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 Sawai Pharmaceutical's website and will be regularly updated.
(see the following URL for details)
https://www.sawai.co.jp/important_news/detail/17
(Available only in Japanese)

*2
For details, see the Japan Generic Medicines Association's website.
https://www.jga.gr.jp/jgapedia/deals/2403.html
(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.

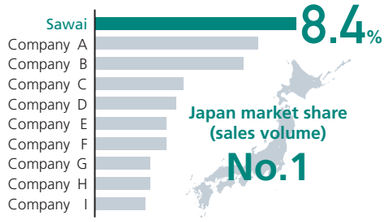
Another advantage is that both for items whose cost of production has dramatically increased and for unprofitable items, Sawai Pharmaceutical began implementing in fiscal 2023 a pricing policy to have them purchased at nearly the National Health Insurance (NHI) drug price without excessive discounts. 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.

Prescription drug sales (tablets) by company (Japan)



Reduction in healthcare costs due to Sawai Group products

¥293.9 billion in FY2023

Difference assuming original drugs are used instead of Sawai Group generic drugs

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[*3] 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.

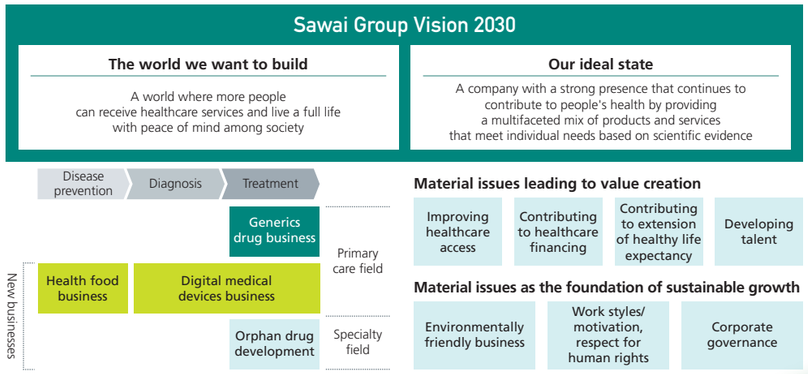
On the other hand, we have significantly enhanced the governance structure. The ratio of external directors has increased to 3 out of 5. In addition, because one person with extensive management experience at pharmaceutical companies has been added as a director, the Board of Directors has become more 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_2 emissions, we will strive to reduce CO_2 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.

*3 Inclusion, Diversity, and Equity Promotion Office

"Sawai Group Vision 2030"and material issues for sustainability



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.

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(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