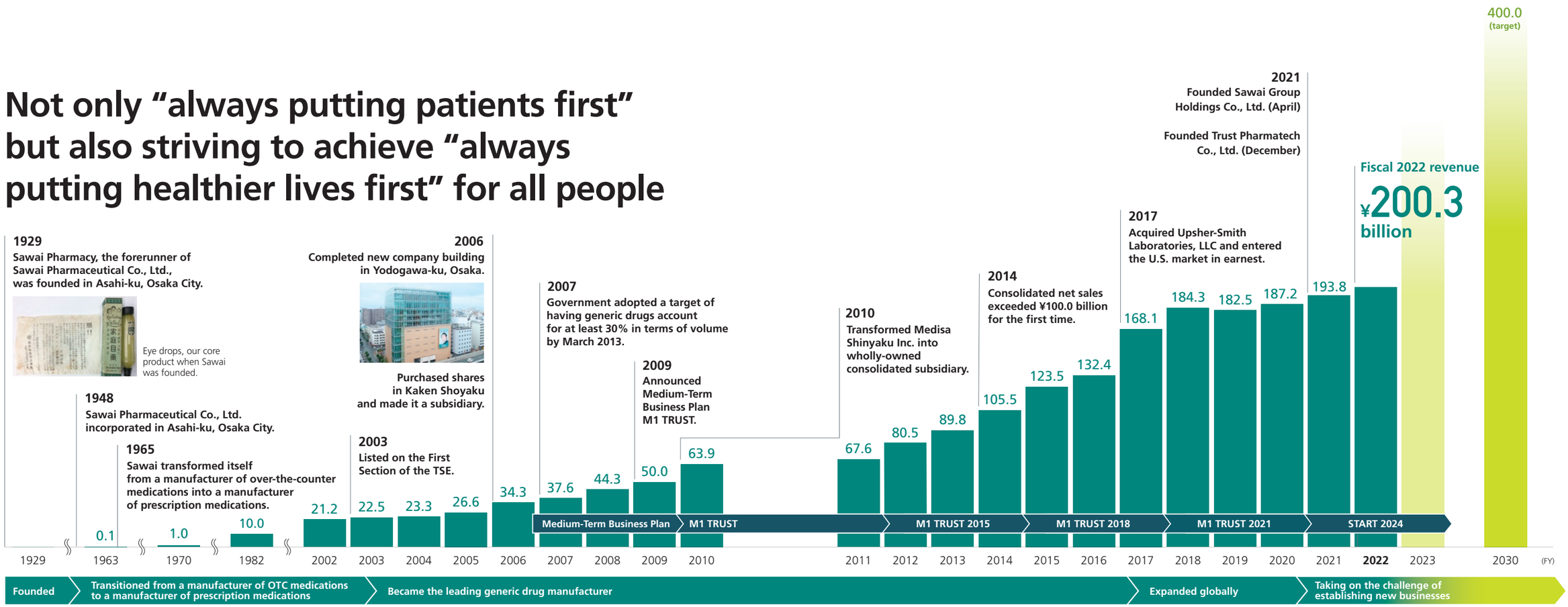
Not only “always putting patients first” but also striving to achieve “always putting healthier lives first” for all people



History of developing non-financial capital

1981

Manufactured capital

Completed the GMP standard–compliant Kyushu Factory

We built the Kyushu Factory in Iizuka City, Fukuoka Prefecture as an advanced factory compliant with GMP standards, the international standards for pharmaceutical manufacturing and quality management. In addition to underpinning the stable supply of high-quality Sawai products, the factory also contributed to developing the brand image of Sawai Pharmaceutical.

1984

Intellectual capital

Opened the Osaka Laboratory to expand research

At that time, few generic drug manufacturers had independent facilities dedicated to R&D. From our earliest days, our stance of stressing R&D has been carried on by the Pharmaceutical Research Center, which opened in 1994, and the Pharmaceutical Development Center, which opened in 2015.

2007

Social and relationship capital

Established a new Corporate Philosophy and Code of Conduct

We established the Corporate Philosophy consisting of the three tenets of mission, challenge, and hope as the basis for the participation of all employees, centered on the Company’s longtime motto “Always putting patients first.” We also established the Code of Conduct as a guide for the implementation of the Corporate Philosophy.

2009

Social and relationship capital

Announced M1 TRUST, its Medium-Term Business Plan

We announced a plan to achieve ¥100.0 billion in consolidated net sales within five years by expanding market share, further strengthening the management structure, and building a solid Sawai brand as the basic policies. The basic policies were carried over into the Company’s subsequent Medium-Term Business Plans.

2013, 2017

Manufactured capital

Kanto Factory

Built the Kanto Factory and the Sanda Nishi Factory to boost production capacity

We built a new formulation factory on the site of the Kanto Factory (Mobara City, Chiba Prefecture) in March 2013, and the Sanda Nishi Factory (Sanda City, Hyogo Prefecture) specializing in packaging processes adjacent to the Sanda Factory in January 2017. This boosted production capacity and risk management, including disaster response.

2015

Intellectual capital

Built Pharmaceutical Development Center

We established a new Pharmaceutical Development Center in Suita City, Osaka Prefecture close to the Head Office. The Pharmaceutical Development Center consolidated some of the functions of the former Pharmaceutical Technology Center, which had been located in Asahi-ku, Osaka City, and the Research Laboratories as a site with responsibilities including commercialization and stable supply of products as well as improvement of launched products, in addition to the development of new products.

2021

Social and relationship capital

sawai
サワイグループ
ホールディングス株式会社

Transitioned to holding company structure through the transfer of shares

To continue to generate sustainable growth into the future, the Group considered it necessary to simultaneously reinforce existing businesses and foster new businesses that meet the demands of the time and determined that transitioning to a holding company structure would be optimal.

2022

Human capital

S-Wing スウィング

Undertook the S-Wing Project

With the goal of “promoting diversity,” one element of the Group’s long-term vision, we conducted project-related activities for about six months, and then related proposals regarding a future action plan were submitted to members of senior management in March 2023.

→ P.30 Topics

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.

Social issues

Rising medical expenses
Medical expenses
¥43.0 trillion
(FY2020)

The Hyper-aging society
Percentage of Japanese population aged 65 or older
29.1%
(September 2022)

Need for affordable and safe drugs
Share (volume) of generic drugs for all prefectures
80% or more
(through March 31, 2023)

Stable supply of drugs

Increasing interest in QOL

Management capital* (Input)

Financial capital
R&I credit rating
A–

Manufactured capital
Production capacity (Japan)
18.5 billion tablets / year

Human capital
MRs
375
Qualified pharmacists
246

Intellectual capital
Patents owned
45

Social and relationship capital
Strongest brand in generic drug industry
13th consecutive year ranked top in approval rating among generic drug companies favored by pharmacists (Research by Nikkei Drug Information)

* as of March 31, 2023

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 based on scientific evidence that meet individual needs

Business activities

Generic drug business

Research and development
- Ability to undertake research and analysis of originator drug patents
- Formulation technology capabilities based on human resources with expertise in API properties and formulation technology

Procurement
- Strong new product API research and procurement abilities
- Selection and procurement of raw materials with primary emphasis on quality and safety

Production and reliability assurance
- Manufacturing know-how for high-mix, low-volume production
- Stringent quality management
- Own production factories located throughout Japan and external partner companies

Sales and marketing
- Provision of accurate information
- Extensive product lineup

Enter into new businesses

Digital medical devices business
We will provide a neuromodulation device and treatment app (DTx) as new treatment methods, and a PHR management app as a health management tool.

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 leading to value creation

Improving healthcare access / Contributing to healthcare financing / Contributing to extension of healthy life expectancy / Developing talent

Material issues as the foundation of sustainable growth

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

Business results* (Output)

Revenue
¥200.3 billion

Operating profit
¥17.0 billion

ROE
6.5%

Production volume
16.6 billion tablets
(Japan business)
2.9 billion tablets
(U.S. business)

New products
23 products
(Japan business)
2 products
(U.S. business)

Patent applications
32

*actual for FY2022

Value provided to society (Outcome)

Improving healthcare access
Sales volume
15.0 billion tablets
(Sawai Pharmaceutical)

Contributing to healthcare financing
Amount of reduction in healthcare costs
¥280.9 billion
(Japan business)
¥131.2 billion
(U.S. business)

Contributing to extension of healthy life expectancy
Personal health record (PHR) management app
Used by more than
400 medical institutions

Developing talent
Employee education and training expenses (Sawai Group in Japan)
¥85.00 million

Research and development

Strength 1 Ability to undertake research and analysis of original drug patents

By utilizing both human assets with extensive experience in patent trials and proceedings and a proprietary database that includes information on patents and proceedings in Japan and overseas, we implement an extremely sophisticated patent strategy. We develop the optimal patent strategy for new issues in collaboration with patent attorneys in Japan and overseas who possess broad knowledge of pharmaceuticals.

In recent years, we have also been keeping an eye on intellectual property trends in the U.S. and Europe and leverage those trends for our intellectual property strategy for Japan. In particular, it is possible to learn a lot from applying for paragraph IV certification in the U.S., and this is a major asset that supports future business activities, which is one of our strengths.

Number of patents held

45

Sawai Pharmaceutical

Strength 2 Formulation technology capabilities based on human assets with expertise in API properties and formulation technology

Another of our Group's 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 international harmonization. Furthermore, we have increased the certainty of our product launches by continually revising and bringing forward development plans. Even while busy with product development, we actively take on the challenge of research linked to future development topics and aggressively work to accumulate and expand our formulation technology.

We will provide drugs that meet the needs of healthcare professionals and patients and introduce first-of-their-kind products using SAWAI HARMOTECH®, a series of formulation technologies born from this research.

R&D expenses

¥12.5 billion

Sawai Pharmaceutical

Number of R&D Division staff

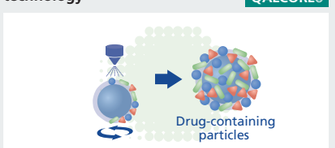
295

Sawai Pharmaceutical

SAWAI HARMOTECH®

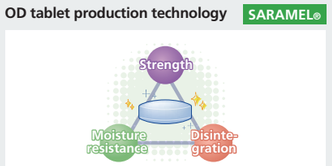
Sawai Pharmaceutical's main formulation technology

Core particle production technology QALCORE®



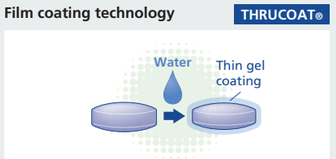
Dry coating, wet coating, and wet adsorption method are three core particle production technologies that allow us to reduce production time and make products comfortable for patients to take.

OD tablet production technology SARAMEL®



Our original additive SARAMEL is a patented technology of Sawai that makes it possible to produce tablets with outstanding strength, moisture resistance, and disintegration properties by simply mixing with API.

Film coating technology THRUCOAT®

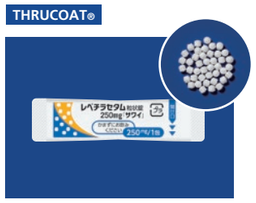


With this technology, a gel coating forms on the surface by moisturizing with water, creating tablets that are easy to take with little force. This makes it easier to take the medicine.

Escitalopram OD Tablets
QALCORE® SARAMEL®

Dia. 7 mm

Levetiracetam Granular Tablets
THRUCOAT®



Dia. 2.1 mm

Message from responsible officer (R&D)

Taking on the challenge of new businesses in addition to being the first to introduce generic drugs

Shoji Yokota, Ph.D.
Director, Senior Managing Executive Officer, Group Chief Research & Development Officer

To undertake product development, which has grown more difficult in recent years, we are not only increasing research efficiency through DX but are also broadly strengthening our R&D foundation, which includes actively undertaking joint research with such entities as independent research institutes and researching physiological models that do not employ animal testing.

We will take on the challenge of being the first to introduce generic drugs and launching new businesses so that no suffering patients are left behind, and this entails developing drugs for rare diseases that lack sufficient treatments and similar activities.

Message from responsible officer (IP)

Promoting robust intellectual property capabilities, including those for new business fields

Nobuko Sugimoto
Senior Executive Officer, Group Chief Intellectual Property Officer

Having handled patent cases, mainly those related to generic drugs, in the past, we will strive to strengthen our intellectual property capabilities in new fields, such as digital medical devices in the future.

Furthermore, we will work to maximize the value of intangible assets throughout the Group by strengthening measures related to training personnel who possess specialized knowledge in various fields, such as intellectual property, formulation, and property analysis; undertaking and maintaining systematic and comprehensive activities, including the formulation of an advanced intellectual property strategy; and promoting the protection and branding of intellectual property, Sawai's original technology, centered on SAWAI HARMOTECH®.

Procurement

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, examining production facilities, quality, etc., and conducting 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 provides support for research and procurement through its specialists in purchasing, including members with experience at new drug manufacturers, API trading companies, and Sawai factories.

Suppliers

Procure a wide range of raw materials from around
500 companies in **30** countries throughout the world

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

In order to deliver even higher quality generic drugs, we inspect the factories of API manufacturers, particularly the Quality Assurance Department. Furthermore, we confirm that API manufacturers' quality management systems meet Sawai standards by checking that the Production Department undertakes manufacturing in an appropriate environment and the Quality Control Department conducts appropriate analysis. 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—that is, procuring the same API from multiple manufacturers in order to ensure stable procurement.

Production and reliability assurance

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 know-how regarding preventing the mixing of principal ingredients.

For tablet presses that form granules into tablets, it takes almost one whole day to switch between products, and Sawai ensures safety by validating each cleaning procedure. This know-how related to validating unique generic drug production processes and managing production makes it possible to conduct high-mix, low-volume production and ensure quality.

Production capacity

15.5 billion tablets
Sawai Pharmaceutical

5.0 billion tablets
Upsher-Smith

Number of products approved to manufacture

Approx. 750
Sawai Pharmaceutical

Approx. 60*
Upsher-Smith

* Calculated according to the counting standards of Japan

Strength 2 Stringent quality management

Quality is managed to exceed government standards through all process, from selection of API and additives to production process, and even post-sales.

We are working to further improve our uncompromising quality in order to provide generic drugs that can be used with peace of mind.

Number of staff in Quality Control Department

411
Sawai Pharmaceutical

68
Upsher-Smith

Strength 3 Own production factories located throughout Japan and external partner companies

Production management and quality control are undertaken, primarily for our eight main factories in Japan. All eight factories observe GMP, and we strive to implement continual improvements by acting in concert and sharing the findings of audits.

We also conduct audits of formulation manufacturing subcontractors at least once every three years.

Number of internal GMP audits

153
Sawai Pharmaceutical

62
Upsher-Smith

Message from responsible officer

Embodying the Group philosophy through continuous efforts to improve quality

The Group has expanded its production capacity within Japan to 18.5 billion tablets, which includes 15.5 billion tablets for Sawai Pharmaceutical's six factories (Kashima, Kanto, Sanda, Sanda Nishi, Kyushu, Daini Kyushu), and 3.0 billion tablets for Trust Pharmatech's Yachi and Seima factories.

Through not only this production capacity but also continually implementing measures to increase quality, we aim to embody the Group's philosophy of "always putting healthier lives first."

Toshiya Hasuo
Senior Executive Officer
Group Chief Production Officer

Topics Working to establish a production system at Trust Pharmatech

Founded as a new subsidiary of the Group in December 2021, Trust Pharmatech launched full production in April 2023 and is moving forward with efforts to establish a production system with an annual capacity of 2.0 billion tablets or more in 2024.

The most important efforts are thoroughly introducing and spreading the corporate philosophy of "always putting patients first" and Sawai quality just like has been done at Sawai Pharmaceutical. In order to spread the corporate philosophy to each and every employee and encourage its implementation, we systematically undertake training and group activities to raise compliance awareness. We are also rebuilding our GMP system and providing continual employee education to spread the Sawai culture regarding quality.

Furthermore, we are transferring production to factories in a planned manner. As for new products, in addition to passing on Sawai standards based on witnessed manufacturing and testing by the Research and Development Division, Sawai Pharmaceutical employees provide onsite guidance for producing and testing existing products. Even for ensuring quality, Sawai Pharmaceutical offers support on all fronts, such as holding guidance meetings and conducting audits by the responsible person in the Quality Assurance Department and Reliability Assurance Division.

Our goal is to achieve an annual production capacity of 3.0 billion tablets in the future by increasing the number of employees involved in manufacturing through 2025.

Trust Pharmatech's Seima Factory 2

Sales and marketing

Strength 1 Provision of accurate information

We provide information to patients and healthcare professionals through three 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.

In addition to undertaking activities for providing accurate information to all healthcare professionals, MRs collect and compile information on side-effects and safety of drugs, and this work is led by the Pharmacovigilance Department. We are working to have our drugs properly used by providing that information to healthcare workplaces as feedback.

Number of MRs

Approx. 370
Sawai Pharmaceutical

Approx. 20
Upsher-Smith

Strength 2 Extensive product lineup

The lineup of products offered by our Japanese Group companies extends to about 800 products. Our ability not only to 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 Sawai Group.

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

Number of products on sale

Approx. 800
Sawai Pharmaceutical

Approx. 140*
Upsher-Smith

* Calculated according to the counting standards of Japan

Aiming to become a corporate group trusted by stakeholders

Basic philosophies

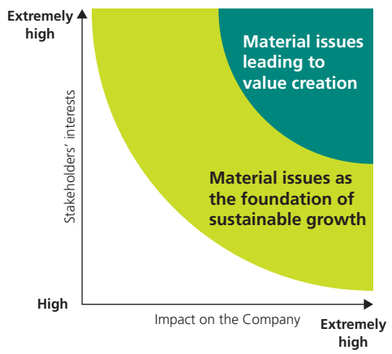
- At the Sawai Group, we believe that a healthy society and its sustainable development are the foundation of why we exist.
- The Sawai Group can only be sustainable if it is recognized as an entity (in other words, an institution of our society) necessary for the realization of a sustainable society, and if it maintains a firm relationship of trust with all our stakeholders.
- As our society changes, the Sawai Group can continue to exist in a sustainable way by rapidly responding to these social changes and by continuing to evolve.

Key policies

- Based on our corporate philosophy of "Always putting healthier lives first," we strive to do our part in realizing a sustainable society through our business, by contributing to the maintenance and development of healthy lives and superb healthcare systems.
- We endeavor to stay engaged (building bonds of mutual trust) with all our stakeholders including patients and consumers, healthcare professionals such as medical institutions, business partners, employees, shareholders, local communities, and the global environment.
- We pursue creativity and constantly evolve along with society, so that the Sawai Group can remain sustainable.

Material issues (set May 2022)

For the Group to achieve a sustained enhancement of its corporate value, we identify material issues (important issues) that should be given priority in resolving from the two perspectives of stakeholders' interests and impact on the Company, which are based on the idea that business activities that take into consideration sustainability for the whole of society are indispensable.



Material issues leading to value creation	
Improving healthcare access	Product quality and safety Maintaining a stable supply Providing meaningful information
Contributing to healthcare financing	Development of high-value-added generic drugs
Contributing to extension of healthy life expectancy	Expanding business to a wider range of healthcare domains, including pre-symptomatic illness and prevention
Developing talent	Training for future management candidates

Material issues as the foundation of sustainable growth	
Environmentally friendly business	Responding to climate change Recycling and waste control Water use reduction Biodiversity
Work styles/motivation, respect for human rights	Realization of work-life balance Maintenance of a safe, healthy workplace environment Diversity promotion
Corporate governance	Stronger risk management/compliance Stakeholder engagement Prevention of bribery/corruption Supply chain management/fair, transparent transactions Stronger information security

Process for setting material issues

The Group's material issues are identified through the following steps. We also regularly review and confirm their appropriateness and revise them around once every three years from a medium- to long-term perspective because it is necessary to take into account changes in the business environment and new social issues.

Step 1
List issues

List the management issues that are considered deeply connected to medium- to long-term corporate value based not only international initiatives, such as the International Integrated Reporting Council (IIRC) Framework, Sustainability Accounting Standards Board (SASB) Standards, GRI Sustainability Reporting Standards, and SDGs but also the Group's corporate philosophy, Group vision, and business environment

Step 2
Extract and evaluate impact of issues

Map issues on the two axes of stakeholders' interests and impact on the Group and classify as either material issues leading to value creation or material issues as the foundation of sustainable growth

Step 3
Check appropriateness

Approve after the Board of Directors deliberates and examines the appropriateness of the issues

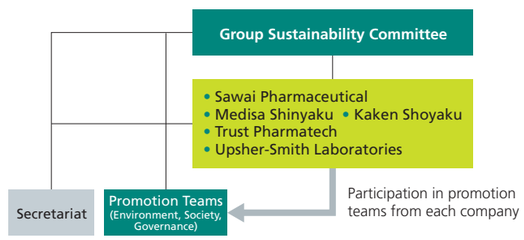
Risks and opportunities and our response

		Risks	Opportunities	Response
Generic drug business		• Decline in drug prices for various reasons including annual drug price revisions • General decline in trust in generic drugs • Increase in launch of AGs • Increase in API and raw material costs due to changes in exchange rates and inflation	• Growing demand because of aging society • Diversification and growing sophistication of healthcare and medicine needs • Movement to review drug price system • Chance to restructure the generic drug industry	• Work to reform the system so that it is possible to provide a long-term stable supply • Promote transition to a responsible corporate group • Work to further reduce costs
Digital medical devices business	Non-invasive neuromodulation device	• Delay in development and issues with business model • Unexpected safety and quality issues due to lack of experience	• Increase in the medical consultation and treatment rate due to the provision of new treatment methods • Provision of new treatment options to patients for whom drug treatment is not appropriate	• Collaborate closely with KOL* and related academic associations • Collaborate with experts knowledgeable in medical devices
	NASH treatment app	• Delays in development or failure of clinical trials • Launch of new drugs by competitors before the app is ready	• Becomes standard treatment and increases medical consultation, diagnosis, and treatment rates	• Cooperate with corporations and entities knowledgeable of DTx • Read KOL* and related academic association needs
	PHR management app (SaluDi)	• Continued differentiation from other apps • Delays in creating in-house system as use of app expands • Entry of overseas IT companies into healthcare services	• Presence established in the pre-symptomatic illness and disease prevention fields • Contribution to achieving a well-being society • Launch of services overseas, including Asia	• Expand disease prevention field and functions that support the field • Secure DX personnel • Introduce services based on collaboration with partners
Health food business		• Fiercer competition • Stricter advertising regulations and system changes due to revisions to laws • Safety and quality issues due to lack of knowledge and experience	• Greater health awareness as people live longer lives • Trust and brand strength built up in GE business	• Clarify target by setting meticulous marketing strategy and sales plans • Recruit human assets who possess professional knowledge and experience
Orphan drug business		• Delay or failure of clinical trials	• Larger market by providing new treatment options • R&D capabilities acquired through the GE business	• Possess sufficient resources and plan flexibility

* KOL(Key opinion leader), an expert with influence in a particular field.

Sustainability promotion structure

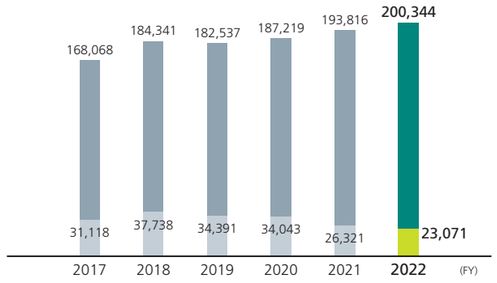
We are promoting initiatives through the Group Sustainability Committee, which is chaired by Sawai Group Holdings Representative Director and President (COO). To undertake practical initiatives, three promotion teams, the Environment (E) Team, Society (S) Team, and Governance (G) Team, subordinate bodies under the committee, were created and conduct related activities. The Secretariat is responsible for aiding the committee, communicating information on sustainability, and supporting the promotion team.



Financial highlights

Revenue / Core operating profit

Revenue ¥200,344 million
Core operating profit ¥23,071 million

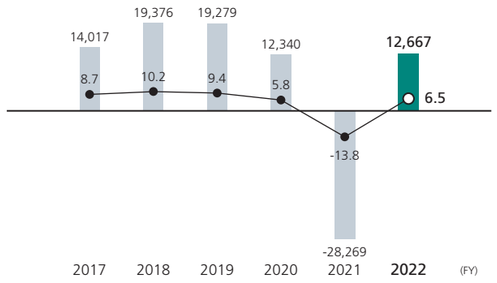


Revenue: For the Japan business, revenue was flat despite drug price revisions because of growth in sales of new drugs and removal of limits on shipments, and for the U.S. business, revenue rose year on year as a result of steady progress with brand drugs and other products and the weaker yen. As a result, revenue surpassed ¥200.0 billion for the first time.

Core operating profit: Core operating profit fell year on year for various reasons, including upfront costs to strengthen production capacity for the Japan business.

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

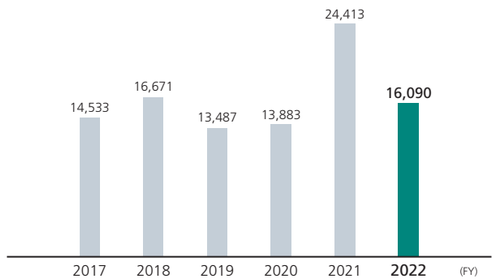
Profit attributable to owners of the Company ¥12,667 million
Return on equity attributable to owners of the Company 6.5%



In a challenging environment for both the Japan business and the U.S. business, the Group worked to secure profits by aggressively reducing raw material and other costs. Despite the impact of upfront costs for the Japan business, there was no impairment loss for the U.S. business as there was in the previous fiscal year, resulting in net profit.

R&D expenses

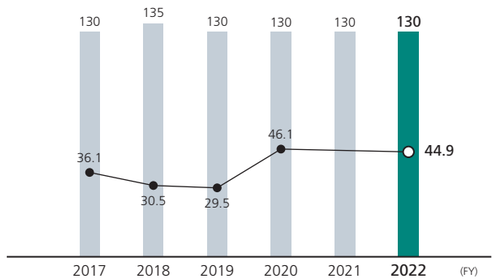
R&D expenses ¥16,090 million



The Sawai Group invested 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. R&D expenses fell 34.1% year on year to ¥16,090 million because not only there was no impairment loss this fiscal year for the U.S. business as there was for the previous fiscal year but expenses were also cut.

Dividends per share / Dividend payout ratio

Dividends per share ¥130
Dividend payout ratio 44.9%



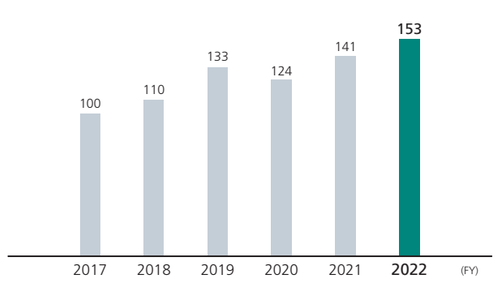
We aim to pay stable and continuous dividends with a target payout ratio of 30%, taking account of the balance between investment for growth and dividends, as well as comprehensively considering the consolidated financial results for each fiscal year, the dividend payout ratio, and other measures aimed at shareholder returns. In fiscal 2022, the Company provided an annual return to shareholders of ¥130 per share.

Non-financial highlights

Scope of data: Sawai Pharmaceutical

Number of GMP audits

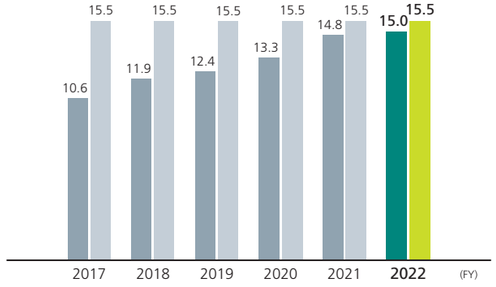
Number of GMP audits 153



Sawai Pharmaceutical has formed a dedicated audit team, which performs more than 100 GMP audits a year. 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.

Sales volume / Production capacity

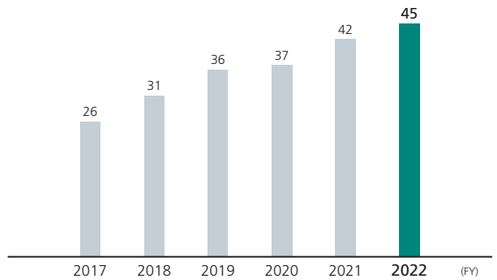
Sales volume 15.0 billion tablets
Production capacity 15.5 billion tablets



The Group's ability to supply a relatively large number of top quality generic drugs is backed by our industry-leading production capacity. In addition to further expanding its production capacity through initiatives such as constructing the Daini Kyushu Factory, the Group will fulfill its role as a generic drug supply infrastructure company.

Number of patents held

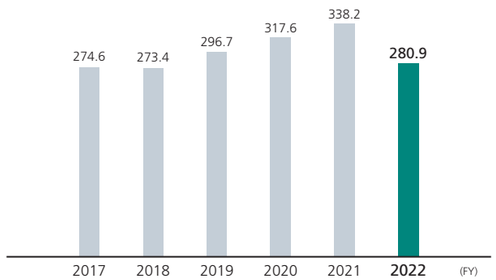
Number of patents held 45



We own a variety of patents, including a patent for reducing the bitterness of active ingredients and a patent for orally dissolving (OD) tablets that can be taken without water. Recently, numerous new technologies have been developed, and there has been an increase in various patent applications and registrations, including ones related to unique Sawai formulation technology (SAWAI HARMOTECH®). The Group is aiming to maximize the value of such intangible assets as patents.

Amount of reduction in healthcare costs

Amount of reduction in healthcare costs ¥280.9 billion



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, they contributed to a reduction in healthcare costs of about ¥280.0 billion, which still substantially exceeds our revenue.