# SAMAI QUALITY



# SAWAI QUALITY for Patients

Our goal is to deliver generics that are both low-priced and reliable to as many patients as possible. This is SAWAI QUALITY.

We began manufacturing generic drugs over half a century ago. Sawai Pharmaceutical places the patient before all else and continuously strives to provide top-quality products. Even today, our goal inspires our endeavors in a variety of areas such as stable product supply, formulation technology, information distribution. Our quality refers not only to our products but also to the people who make and deliver them as well as the environment where they are created and the extensive range of accurate information we possess.

We consider all of these to be SAWAI QUALITY.

By delivering patients with top-quality generic pharmaceuticals and encouraging their widespread adoption,

we hope to contribute to the further development of society.



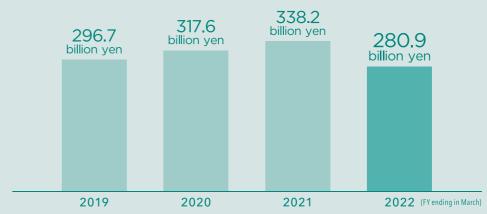


#### Our Pride in Quality Toward Societal Contribution

Helping revitalize health financing and improving access to health care through our business activities

Through the production and sale of low-cost generic drugs, as compared to brand-name competitors, we believe reducing patients' financial burdens and medical expenses is our most important social responsibility. We will focus on the continuation and development of our business activities.

Amount of medical expenses reduced. \*estimated by the Company







# SAWAI QUALITY

#1 Product supply capability

#### Nationwide network of 6 factories.

Our nationwide network of 6 factories features cutting-edge equipment and facilities. Here, we supply a variety of high-quality generic pharmaceuticals such as tablets, OD (Orally Disintegrating) tablets, and injectables. To ensure patients receive the required amount of drugs at the required time, it is essential to have a comprehensive system in place at all times. This is why Sawai Pharmaceutical cuts no corners in its operations.







#### SAWAI QUALITY #1 Product supply capability

#### Production system that accommodates a lineup of more than 800 products.

Whether it be anticancer drugs, antibiotics, or medicines for treating patients with allergies or lifestyle diseases such as high blood pressure, diabetes, or hyperlipidemia, generic pharmaceuticals are available for all types of illnesses and come in a variety of forms: tablets, OD tablets, capsules, injections, eyedrops, transdermal patches, and more. To address current needs and the symptoms of each patient, Sawai Pharmaceutical carries a lineup of more than 800 products. The reason we are able to produce and reliably supply such a large number of drugs is because of the technology we possess for researching a diverse array of active ingredients and combining these to create new products.



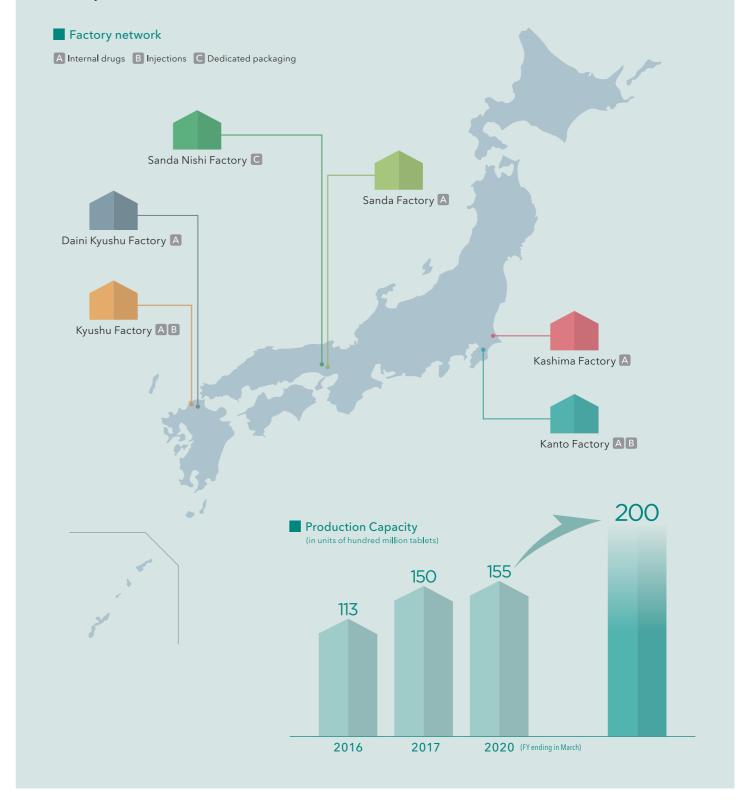
#### We carry out meticulous quality control by instituting strict quality standards for each process at all of our factories.

We carry out meticulous quality control based on strict government-designated standards for each process at our factories, from the acquisition of raw materials and packaging materials to intermediate and final product inspections before shipment. After our quality assurance managers verify these records, product shipment is finalized. We are also committed to hygienic management to ensure our factories always remain clean. We work to guarantee a stable supply of products within a safe and reliable environment.



#### Our industry-leading production system of 6 factories.

To meet the growing demands of the generic drug market, Sawai Pharmaceutical has worked to strengthen its production system over the years. In 2013, our Kanto Factory pharmaceutical plant was completed and in 2015 we took over our Kashima Factory. In 2016, our Sanda Nishi Factory, which specializes in packaging processes, was completed and began product shipments from 2017. By distributing our production across 7 bases, we have taken measures to avoid any damage that may be incurred from natural disasters such as earthquakes and typhoons. Through the full operation of this industry-leading production system equipped with cutting-edge equipment and facilities, we work to provide a stable supply of high-quality products. Looking ahead, we aim to establish a production capability of more than 20 billion tablets a year as soon as possible.





## #2 Formulation technology

Our formulation design is conceptualized around the idea of "being uncompromising in everything from the selection of active ingredients to pursuing products that are easy-to-use for patients and easy-to-handle for medical professionals."

At Sawai Pharmaceutical, we focus on quality a step above the rest starting with the selection of the active ingredients that are the raw materials for generic drugs. We have independently established a set of high standards and carry out thorough analyses before selection. Using these high-quality active ingredients, we execute a variety of innovations only possible with generic drugs in order to create our pharmaceuticals. This includes reducing the size of large tablets, decreasing bitterness, or making a tablet drinkable without water. In addition to making our medicines easy for patients to use, we also make sure medical professionals can easily dispense prescriptions. We have designed our formulations placing primary importance on the people who will be using the drugs. This too is SAWAI OUALITY.







### We have established a stricter set of standards than those designated by government for selecting the active ingredients used as raw materials in our drugs.

At Sawai Pharmaceutical, we use active ingredients that conform with a set of original standards more extensive than those designated by the government. First, our R&D Department carries out a strict evaluation of the pharmaceutical ingredients' quality before settling on a manufacturer. Next, an audit led by the Quality Assurance Department is conducted on the pharmaceutical ingredient manufacturer's factory to determine whether production is taking place in a suitable environment and if quality control is being executed based on appropriate analyses. After determining this, we confirm whether the manufacturer's quality control system matches the standards set by Sawai Pharmaceutical. By linking together multiple sections such as our R&D, Quality Assurance, and Production departments in such a way, we are able to join together to produce high-quality products. And by cooperating with pharmaceutical ingredient manufacturers, we are able to continuously monitor our supply capacity and make purchases from multiple manufacturers to sustain stable procurement of pharmaceutical ingredients.









■ The process behind generic drug production

**Patent inspection** 



#### **Examining formulations**

(ingredient selection, development of analytical procedures, formula design)



Audit before authorizing a manufacturer



Acquisition of application data



Application/Responding to inquiries/ Compatibility inspection



Manufacturer audit



Authorization of manufacturing and sales



**NHI** pricing list

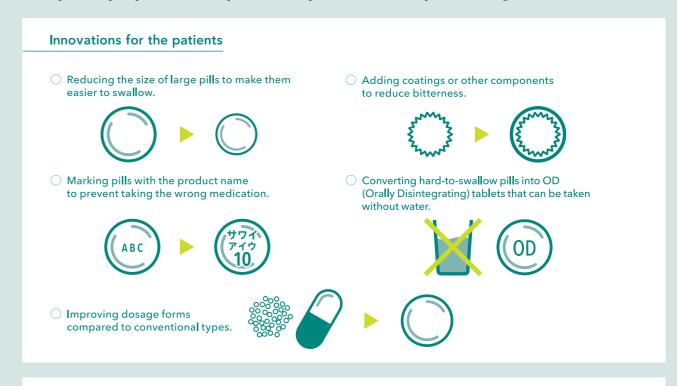
Example of a successful formulation bypassing various patents

Sale of orally disintegrating tablets with both sustained-release properties and concentrated effectiveness

It is necessary for generic drugs to show that they possess the same dissolution properties and pharmacokinetics as brand-name drugs while bypassing various patents for manufacturing processes, including substance patents. One example of this was the creation of generics that dissolve rapidly in the mouth (orally disintegrating tablets), while gradually releasing their active ingredients within the body (sustained-release). Working around numerous inter-related patents and carrying out various successive studies, we became one of the first companies to sell tablets that offered both high concentrated effectiveness and properties identical to the leading brand-name drugs. (patent approved)

### The pharmaceutical innovations made possible by generics: addressing diverse demands for shape, improvements to bitterness, and more.

Generic drugs are sold after the patents owned by the company that made the original medicines have expired. The technology for making drugs evolves every day, and we use it to our advantage in helping develop our generics, along with employing the opinions of numerous patients and medical professionals. In addition, we make use of our formulation techniques to acquire patents related to pharmaceutical products and to develop new technologies.



#### Innovations for medical professionals

 Larger display of product names to prevent mishandling.









- $\bigcirc\,$  Pre-packaging injections into syringes for ready-made kits.
- O Allowing easy removal from PTP.

O Displaying the drug's product name and/or indication to blister packs, which is the most common packaging style in Japan, to prevent mistakes when dispensing pharmaceuticals.



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Developing designs that reflect the product's indication (design registration)

Example of a value-added product derived from repeated studies

Development of a sleep-inducing drug that can be taken without water (OD tablet)

Taking a sleep-inducing drug with water directly before bed may induce the urge to urinate, thereby inhibiting sleep. There is also a danger the patient may fall over when using the toilet at night. From the desire to mitigate patients' concerns as much as possible, we developed OD tablets that can be taken without water. (patent approved)

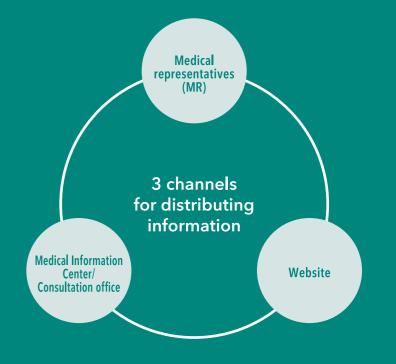


# SAWAI QUALITY

# #3 Distributing information

The quick delivery of accurate information so clients can use our products without concern is one more feature of Sawai's quality. Through our three systems of support, we provide information covering all types of topics.

We have 3 channels at Sawai Pharmaceutical that we use to distribute information: medical representatives (MR), the Drug Information Center for customer inquiries, and our website. Each of these channels functions by sharing information to create a solid system of support and promotes proper usage of products to medical professionals and patients. For medical professionals, it is possible to get the information you need from our Medical Information Center and website, in addition to that available through MR. Patients can get information on our products and initiatives at our website and consultation office. Through this fully-supportive system, we address the concerns of patients and medical professionals alike.



#### SAWAI QUALITY #3 Distributing information

#### Medical representatives have expanded their efforts for providing information to medical professionals.

Believing that "information on products is another aspect of quality," we engage numerous medical representatives in the proactive distribution of information. Our MR also collect information on drug side effects and safety, which is later compiled at our Pharmacovigilance Department. By applying this data to actual medical settings, we work to ensure our products are used appropriately. After selling our products, we diligently gather feedback from the patients and medical professionals who used them and utilize this in making improvements to deliver even higher quality products.



### We offer an extensive output of product information and corporate initiatives to patients and medical professionals who visit our website.

Sawai Pharmaceutical offers information through a network of four websites. On the Sawai Medical Site, which serves as a comprehensive source of information for medical professionals, we provide the latest product details as well as information that can be used in medical care and for guidance on medications. On the Sawai Oncology website page, we deliver information to assist medical personnel who are engaged in treating cancer. At the Sawai Pharmaceutical Corporate site, we publish explanations of generic drugs for patients as well as offer a search function for checking the availability of generic medications. And on the Sawai Health Promotion Department and Zutsu Online, we offer health-related information to support better communication between patient and practitioner.



Sawai Medical Site - an informative site for medical professionals\* https://med.sawai.co.jp/



Sawai Health Promotion Dept.\* https://kenko.sawai.co.jp/



Sawai Pharmaceutical Corporate Site https://www.sawai.co.jp/



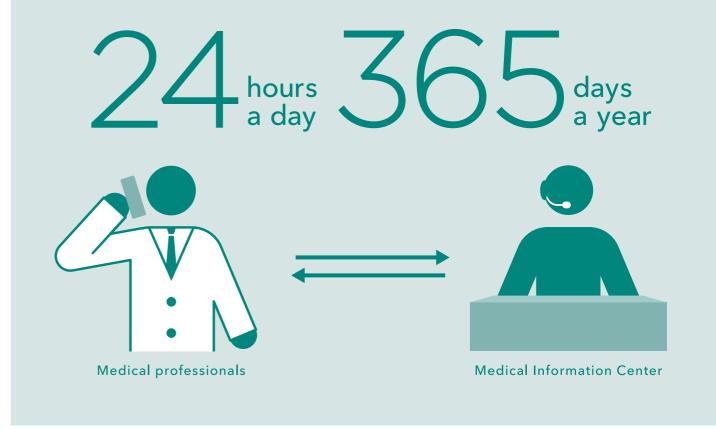
Zutsu Online - an informative site for patients with headache\* https://zutsu-online.jp/

\*Japanese Only

We have set up a Medical Information Center for medical professionals that can be contacted for support 24 hours a day, 365 days a year.



To be able to respond immediately to inquiries from medical sites - even on holidays or at night - we have set up a Medical Information Center that can be contacted for quick and accurate information as well as reliable support 24 hours a day, 365 days a year. Our Medical Information Center receives thousands of inquiries per month on matters concerning drug properties and usage as well as safety and more. We have also established a consultation office to field inquiries from patients. We share the feedback and requests received on products internally and apply them in delivering even higher quality products.



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Our goal is to make reliable generics available to as many patients as possible.



At Sawai Pharmaceutical, we hope to benefit society by dedicating ourselves to the production of high-quality generic pharmaceuticals.

Our corporate philosophy of always putting patients first forms the bedrock of all our activities.

In the end, it is the patient who experiences a drug's true effectiveness.

For this reason, our goal is to deliver generics that are both low-priced and reliable to as many patients as possible.

We will continue to pursue generic drugs of increasingly higher quality in the belief that the cumulative effect of this effort will lead to progress that will benefit humanity, society, and medicine.

President, Representative Director

Motohiko Kimura

It is Sawai's mission to enable people to live healthy lives through pharmaceutical products imbued with our whole-hearted dedication.

Our mission at Sawai Pharmaceutical is to always deliver medications that bring happiness and peace of mind to patients and are trusted by medical professionals. The low cost of generics leads to reductions in medical expenses for patients, health insurance associations, and local and national governments. This is why we believe that by dedicating ourselves to the provision of high-quality generic drugs we can enable people to live healthy lives and contribute to the betterment of society.

It is Sawai's challenge to grow in tandem with society through innovation and cooperation, while pursuing creativity.

In the rapidly changing field of medical care in Japan, corporations cannot grow without innovation. Whether in R&D, production, sales, or management, each employee must exercise their creativity and actively challenge themselves in whatever field they are engaged. Achieving this is what Sawai Pharmaceutical believes increases corporate value. We know that placing importance on cooperation and new encounters with people while pursuing harmony with society is essential to a company's growth.

It is Sawai's hope that we will become an indispensable part of society through our desire to serve others.

As a pharmaceutical company, we make sure our desire to serve patients and medical professionals also extends to our clients, partners, local communities, employees, friends, and families. We believe that a company with employees such as ours is truly able to earn the trust of society. Through our continued and constant efforts, we hope that both Sawai Pharmaceutical and its individual employees will become indispensable to medical sites, society, and the numerous people intersecting the two.

#### Corporate Profile

Company name Sawai Pharmaceutical Co., Ltd.

April 1, 1929

41.2 billion Yen (as of March 31, 2023)

No. of employees 2,592 (as of March 31, 2023)

Business outline Manufacturing and sales, export and import of pharmaceutical products, manufacturing and sales of health foods

Line of products More than 800 ethical pharmaceuticals, such as cardiovascular drugs, antihyperlipidemic agents, diabetes drugs, anticancer drugs

#### Offices

#### Head Office/Research Laboratories

Daini Kyushu Factory

Head Office Research Laboratories	5-2-30, Miyahara, Yodogawa-ku, Osaka 532-0003, Japan	Tel. +81-(0)6-6105-5711	Fax. +81-(0)6-6394-7311
Branches			
Sapporo Branch	4-5-1, Kita 7-jo Nishi, Kita-ku, Sapporo, Hokkaido 060-0807, Japan	Tel. +81-(0)11-700-3601	Fax. +81-(0)11-707-3620
Sendai Branch	4-2-3, Tsutsujigaoka, Miyagino-ku, Sendai, Miyagi 983-0852, Japan	Te <b>l</b> . +81-(0)22-295-5355	Fax. +81-(0)22-295-5359
Kitakanto Branch	206, Aramachi, Takasaki, Gunma 370-0831, Japan	Tel. +81-(0)27-310-5536	Fax. +81-(0)27-310-5537
Tokyo Daiichi Branch	2-11-2, Nihonbashi, Chuo-ku, Tokyo 103-0027, Japan	Tel. +81-(0)3-6273-4665	Fax. +81-(0)3-6281-9445
Tokyo Daini Branch	4-1, Shintoshin, Chuo-ku, Saitama 330-0081, Japan	Tel. +81-(0)48-600-6110	Fax. +81-(0)48-600-6113
Nagoya Branch	3-11-31, Sakae, Naka-ku, Nagoya, Aichi 460-0008, Japan	Tel. +81-(0)52-249-5370	Fax. +81-(0)52-249-5377
Osaka Branch	2-7-4, Akagawa, Asahi-ku, Osaka 535-0005, Japan	Te <b>l</b> . +81-(0)6-6921-9675	Fax. +81-(0)6-6921-9710
Hiroshima Branch	5-20, Teramachi, Naka-ku, Hiroshima 730-0801, Japan	Tel. +81-(0)82-234-0605	Fax. +81-(0)82-234-0559
Fukuoka Branch	4-1-33, Chiyo, Hakata-ku, Fukuoka 812-0044, Japan	Tel. +81-(0)92-409-0122	Fax. +81-(0)92-643-6080
Sales Offices			
Tokyo Nishi Sales Office	3-1-2 Nishikicho, Tachikawa, Tokyo 190-0022, Japan	Te <b>l</b> . +81-(0)42-548-0930	Fax. +81-(0)42-548-0931
Yokohama Sales Office	2-8-12, Shin-Yokohama, Kohoku-ku, Yokohama, Kanagawa 222-0033, Japan	Tel. +81-(0)45-476-1551	Fax. +81-(0)45-475-1048
Atsugi Sales Office	2-7-6, Nakacho, Atsugi, Kanagawa 243-0018, Japan	Te <b>l</b> . +81-(0)46-297-0227	Fax. +81-(0)46-225-5416
Chiba Sales Office	1-3, Nakase, Mihama-ku, Chiba 261-8501, Japan	Te <b>l</b> . +81-(0)43-298-3821	Fax. +81-(0)43-276-8610
Shizuoka Sales Office	11-30, Miyukicho, Aoi-ku, Shizuoka 420-0857, Japan	Te <b>l</b> . +81-(0)54-251-3331	Fax. +81-(0)54-251-3332
Kyoto Sales Office	30-1, Nishikujo Zaocho, Minami-ku, Kyoto 601-8414, Japan	Te <b>l</b> . +81-(0)75-694-1152	Fax. +81-(0)75-661-0433
Kobe Sales Office	2-4-4, Tamondori, Chuo-ku, Kobe, Hyogo 650-0015, Japan	Te <b>l</b> . +81-(0)78-362-6761	Fax. +81-(0)78-362-6763
Takamatsu Sales Office	2009-2, Kamifukuokacho, Takamatsu, Kagawa 760-0077, Japan	Te <b>l</b> . +81-(0)87-863-0610	Fax. +81-(0)87-863-0612
Okayama Sales Office	3-13-39, Noda, Kita-ku, Okayama 700-0971, Japan	Tel. +81-(0)86-245-7315	Fax. +81-(0)86-245-7150
Kumamoto Sales Office	3-1-12, Hattanda, Higashi-ku, Kumamoto 861-8034, Japan	Tel. +81-(0)96-388-7767	Fax. +81-(0)96-388-7768
Factories/Research Laboratories			
Pharmaceutical Development Center	12-34, Hiroshibacho, Suita, Osaka 564-0052, Japan	Tel. +81-(0)6-6190-0520	Fax. +81-(0)6-6337-0330
Kashima Factory	14-6, Sunayama, Kamisu, Ibaraki 314-0255, Japan	Te <b>l</b> . +81-(0)479-46-7272	Fax. +81-(0)479-46-4630
Kanto Factory	1900-1, Togo, Mobara, Chiba 297-0017, Japan	Tel. +81-(0)475-23-3261	Fax. +81-(0)475-23-4981
Sanda Factory	2-1, Techno Park, Sanda, Hyogo 669-1339, Japan	Te <b>l</b> . +81-(0)79-568-4927	Fax. +81-(0)79-568-4938
Sanda Nishi Factory	18-8, Techno Park, Sanda, Hyogo 669-1339, Japan	Te <b>l</b> . +81-(0)79-558-7200	Fax. +81-(0)79-558-7206
Kyushu Factory	1238-1, Uruno, lizuka, Fukuoka 820-0021, Japan	Te <b>l</b> . +81-(0)948-24-7117	Fax. +81-(0)948-24-7115

1144-3, Hiratsune, lizuka, Fukuoka 820-0073, Japan

#### \*The information in this report is as of July, 2023, unless otherwise stated.

Tel. +81-(0)948-24-1400 Fax. +81-(0)948-24-1410

#### Network







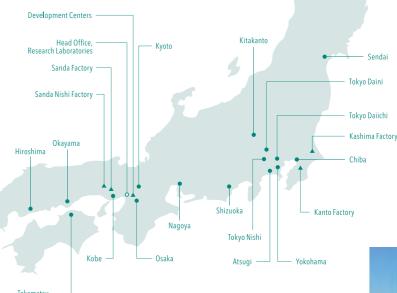






Daini Kyushu Factory -

Kyushu Factory







#### History

