounting for 10% or more of department managers and 15% or more of managers by the end of March 2027. We will continue to promote the active participation of women, aiming to create a lively and vibrant company.

### (2) Support for seniors’ success

The Sawai Group has established the “employment extension system” that enables full-time employees to work up to the age of 70, even after the mandatory retirement age of 60, from the perspective of the declining birthrate and aging population in Japan, as well as the advent of a society of healthy longevity. This measure is intended to be one of the ways of supporting the active engagement of diverse talent. In addition, we allow employees over the age of 55 to choose to work alternate days or shorter hours so that they can use the resulting time off for community service, volunteering, or other activities. In this way, we encourage senior employees to work cheerfully in a flexible way.

#### Number and percentage of female managers



<sup>\*4</sup> Sawai Pharmaceutical (before FY2022), Sawai Group (from FY2023 onward). Target ratio of female employees in managerial positions: 15% and above by the end of March 2027.

### Initiative for health management

With a corporate philosophy of “always putting healthier lives first,” the Group focuses on creating an environment in which employees can work while maintaining their health, based on the idea that “high-quality drugs come from workplaces that are both mentally and physically healthy.”

We have placed public health nurses at the main offices and created an environment in which the physical and mental problems of employees can be quickly dealt with in collaboration with an occupational physician. We also cover the full cost of flu vaccinations for employees, as one of our measures to prevent infectious diseases.

We will consider expanding the current system in the future so that employees can feel free to seek advice about their health and life-related concerns.

Furthermore, to ensure that all employees can comfortably work with psychological security, we are striving to eliminate harassment by clearly stating the Company’s stance toward ending harassment in our work rules and other material and operating a harassment helpline.

## Message from General Manager of Group Finance Department

### Strengthening our business foundation by revising the business portfolio and capital policy to meet the needs of shareholders

**Jun Tsujii**

General Manager of Group Finance Department



#### Revising our business portfolio and capital policy

Since fiscal 2021, our PBR has stagnated at less than 1, and in January 2024, we published “Sawai Group Holdings to Review Business Portfolio and Capital Policy” in order to overcome this situation.

Regarding revising our business portfolio, we have withdrawn from the U.S. business, whose profitability continues to be less than the cost of capital. And then we prioritized investments in the Japan generic drug business, which is forecast to see greater profitability.

Furthermore, as part of our fundamental review of assets held, we will reduce our cross-shareholdings by half and sell off idle assets, including the site of the former head office and Osaka factory.

In addition, we are changing the KPIs that prioritize management from profit loss statement–centered ones to KPIs that are more conscientious of the cost of capital, including balance sheet and statement of cash flows.

In particular, we are aiming to generate an ROE of 10% or more, an ROIC of 8% or more, a net D/E ratio of 0.4 or less, capital ratio of 50% or more, and DOE of 3.0% or more. We consider that capital ratio of 50% or more is necessary to maintain our A- rating, and we will use debt financing to the extent that we can maintain our rating.

To implement management that is conscious of the cost of capital, the key question is whether not only management but also each employee considers this an issue that impacts them and actively works with this in mind. Using an inverted ROIC tree as depicted in figure 1, we aim to achieve the targets for improved capital efficiency by having the whole company work together and by incorporating the inverted ROIC tree into KPIs for each department and key measures for each workplace.

#### Cash allocation plan

Figure 2 is our cash allocation plan for the next three years, which appears in the Medium-Term Business Plan Beyond 2027.

We will use approximately ¥190.0 billion, roughly ¥145.0 billion from cash flows from operating activities generated from the generic drug business and ¥45.0 billion in proceeds from sale of the U.S. business and cross-shareholdings, for capital expenditures to strengthen production capacity and reinforce reliability assurance systems, which includes structure reinforcement, which includes investments in R&D, the source of growth.

#### Shareholder return and dividends policy

Having positioned paying profit to shareholders as an important management issue, we have revised our shareholder return and dividends policy to meet those expectations.

In addition to focusing even more on cost of capital and paying a stable, sustainable dividend, we replaced the payout ratio with the DOE as our benchmark, and we aim to generate a DOE of 3.0% or more. Over the three years of the Medium-Term Business Plan, we plan to pay total dividends of at least ¥19.0 billion and spend at least ¥33.0 billion on the purchase of treasury shares.

#### Future plans

By reinforcing our financial management system, we will achieve the numerical targets in the Medium-Term Business Plan through KPI management, greater ability to generate cash, and efficient investing and fund allocation.

Figure 1. Initiatives to improve capital efficiency

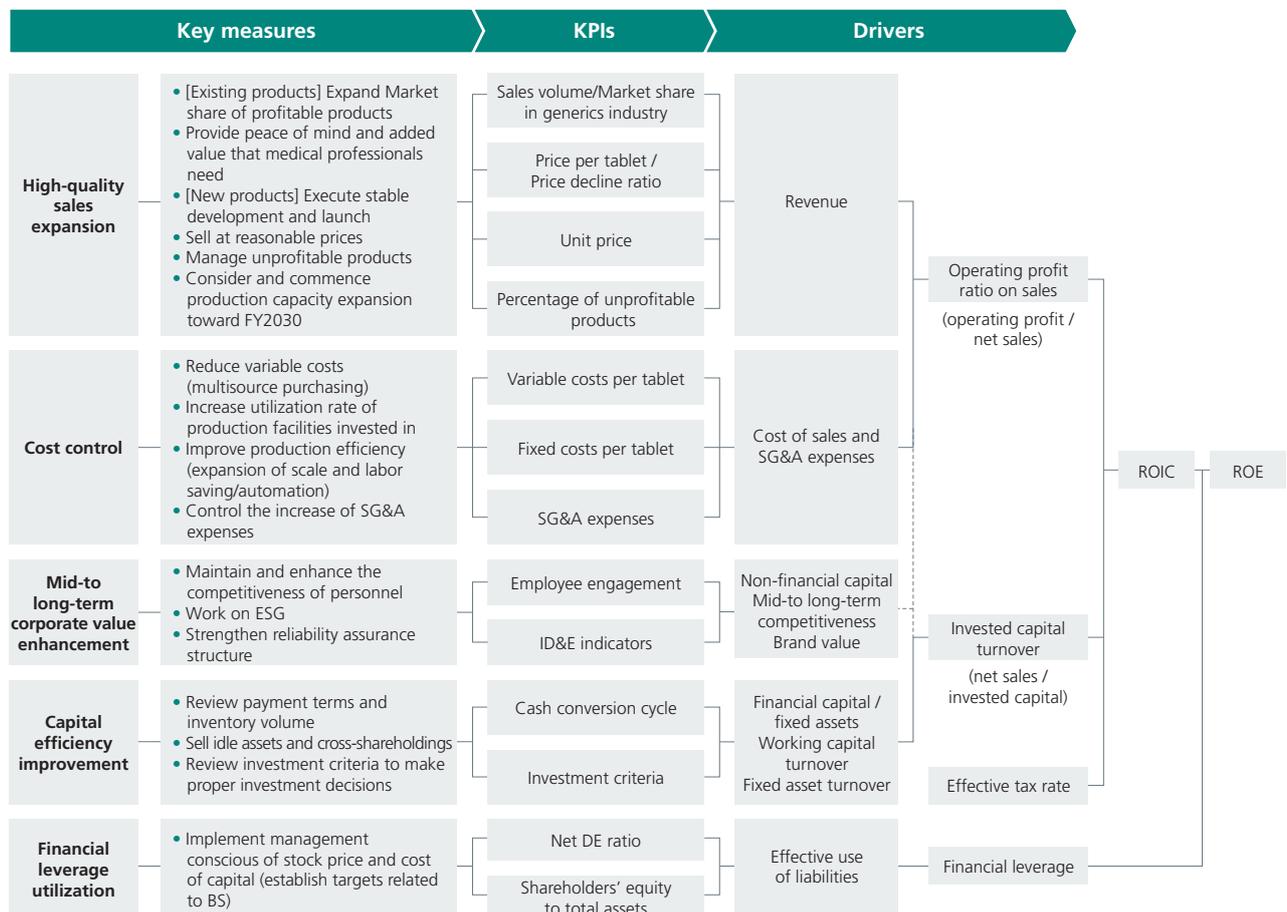


Figure 2. Cash allocation plans

	Purpose	Amount	Policy
<b>Expected generics business operating cash flow* over three years:</b> approx. ¥145.0 billion *Before deducting R&D Expenses	<b>R&amp;D investment</b> (generics business)	<b>Approx. ¥35.0 billion</b>	<ul style="list-style-type: none"> <li>R&amp;D investment for launching new products, which are our sources of growth</li> </ul>
	<b>Generics business</b>	<b>Approx. ¥78.5 billion</b>	<ul style="list-style-type: none"> <li>Renewal of facilities at the factories (¥27.0 billion yen over three years)</li> <li>Expansion of production capacity (¥31.2 billion yen over three years)</li> <li>Investment in systems to strengthen reliability assurance structure (¥3.7 billion)</li> <li>Other investments</li> </ul>
	<b>New businesses</b>	<b>Approx. ¥3.5 billion + α</b>	<ul style="list-style-type: none"> <li>Investment in new businesses (SG&amp;A expenses for SWD001, R&amp;D expenses for SWD002, R&amp;D expenses for exporting generics, etc.)</li> </ul>
	<b>Flexible allocation</b>	<b>Approx. ¥21.0 billion + α</b>	<ul style="list-style-type: none"> <li>Expansion of production capacity toward FY2030</li> <li>Growth investment other than the plan</li> </ul>
<b>Sales of US business, cross-shareholdings, etc.:</b> approx. ¥45.0 billion	<b>Shareholder returns:</b>	<b>Approx. ¥33.0 billion + α</b>	<ul style="list-style-type: none"> <li>Liquidation of the increase in equity capital due to the capital increase made at the time of acquiring Upsher-Smith, using proceeds from sale of the U.S. business and cross-shareholdings</li> </ul>
<b>Flexible financing capabilities + α with R&amp;I rating of A-</b>	<b>Dividends</b>	<b>¥19.0 billion or more in total dividends over three years</b>	<ul style="list-style-type: none"> <li>Stable and consistent dividend payments, with overall consideration of medium- to long-term profit levels, DOE (targeting 3% or more), etc.</li> </ul>

# Environment

## Disclosure based on TCFD recommendations (summary)

Climate change has a major impact on society and the economy, and it may have a dramatic financial impact on the Group. Having designated addressing climate change as a material issue, we not only support international policies, including the Paris Accords, and laws and government policies related to nationally determined contributions (NDC)

and climate change but also are working to reduce our greenhouse gas emissions. In addition, we announced our support for TCFD recommendations in September 2021 and disclose climate change-related information based on the four pillars of governance, strategy, risk management, and metrics and targets, which are recommended by the TCFD.

### Risks and opportunities related to climate change (Covered period: FY2021 to FY2030)

Type	Risk overview	Impacts on the Group's businesses, strategy, and financial planning	Magnitude of impacts		The Group's methods for addressing climate-related risks	
			1.5°C scenario	4.0°C scenario		
Risks	<b>Transition risks</b>					
	<b>Policy and legal risks</b>	Introduction of carbon pricing (a carbon tax and an emissions trading scheme) and the resulting increased burdens	<ul style="list-style-type: none"> <li>Burden created by carbon pricing on the Group</li> <li>Need to pass on the carbon pricing-created financial burdens of suppliers with high GHG emissions to the Group's purchase prices of raw materials</li> <li>The Group's burden of capital investment in energy saving necessary to reduce GHG emissions</li> </ul>	Moderate	Minor	<ul style="list-style-type: none"> <li>Considering the introduction of renewable energy</li> <li>Devising and implementing measures to enhance production efficiency, including reducing waste products</li> </ul>
	<b>Population, economic, and geopolitical risks</b>	Price hike for bio-derived raw materials due to population growth and temperature increases	<ul style="list-style-type: none"> <li>Population growth, especially in emerging economies, will cause an increase in the prices of grain and grain-based products (starch, sucrose, corn, etc.) for food and feed use and consequently in the prices of raw materials of additives for pharmaceutical products</li> </ul>	Minor	Moderate	<ul style="list-style-type: none"> <li>Diversifying suppliers</li> <li>Studying alternative technologies</li> </ul>
	<b>Physical risks</b>					
	<b>Flood risks (acute risks)</b>	Increased frequency of typhoons, torrential rains, floods, heavy snow, etc.	<ul style="list-style-type: none"> <li>Increased risk of damage to the Group's business sites</li> <li>Increased risk of damage to the business sites of the Group's suppliers</li> </ul>	Minor	Major	<ul style="list-style-type: none"> <li>Sandbagging the areas where product inventories are stored</li> <li>Obtaining damage insurance coverage</li> <li>Formulating BCPs for the Group and its supply chain</li> </ul>
<b>Opportunities</b>	As a result of our analysis and evaluation of climate-related opportunities that can have impacts on the Group's operations, we have so far not identified any opportunities that can have significant impacts on the Group's businesses, strategy, and financial planning.					

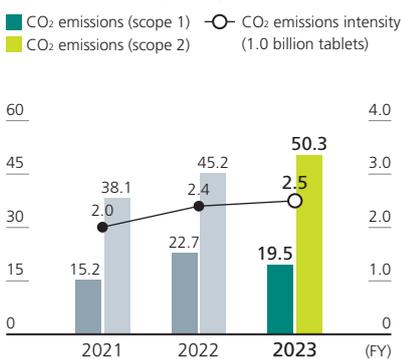
Scope of coverage: Sawai Group

Impact classification:

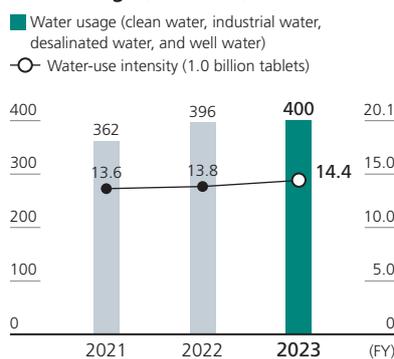
Major: Major impacts on the Group's businesses, strategy, and financial planning that the Group estimates to be worth approximately ¥6.0 billion or more  
 Moderate: Moderate impacts on the Group's businesses, strategy, and financial planning that the Group estimates to be worth approximately ¥3.0 billion or more  
 Minor: Minor impacts on the Group's businesses, strategy, and financial planning that the Group estimates to be worth approximately less than ¥3.0 billion

## Environment data

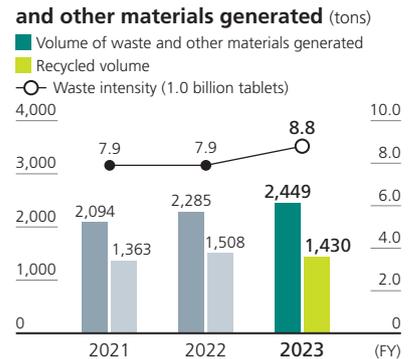
### CO<sub>2</sub> emissions (kt-CO<sub>2</sub>)



### Water usage (thousand m<sup>3</sup>)



### Volume of waste and other materials generated (tons)





**ESG Data:** <https://global.sawaigroup.holdings/sustainability/esg/>  
**Disclosure Based on TCFD Recommendations (detailed information):**  
<https://global.sawaigroup.holdings/sustainability/environment/tcfd/>

## Topics

### Third-party verification of environmental data

With growing focus on ESG data when evaluating corporate activities, we are moving forward with reinforcing disclosure of ESG information. In fiscal 2023, we introduced third-party verification of environmental data. A sample verification was made at three sites, and we conducted a detailed check of inconsistencies and deficiencies with our monitoring plan using the environmental data management system Eco Track.

We plan to gradually conduct on-site verifications at all sites. We expect that this will lead to increased transparency of and trust in the Company and make environmental data management more effective.



Checking water equipment

### Launching material recycling of PTP packaging waste

The Kashima Factory launched recycling of waste material from PTP sheets, which consist of aluminum film attached to plastics shaped with pockets for tablets and capsules. In the past, this waste material was incinerated because it was impossible to separate the two materials into a recyclable form.

However, each material can now be recycled because a new technology was developed that completely separates the aluminum from plastic parts, which has made it possible to not only reduce waste but also cut CO<sub>2</sub> emissions approximately 94% compared to before.



PTP sheets

### Kinki Electric Power Utilization Rationalization Committee recognizes Sanda Nishi for switching to green electricity

After introducing solar power generation and optimized control of packaged air conditioners in January 2022, the Sanda Nishi factory has reduced its electricity consumption by approximately 330,000 kWh annually since April of 2022.

These efforts were recognized by the Kinki Electric Power Utilization Rationalization Committee, which is composed of government offices, power companies, academics, and similar parties in the Kinki region, as contributing to the promotion of electricity use rationalization.



2023 Kinki Region Energy Conservation Month Award Ceremony

### Conducting research to increase trust in and sustainability of companies

In fiscal 2023, we conducted an environmental compliance survey at five sites to check whether they were appropriately handling environment-related laws and regulations.

The results of the survey showed that there were several points to be improved, including submission of plans related to diluted sulfuric acid tanks based on the Industrial Safety and Health Act. Excluding some items that require capital expenditures, we completed addressing most of the issues during fiscal 2023. Starting in fiscal 2024, we plan on conducting a survey at one location each year on a rotating basis.



Checking waste management

# Monitoring and supervision that leverages specialization to achieve sustainable increase in corporate value

The Company has three external directors who are responsible for monitoring and supervising management from an outside perspective by leveraging their particular specializations. In fiscal 2023, there were multiple incidents that required difficult decisions, such as the disposal of U.S. subsidiary Upsher-Smith shares and the discovery of inappropriate Teprenone Capsules testing at the Kyushu Factory. In addition, there were lively deliberations regarding the new Medium-Term Business Plan, which was announced in June 2024. In this roundtable discussion, external directors look back at how the Board of Directors handled these issues from their particular expert perspectives.

## Could you tell us about the deliberations and your thoughts on withdrawing from the U.S. business?

### Ohara

With the usage ratio of generic drugs reaching nearly 80% in Japan, I think that following a search for a new market, management's decision to enter the U.S. market was not a mistake. However, when the business was actually launched, price competition was fiercer than expected due to the entry of some Indian manufacturers, which was not envisioned in due diligence, and it became clear that it would be difficult for conditions to improve because of our precarious market position. Considering the situation, it is my opinion that it was a rational decision to withdraw from the market in order to avoid even greater losses.

There was one difficult aspect of the withdrawal, which was that we had to obtain the consent and approval of Sumitomo Corporation, a joint investors. But after the decision to withdraw was made, we received reports on the cautious process to limit losses as much as possible, which I appreciate.

### Mitsuka

I think this was a decision that was necessary so that both the U.S. business and Japan business could grow. Under the holding company, it was difficult for the U.S. business and Japan generic drug business to mutually generate synergy

because they handled different products and faced different market demands. As for the best way for each business to achieve a sound expansion in the medium and long term, it was determined that the U.S. business was more likely to grow through an alliance with Taiwan-based Bora Pharmaceuticals, which is aggressively investing in its U.S. generic drug business, than it would be by collaborating with Sawai Pharmaceutical.

On the other hand, in Japan, it is extremely important that companies of an appropriate size provide the Japanese people with quality generic drugs at an affordable price, not an excessively low price. I think that even for the Japan business, the time had come for a decision to focus the investment of business profit into the domestic business.

### Todo

In the end, our reading of conditions was definitely overly optimistic, but we still retain the results and experience of this bold challenge. Even at the Board of Director meeting, I said that I want the Company to learn something from this.

## What have you said about the inappropriate testing of Teprenone and related recurrence prevention measures?

### Mitsuka

There are several key evaluation items related to improving quality reliability, which are managed internally by the



**Masayuki  
Mitsuka**

**Nawomi  
Todo**

**Masatoshi  
Ohara**

Manufacturing Division and Quality Control Department, and I have stated at the Board of Directors meetings that I would like to see those raised to company-wide targets and included in the next medium-term business plan if possible. I want them included as quantitative non-financial targets, which I want the whole company to pursue, and for those numerical results to be communicated to customers and investors.

Another point is that, although a report on this incident was submitted to external officers, I requested that two items be clarified, the first being criteria regarding what incidents should be reported, and the second being what should be included in future incident reports. Furthermore, discussions regarding measures to mitigate the impact of various problems are moving forward as part of recurrence prevention measures.

#### **Ohara**

That is exactly right. There are two issues here. The first one is to what extent is there a system to prevent this type of incident and whether that system is properly operating. The second one is whether there is a system so that we as external directors are sure to obtain this information in a timely manner.

Let's consider the first question. As a member of the legal profession, I have had the opportunity to be asked for advice on responding to various problems and scandals. Based on this experience, it is important to provide detailed and clear rules to prevent recurrences, and I think that the

necessary measures are being taken at the workplace level, even at Sawai Pharmaceutical. However, I do not consider these steps sufficient enough and believe that it is necessary to reform the corporate culture and the awareness of employees.

As for the second issue, external officers received a report on the incident shortly after it occurred. However the issue remains that it took time to determine the causes and detailed results and to report that to the Board of Directors. In response to this incident, the Board of Directors seriously deliberated on the issue, and there have been calls for the development and construction of a system for timely reports to the Board of Directors based on an appropriate process. I think that this will correct the issue.

#### **Todo**

I also said that what occurred should have been reported first to the Board of Directors. It was an inexcusable problem. We must further strengthen initiatives to prevent recurrences as well as initiatives regarding the quality we have built up. One element of corporate governance is supervising management, which includes compliance issues, and this is one of the core roles of external directors. This incident reinforced for me the notion that this duty must be fulfilled.

#### **Mitsuka**

Currently, there is a shortage of generic drugs throughout Japan, and there are still many items with supply restrictions. Therefore, manufacturing workplaces face a lot of pressure regarding production volume. To prevent recurrences, it is

extremely important that employees in production fully understand that they must both ensure quality and expand production while lowering costs, which the Company demands.

There are three key points for that understanding. First, there must be reforms of the organizational culture, as Director Ohara said. Second, the figures for important evaluation items related to improving product reliability, which each division already has, must become targets for the whole company. Finally, we must invest in equipment, systems, and people which includes factory equipment, systems that automatically record data, and employees who work at factories.

Regarding staffing, the current Medium-Term Business Plan includes plans to increase the number of employees, particularly for Quality Control Departments at factories, by about 130. However, although this has already been said, the most important point is that employees on the frontline of manufacturing understand that the company has united to give the greatest priority to the quality of its products. Without that, I am concerned that there is a risk that the same problem could occur again.

**Could you tell us about the considerations and deliberations carried out in formulating the Medium-Term Business Plan?**

**Todo**

Regarding deliberations on the Medium-term Business Plan, I noted that I would ask executive officers to focus on capturing the hearts of all stakeholders who want to support our employees and Sawai. Since taking up the



**Nawomi Todo**

Nawomi Todo is a physician and an occupational physician licensed by the Japan Medical Association. She has served as a Sawai Pharmaceutical Director since 2015 and as a Sawai Group Holdings Director since April 2021.



**Masayuki Mitsuka**

Having served as the Representative Director and President of Mitsubishi Tanabe Pharma Corporation for six years, since 2014, Masayuki Mitsuka is knowledgeable of management issues faced by pharmaceutical companies. He has served as a Director of the Company since 2023.

position of external director, I have repeatedly said that we should communicate a clear, appealing vision. Of course, without profit, we cannot pay our employees or pay dividends to our shareholders. I believe, however, that in order to ensure the sustainability of a company, the core element lies in its vision.

**Ohara**

As for figures, I think it is important to take a close look at the evidence that a target is achievable. Therefore, when deliberating on the new Medium-Term Business Plan, I expressed the opinion that we have to incorporate things that the company should be sure to implement based on figures grounded in reality, not forecasts of how we want things to be. I truly feel that during recent Board of Directors deliberations, not only those for the Medium-Term Business Plan, we have made quite good progress in examining things from a perspective of whether it is an effective use of capital.

**Mitsuka**

I think that non-financial indicators—that is, ESG related items—are extremely important. In particular, governance and sustainability issues are directly linked to the continuity of the generic drug business, our core business, and sustainable earnings growth. Building a strong governance system, manufacturing products in a stable manner, guaranteeing quality, collecting safety information, and supplying numerous products without shortages — for us, these efforts are directly tied to medium-term profits. Even for indicators that do not appear to be directly linked to finances, I believe that setting targets and being sure to improve efforts ultimately leads to profits.

The government also recognizes companies that are making efforts to ensure quality and stable supply, which is also reflected in NHI drug prices. This means that the

government will help ensure that our ESG efforts lead to increased profits in the medium term. Because this is a business for which it is easy to make the case that contributing to society is linked to growth as a company, it is important that we actively communicate this to society.

**Todo**

This means that the reason of the company's existence is aligned with generating a profit.

**Mitsuka**

For example, it would probably be good to have an ESG briefing after the Medium-Term Business Plan briefing. This would be regarded highly by people, and if we can build that reputation every year, we can link it to employee satisfaction and pride among employees and employee engagement with the company.

**Todo**

Pride is necessary. Pride can be said to be the source of sustenance for life.



**Masatoshi Ohara**

Masatoshi Ohara is a lawyer and partner at Kikkawa Law Offices. He is also a licensed attorney in New York, U.S. He has served as a Sawai Pharmaceutical Director since 2019 and as a Sawai Group Holdings Director since April 2021.

**What do you think about the orientation of efforts to reinforce governance and the human asset strategy that the Company is aiming to implement?**

**Mitsuka**

In terms of governance, our greatest priority should be strengthening the functions of the Board of Directors. Quite a while ago, we diligently worked to comply with the corporate governance code, and we are working to gradually make improvements every year.

We have also built a system that will, starting this time, use an external organization to evaluate the effectiveness of the Board of Directors. I believe this will produce quite a large amount of data that can be compared

to our competitors. I think that using this data to run through the PDCA cycle to decide how to improve the necessary items and then communicating that to people outside the Company will make it easier for people to understand how we are reinforcing governance.

Another point I would like to stress is that human capital is extremely important in our business. Unfortunately, there continues to be a high turnover rate, particularly at manufacturing workplaces. When frontline workers are asked about this, they say that they are busy working in a difficult situation. I think that it is important to encourage people to work for the Company for a long time and to develop an environment in order to improve conditions and raise employee skills.

**Ohara**

For human resources-related issues, it is extremely important to utilize diverse human resources. We continue to welcome experienced people from various companies through mid-career hiring, but it will become important to have an HR policy that develops people from within the Company, rather than just human resources from outside the Company.

**Todo**

I have always said that we need to take our time and develop all employees, not only women, within the company. I also believe that one of our most important issues is to have female directors and executive officers from within the Company.

**Mitsuka**

Our Group makes aggressive use of mid-career hires, and many members of management joined the Company as mid-career hires. I think that the Company already has diversity in know-how and experience. This raises several questions. To what extent can we match them with employees who have worked at the company for many years, and to what extent can we make the most of them by developing their skills? How can we match them to the management strategy and HR strategy outlined in the current Medium-Term Business Plan? I would like executive officers to actively explain these points.

**Ohara**

Fortunately, each external director has a different area of expertise. We have Director Todo, who is knowledgeable about healthcare, and Director Mitsuka, who is well-versed in business, particularly pharmaceutical companies. As a lawyer, I am well informed of legal issues, trends, and cases outside the company and express my opinions from a governance and compliance perspective. I believe that not only internal deliberations and perspectives but also Board of Directors discussions that include a broad range of diverse opinions based on different areas of expertise will be beneficial for the company.

# Board of Directors (as of June 25, 2024)

## Board of Directors information

- Directors
- Audit & Supervisory Board Members

Name	Mitsuo Sawai	Shoji Yokota, Ph. D.	Masatoshi Ohara	
				
<b>Position</b>	Representative Director, Chairman and President (Group Chief Executive Officer and Group Chief Operating Officer)	Director, Senior Managing Executive Officer, and Group Chief Research & Development Officer	External Director (Independent Officer)	
<b>Date of birth</b>	Born in 1956	Born in 1957	Born in 1951	
<b>Governance Committee on Nominations &amp; Remuneration</b>	●		● (Committee Chairman)	
<b>Board of Directors meeting attendance*</b>	14/14 times	11/11 times (elected June 2023)	13/14 times	
<b>Audit &amp; Supervisory Board meeting attendance*</b>	—	—	—	
<b>Shares of the Company held</b>	1,057,200 shares	700 shares	1,100 shares	
<b>Career summary</b>	<p>April 1982 Joined Kyowa Hakko Kogyo Co., Ltd. (currently Kyowa Kirin Co., Ltd.)</p> <p>January 1989 Joined Sawai Pharmaceutical Co., Ltd.</p> <p>June 2000 Director and Deputy Senior Vice President of Sales Division of Sawai Pharmaceutical Co., Ltd.</p> <p>June 2002 Managing Director and Senior Vice President of Sales Division of Sawai Pharmaceutical Co., Ltd.</p> <p>June 2008 Representative Director and President of Sawai Pharmaceutical Co., Ltd.</p> <p>June 2020 Representative Director and Chairman of Sawai Pharmaceutical Co., Ltd. (incumbent)</p> <p>April 2021 Representative Director and Chairman and Group Chief Executive Officer of Sawai Group Holdings Co., Ltd.</p> <p>June 2023 Representative Director, Chairman and President, Group Chief Executive Officer and Group Chief Operating Officer of Sawai Group Holdings Co., Ltd. (incumbent)</p>	<p>April 1982 Joined Yamanouchi Pharmaceutical Co., Ltd. (currently Astellas Pharma Inc.)</p> <p>September 2016 Joined Sawai Pharmaceutical Co., Ltd.</p> <p>June 2017 Corporate Officer, Deputy Senior Vice President of Research &amp; Development Division, and Director of Analytical Chemistry Department of Sawai Pharmaceutical Co., Ltd.</p> <p>April 2021 Senior Executive Officer of Sawai Group Holdings Co., Ltd.</p> <p>June 2023 Director, Senior Managing Executive Officer, and Senior Vice President of Research &amp; Development Division of Sawai Pharmaceutical Co., Ltd. (incumbent)</p> <p>June 2023 Director, Senior Managing Executive Officer of Sawai Group Holdings Co., Ltd. (incumbent)</p>	<p>April 1979 Registered as a lawyer at Osaka Bar Association</p> <p>Joined Kikkawa Sogo Law Offices (currently Kikkawa Law Offices)</p> <p>February 1987 Attorney registered in the State of New York, in the U.S.</p> <p>January 1988 Partner of Kikkawa Law Offices (incumbent)</p> <p>April 2017 President of Osaka Bar Association, Vice President of Japan Federation of Bar Associations</p> <p>June 2019 Director of Sawai Pharmaceutical Co., Ltd.</p> <p>April 2021 Director of Sawai Group Holdings Co., Ltd. (incumbent)</p>	

\* Period April 1, 2023–March 31, 2024

## Skill matrix

	Reason considered important
<b>Corporate management</b>	Experience in making decisions in line with the corporate philosophy and being responsible for business is important for the Group's management decisions.
<b>Legal affairs/risk management</b>	When trying to maximize corporate value, it is important to make decisions that balance set rules and risk tolerance.
<b>Finance, accounting, tax affairs</b>	These are important for accurately ascertaining and calculating the Group's corporate value and properly paying taxes.
<b>Production and quality</b>	Advanced quality and production management are important so that consumers can use the Group's products, etc. with peace of mind.
<b>Marketing and sales</b>	Communicating the merits of products and services that the Group produces and provides and broadly gathering information on needs are important.
<b>Research, development, technologies</b>	This is important to continue to provide high value-added products and services that meet the needs of society.
<b>Medicine and pharmaceuticals</b>	Medicine and pharmaceuticals-related skills are important for the Group, which aims to become a general healthcare company related to life and health.

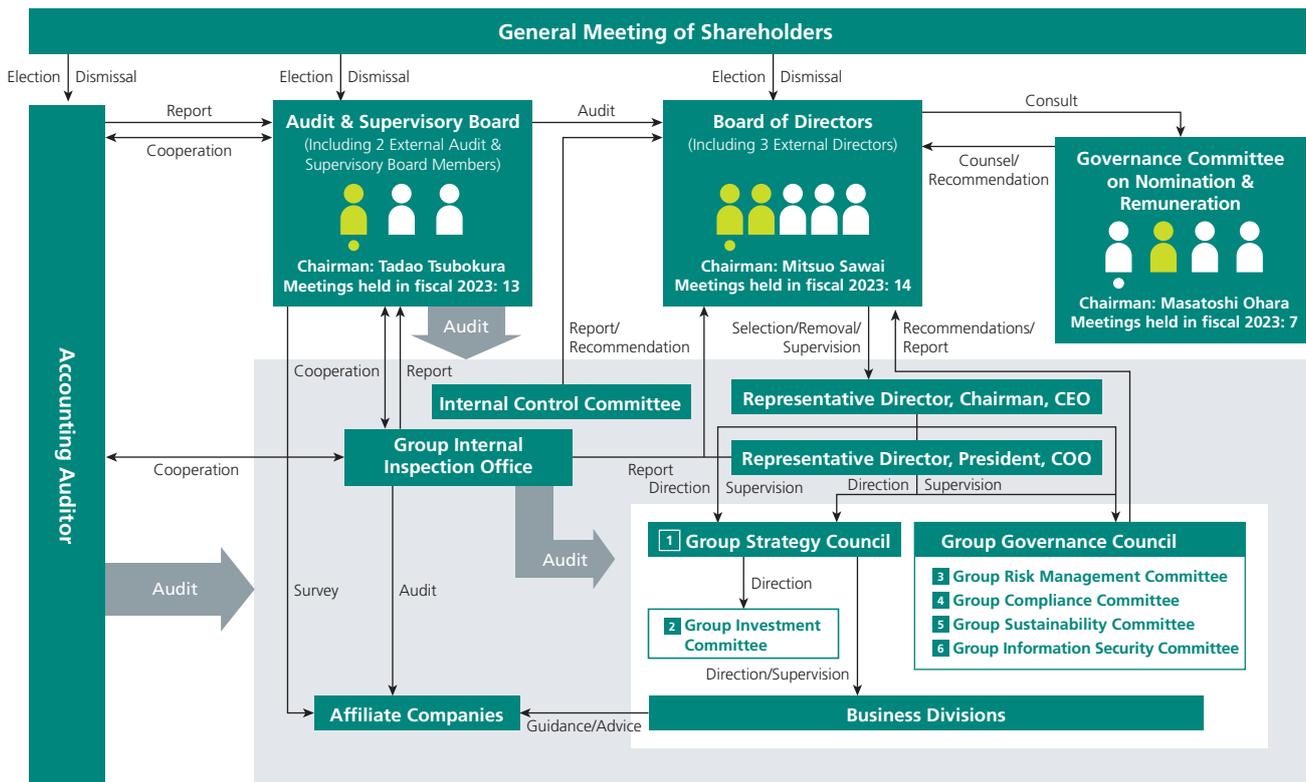
	Nawomi Todo	Masayuki Mitsuka, Ph. D.	Tadao Tsubokura	Takanobu Tomohiro	Junichi Hirano
					
	External Director (independent officer)	External Director (independent officer)	Full-time Audit & Supervisory Board Member	External Audit & Supervisory Board Member (independent officer)	External Audit & Supervisory Board Member (independent officer)
	Born in 1959	Born in 1954	Born in 1961	Born in 1958	Born in 1955
	●	●			
	14/14 times	11/11 times (elected June 2023)	14/14 times	14/14 times	14/14 times
	—	—	13/13 times	13/13 times	13/13 times
	1,200 shares	0 shares	1,000 shares	400 shares	400 shares
	June 1984 Obtained doctor's license July 1984 Staff Doctor at Osaka University Hospital January 2002 Staff Doctor at Osaka-tetsusyou Health Insurance Society (incumbent) January 2007 Obtained Certified Occupational Physician Qualification of Japan Medical Association June 2015 Director of Sawai Pharmaceutical Co., Ltd. April 2021 Director of Sawai Group Holdings Co., Ltd. (incumbent)	April 1982 Joined Mitsubishi Chemical Industries Co.,Ltd (currently Mitsubishi Chemical Corporation) June 2009 Board Director, Executive Officer, General Manager of Global Product Strategy Department of Mitsubishi Tanabe Pharma Corporation April 2012 Board Director, Managing Executive Officer, Division Manager of Development Division of Mitsubishi Tanabe Pharma Corporation June 2014 President & Representative Director, Chief Executive Officer of Mitsubishi Tanabe Pharma Corporation June 2023 Director of Sawai Group Holdings Co., Ltd. (incumbent)	July 2008 Joined Sawai Pharmaceutical Co., Ltd. General Manager, Controller Department of Sawai Pharmaceutical Co., Ltd. April 2012 General Manager, General Affairs Department of Sawai Pharmaceutical Co., Ltd. June 2018 Full-time Audit & Supervisory Board Member of Sawai Pharmaceutical Co., Ltd. April 2021 Full-time Audit & Supervisory Board Member of Sawai Group Holdings Co., Ltd. and Auditor of Sawai Pharmaceutical Co., Ltd. (incumbent)	April 1991 Registered as an attorney Joined Kogoshi Takizawa Law Office (currently Kobe-Kaito Law Office) April 1994 Partner of Kobe-Kaito Law Office (incumbent) June 2016 Audit & Supervisory Board Member of Sawai Pharmaceutical Co., Ltd. April 2020 President of Hyogo Bar Association April 2021 Audit & Supervisory Board Member of Sawai Group Holdings Co., Ltd. (incumbent)	July 2013 Director, Co-ordination Division, Second Large Enterprise Examination Department, Osaka Regional Taxation Bureau July 2014 District Director, Higashi Yodogawa Tax Office July 2015 District Director, Himeji Tax Office August 2016 Established a certified tax accountant office, which he serves as representative of (incumbent) June 2017 Audit & Supervisory Board Member of Sawai Pharmaceutical Co., Ltd. April 2021 Audit & Supervisory Board Member of Sawai Group Holdings Co., Ltd. (incumbent)

	Mitsuo Sawai	Shoji Yokota	Masatoshi Ohara	Nawomi Todo	Masayuki Mitsuka	Tadao Tsubokura	Takanobu Tomohiro	Junichi Hirano
	●				●			
			●				●	
						●		●
		●						
	●				●			
		●			●			
		●		●	●			

# Corporate governance

Corporate governance structure ● Internal ○ External ●○ Chairman

(as of June 25, 2024)



	Chairman	Role/function	Meetings held in fiscal 2023
<b>1 Group Strategy Council</b>	Representative Director and President (Group COO)	The Group Strategy Council deliberates on important matters to be submitted to the Board of Directors, discusses and decides the execution policy of matters resolved at the Board of Directors meetings, and analyzes business results and discusses the countermeasures.	14
<b>2 Group Investment Committee</b>	Representative Director and Chairman (Group CEO)	The Group Investment Committee undertakes objective, rational, and careful deliberations when examining and making decisions regarding important investment projects and the annual investment budget.	17
<b>3 Group Risk Management Committee</b>	Group Chief General Affairs Officer	To reinforce the management of various risks that the Company and Group companies face, the Group Risk Management Committee oversees risk management, manages and evaluates progress in managing risks, and works to continually improve risk management.	2
<b>4 Group Compliance Committee</b>	Group Chief Compliance Officer	The Group Compliance Committee conducts education and enlightenment activities, etc., for officers and employees and strives to raise awareness of compliance throughout the Group.	4 (total of 9 times*)
<b>5 Group Sustainability Committee</b>	Group Chief Sustainability Officer	The Group Sustainability Committee deliberates and decides on the Group's basic policy on sustainability, establishes and maintains a system for promoting sustainability, assists Group companies in establishing and maintaining their own systems for promoting sustainability, and receives reports.	4
<b>6 Group Information Security Committee</b>	Group Chief Digital Transformation Officer	The Group Information Security Committee shares information on information security, examines and deliberates on responses to issues, and works to smoothly manage information security.	3

\* Held monthly, five times between November and March, as part of the Corporate Culture Reform Project



**ESG Data:** <https://global.sawaigroup.holdings/sustainability/esg/>  
**SASB Index:** <https://global.sawaigroup.holdings/sustainability/sasb/>

## Governance system and reason for its adoption

Having directors with detailed knowledge of the prescription drug industry, the Group's core business, and the state of the Company involved in running the business while maintaining high ethics and keeping an eye on the various parts of the Company is the best way to pursue management efficiency and legality. Furthermore, an Audit & Supervisory Board, in which external directors and Audit & Supervisory Board members supervise management, was adopted, as it is considered the most appropriate, taking the size of the Company, the direction management is moving, and other issues into comprehensive consideration.

### Governance system charts

<b>Organizational design</b>	Company with an Audit & Supervisory Board
<b>Board of Directors Chairman</b>	Chairman
<b>Number of directors</b>	5 (including 3 external directors)
<b>Term of directors</b>	1 year
<b>Introduction of corporate officer system</b>	Yes
<b>Board of Directors optional advisory committee</b>	Nomination, Remuneration and Other Governance Committee
<b>Incentives for directors (excluding external directors)</b>	Introduced performance-linked remuneration scheme and stock options scheme, which includes evaluation of ESG-related initiatives
<b>Accounting auditor</b>	KPMG AZSA LLC Japan

It is expected that external directors and external Audit & Supervisory Board members possess professional knowledge of such fields as law, taxes, accounting, and medicine and pharmaceutical sciences and provide useful advice, make decisions, and audit and supervise from an independent perspective.

The Governance Committee on Nominations & Remuneration, to which one more external director with experience in management was added in fiscal 2023, conducted extensive deliberations regarding such issues as the appointment, termination, and remuneration of the management team.



### Corporate Governance

[https://global.sawaigroup.holdings/sustainability/governance/corporate\\_governance/](https://global.sawaigroup.holdings/sustainability/governance/corporate_governance/)

#### Main items

- Policy and Basic concept
- Governance system
- Audit system
- Nomination, Remuneration and Other Governance Committee
- Group Sustainability Committee
- Group Governance Council
- Other committees
- History of measures to strengthen governance
- Group Strategy Council

## Remuneration for directors and Audit & Supervisory Board members

Decisions concerning Director remuneration are reported to the Board of Directors upon deliberation of matters concerning Director remuneration at meetings of the Governance Committee on Nomination & Remuneration.

Remuneration for Directors (excluding External Directors) consists of a basic remuneration (fixed remuneration), performance-linked remuneration (bonus), and stock options (new share acquisition rights) as a medium and long-term incentive. Basic remuneration and bonuses are generally paid at a 3:1 ratio. Stock options generally account for at least 10% of total remuneration and are granted based on Director position and years of service, and in accordance with the separately determined internal regulations of the Company.

The remuneration limit for Directors is ¥670 million per year (of which, no more than ¥100 million is for External Directors). There is also a remuneration limit for Audit & Supervisory Board Members of ¥50 million per year. The

remuneration system, including for Director remuneration, will be reviewed every three years, in principle, based on a comprehensive accounting of market trends concerning Director remuneration, the Company's performance trends, and cost of living trends. Taking seriously the administrative punishment for inappropriate testing found at Sawai Pharmaceutical in fiscal 2023, the Governance Committee on Nominations & Remuneration carefully deliberated on the appropriateness of the punishment of the officers concerned and the offer to return executive remuneration, and made a recommendation to the Board of Directors, which then resolved the punishment at its meeting.

### Distribution of director remuneration fiscal 2023



### Distribution of remuneration for directors and Audit & Supervisory Board members (A & SB members)

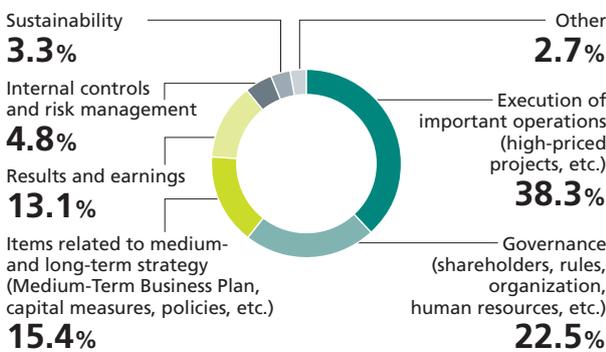
Classification	Total remuneration (Millions of yen)	Total remuneration by category (Millions of yen)			Number of eligible persons
		Fixed remuneration	Performance-linked remuneration	Stock options	
<b>Directors (not including External Directors)</b>	118	77	26	15	5
<b>A &amp; SB Members (not including External A &amp; SB Members)</b>	18	18	–	–	1
<b>External Directors and A &amp; SB Members</b>	42	42	–	–	5

## Main Board of Directors Issues

The Company continually implements improvements of the operation of the Board of Directors and ensures in-depth deliberations on management by securing the necessary time for deliberations. The following are important issues deliberated on by the Board of Directors in fiscal 2023.

- (1) Analysis of the causes for not achieving business results and examination of strategic projects
- (2) Investments that lead to new growth
- (3) Business portfolio that takes into consideration cost of capital
- (4) Ascertaining risks accompanying promotion of the management strategy
- (5) Risk management, including whistleblower system and representations and warranties
- (6) Examination of quality problems and formulation of recurrence prevention measures
- (7) Human capital investments that lead to growth
- (8) Disposal of pediatric formulations, unconscious bias, etc.
- (9) Accountability to shareholders and shareholders return policy

### Breakdown of time spent on deliberations and reports



## Board of Director deliberations regarding ESG

The Board of Directors receives regular reports on the Group Sustainability Committee and deliberates on related issues. During fiscal 2023, the Board of Directors deliberated on the following issues.

In the environment field, there was an examination of the response to climate change risk, more efficient use of resources, and biodiversity preservation.

In the society field, there was an examination of securing human resources (human capital investment, engagement, diversity, recruiting, and labor environment), in-house and outside supply chain management, and contributions to local communities. In the field of governance, response to the Corporate Governance Code, internal controls, compliance, and risk management were examined.

In response to these deliberations, it was decided to set sustainability-related targets in the Medium-Term Business Plan.

## Evaluation of the effectiveness of the Board of Directors

The Company regularly analyzes and evaluates the effectiveness of the Board of Directors once a year and strives to implement continual improvements. An evaluation of the effectiveness of the Board of Directors was conducted in fiscal 2023 as outlined below. Initiatives regarding the following three issues were launched in response to the finding of the previous year's evaluation.

### Fiscal 2023 initiatives in response to the evaluation of the effectiveness of the Board of Directors for the previous fiscal year

- Expanding deliberations related to management strategy and plans
- Relationship of human capital and human resource training outlook with management strategy
- Strengthening relationship with stakeholders

## Analysis and evaluation of the Board of Directors' effectiveness in fiscal 2023

Implementation method and results	Main opinions	Fiscal 2024 initiatives
<ul style="list-style-type: none"> <li>• The third-party organization administered self-evaluation by anonymous questionnaires</li> <li>• The third-party organization collected the questionnaires and analyzed the results</li> <li>• The Board of Directors verified and discussed the results based on the report received from the third-party organization</li> <li>• Based on the above results, the Company's Board of Directors is considered to fulfill its roles and functions properly</li> </ul>	<ul style="list-style-type: none"> <li>• Active discussion and suggestions should be made on developing and operating the succession planning for the CEO, etc.</li> <li>• There are some inadequacies in the follow-up of matters resolved by the Board of Directors.</li> <li>• The Board needs to discuss the Group's long-term (5-10 years) business strategy more actively.</li> <li>• The Board of Directors should avoid a skills (map) shortage associated with the relative decline in the number of internal directors.</li> <li>• The Board of Directors should to increase opportunities for information sharing and opinion exchange with the internal audit department.</li> </ul>	<p>We will work to improve the following five items.</p> <ol style="list-style-type: none"> <li>1) Succession planning</li> <li>2) Follow-up monitoring of progress</li> <li>3) Further enhancement of discussions on management strategies and plans</li> <li>4) Composition and skills of the Board of Directors</li> <li>5) Operational method of the Board of Directors</li> </ol>



**ESG Data:** <https://global.sawaigroup.holdings/sustainability/esg/>  
**SASB Index:** <https://global.sawaigroup.holdings/sustainability/sasb/>

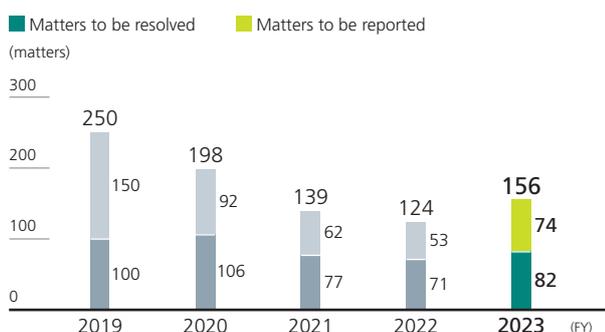
## Improving the operation of the Board of Directors

The Board of Directors deliberates important matters in the Group Investment Committee and the Group Strategy Council before referring them to the Board of Directors, in order to ensure that in-depth discussions focus on the most important points. In addition, based on “the Regulations on Affiliated Company Management,” the Board of Directors is informed of the important management status of Group companies and delegates authority to Group companies to make decisions on matters within certain criteria, thereby achieving a balance between supervision of Group companies and speedy decision-making.

### Key questions and comments from external directors at the fiscal 2023 Board of Directors meeting

- (In response to the findings of the investigation into inappropriate testing) We can be reassured by the findings that there was no evidence of organizational involvement, but there may have been a disposition that supply could not be stopped or that growth was a priority above all else.
- (Regarding investment in human capital) We should put this forward as one of the major issues for future growth.
- (In terms of cost-of-capital management) It is important to manage the business portfolio with an awareness of the cost of capital, as well as shareholder returns.
- (In terms of defensive risk measures) The system should be strengthened by including someone familiar with GMP/GQP in the whistle-blowing office. Speed and depth are important.
- (In terms of contributions to the sustainability of society) Pediatric formulations should be discussed, including the issue of disposal, while removing the unconscious bias.

### Number of proposals



### Board of Directors

<https://global.sawaigroup.holdings/sustainability/governance/board/>

#### Main items

- Skills Matrix
- Improving the operation of the Board of Directors
- Corporate Officer Remuneration System
- Training policy for Directors and Audit & Supervisory Board members
- Supporting system for External Directors and/or Audit & Supervisory Board members
- Independence standards for External Directors / Audit & Supervisory Board members
- Evaluation of the effectiveness of the Board of Directors
- Policy and process for appointing Executive Officers, candidates for Directors and candidates for Audit & Supervisory Board members
- Succession planning for the CEO and other executives
- Policy for cross-shareholdings, and voting Guidelines

## IR communication

The Representative Director and President, and the person in charge of information disclosure shall actively participate in dialogue with shareholders and investors, provide substantial information on management strategies and finances, etc., and strive for two-way constructive communication with shareholders and investors. In addition, the results of the dialogue shall be reported to the Board of Directors, and the opinions of shareholders shall be actively utilized in the management of the Company.

The department responsible for IR handles reasonable requests for dialogue from shareholders and investors, and directors and senior managers play an active role when their schedules permit. The department responsible for IR also handles e-mail and phone inquiries orally or in writing.

### Fiscal 2023 IR meetings

Meetings with Japanese and overseas investors	191
Meetings with the media	38

## Information security governance

The Group stresses information security governance in order to preserve and manage information assets. We undergo regular information security assessments by independent entities, and we use those objective evaluations to develop a medium-term information security plan.

In fiscal 2023, we offered two e-learning classes as part of employee education, two targeted email-attack training classes, and a cybercrime response class, which was taught by an outside instructor, as part of responsible staff training. Furthermore, the Group IT department handled the ISMS certification audit following revisions to certification criteria, objective proof that we properly conduct information security management and countermeasures. Every year, we strengthen our technical response, which includes such activities as expanding the scope of various logs collected with a follow-up survey in mind.

## Financial indicators

(Sawai Group Holdings Co., Ltd. and its subsidiaries)

	Japanese GAAP →		
	FY2013	FY2014	FY2015
<b>For the fiscal year (Millions of yen)</b>			
Net sales / Revenue	89,824	105,454	123,492
Cost of sales	48,353	60,048	71,858
Gross profit	41,471	45,406	51,634
Selling, general and administrative expenses/ Selling, general and administrative expenses (including research and development expenses)	22,380	24,718	28,449
Operating income / Operating profit (loss)	19,091	20,688	23,185
Profit before income taxes / Profit (loss) before tax	18,990	20,298	23,092
Profit attributable to owners of parent / Profit (loss) attributable to owners of the Company	12,193	14,053	17,156
Research and development (R&D) expenses	5,170	6,110	8,019
Capital expenditures	7,353	13,251	17,775
Depreciation and amortization	4,989	5,863	7,044
<b>At fiscal year-end (Millions of yen)</b>			
Total assets	149,348	166,180	206,492
Inventories	39,182	44,663	55,668
Total current liabilities	39,097	42,209	50,078
Total long-term liabilities / Total non-current liabilities	8,949	11,572	30,692
Net assets/Total equity	101,302	112,399	125,722
<b>Cash flows (Millions of yen)</b>			
Net cash provided by operating activities/Cash flows from operating activities	13,422	12,112	19,975
Net cash used in investing activities/Cash flows from investing activities	(8,283)	(14,123)	(22,937)
Net cash provided by (used in) financing activities/Cash flows from financing activities	(178)	(922)	13,473
Cash and cash equivalents at end of year/Cash and cash equivalents at the end of the year	25,537	22,604	33,096
<b>Financial indicators (%)</b>			
Ratio of R&D expenses to sales/Ratio of research and development expenses to revenue	5.8	5.8	6.5
Return on equity/Return on equity attributable to owners of the Company	15.0	13.2	14.4
Shareholders' equity to total assets/ Ratio of equity attributable to owners of the Company to total assets	67.8	67.6	60.8
<b>Per share information (yen)</b>			
Net income–basic / Basic earnings per share	365.18	382.26	465.57
Net income–diluted / Diluted earnings per share	330.41	381.85	465.25
Cash dividends applicable to period / Dividends per share	95.00	105.00	120.00
Net assets / Equity attributable to owners of the Company per share	2,755.29	3,053.29	3,405.20

## Non-financial indicators

(unless specially noted, for Sawai Pharmaceutical)

	FY2013	FY2014	FY2015
Sales volume (Billion tablets)	6.5	8.0	8.9
Production capacity (Billion tablets)	8.6	10.0	11.3
Number of new products launched	23	28	25
Number of patents held	14	19	21
Number of GMP audits	–	–	–
Number of employees (consolidated)	1,121	1,239	1,490
Number of female employees in managerial positions	9	10	10
Ratio of female employees in managerial positions (%)	4.8	5.2	4.5
Employee training expenses (Sawai Group) (Millions of yen)	65	83	90
Number of employees who have received training (Sawai Group)	323	418	596
Number of employees involved in production (Sawai Group)	350	414	628
Number of employees involved in R&D (Sawai Group)	167	185	209
Energy used (Sawai Group) (Crude oil conversion kl)	17,931	20,473	26,781

Notes 1. If there are differences in representation between Japanese GAAP and IFRS (voluntarily applied since fiscal 2017), the item is marked "Japan GAAP / IFRS."

2. Capital expenditures are presented on a cash flow basis.

3. As the Company split its common stock two for one on October 1, 2013, amounts per share for fiscal 2013 were recalculated to reflect the share split.

4. Dividend per share in fiscal 2018 included our 90th anniversary commemorative dividend of ¥5.

5. The U.S. business was classified as a non-continuing business in fiscal 2023. Fiscal 2022 and fiscal 2023 revenue, operating profit, and profit before tax are those for continuing businesses, excluding non-continuing business.



## **Sawai Group Holdings Co., Ltd.**

5-2-30 Miyahara, Yodogawa-ku, Osaka 532-0003, Japan

TEL: +81-6-6105-5818 FAX: +81-6-6394-7311

URL: <https://global.sawaigroup.holdings>