

# S Society

## Quality management

### Sawai Pharmaceutical

We conduct annual audits of our own factories, and we plan to start conducting unannounced audits from fiscal 2021.

In terms of the quality of APIs, we rigorously check whether each manufacturing factory complies with Good Manufacturing Practices (GMP) stipulated by law by conducting onsite verifications, etc.\* of API manufacturing sites for some 300 ingredients (a total of approximately 500 manufacturing sites), and only use APIs that have passed the verifications.

At our formulation factories, we implement manufacturing management and quality control in compliance with GMP. Furthermore, in accordance with GQP standards, Head Office and the Quality Assurance Department constantly check whether manufacturing factories observe GMP through onsite verifications, etc. to confirm that manufacturing management and quality control comply with standards.

In the supply chain, we also conduct audits of API manufacturers at least once every five years and formulation manufacturing subcontractors at least once every three years.

\* Evaluation by Sawai Pharmaceutical: 98%, Evaluation of results of audit by other company based on Sawai Pharmaceutical's standards: 2% (as of December 3, 2020)

## Active pharmaceutical ingredients (API) country of manufacture disclosure

### Sawai Pharmaceutical

Since July 2019, we have made public the "API country of manufacture" for our products on Sawai Pharmaceutical's comprehensive information website for healthcare workers.

We disclose information on the percentage of API manufacturing countries and final drug substance manufacturing locations by country so that healthcare workers can use drugs sold by the Company with peace of mind.



## Preventing counterfeit pharmaceuticals

### Sawai Pharmaceutical

We have introduced technologies for determining authenticity if a suspected counterfeit product is found. Some examples of this include holographic boxes with characters that change depending on the angle a box is viewed from, and sealing tape that leaves some of the printing on the tape behind on the box once it is peeled off, making it possible to check whether a box has been resealed.

### Box seal

#### 1 Adhesive seal/push open-type

(e.g.) OSELTAMIVIR Capsules 75mg SAWAI



1. Unopened box 2. Opening method 3. Opened box

#### 2 Adhesive seal/pull open-type

(e.g.) LIMAPROST ALFADEX Tablets 5µg SAWAI



1. Unopened box 2. Opening method 3. Opened box

#### 3 Tape seal/push open-type

(e.g.) Oseltamivir DS3% SAWAI



1. Unopened box 2. Opening method 3. Opened box

### Upsher-Smith

Upsher-Smith and its pharmaceutical supply chain are promoting initiatives required under the Drug Supply Chain Security Act (DSCSA). The DSCSA is being implemented in stages with final compliance currently set for November 2023. At that point, Upsher-Smith products will be identified and traced using the product ID (serial number, global trade item number (GTIN), lot, and expiration) included on the product label in accordance with the DSCSA.

Number of forcible searches, seizures, arrests and/or actions resulting in criminal prosecution related to counterfeit products

Sawai Pharmaceutical: 0 / Upsher-Smith: 0

## Business ethics

### Sawai Pharmaceutical

We have established an item on compliance with legal and promotional codes in the Sawai Code of Conduct, stipulating that we comply with relevant laws and industry standards in all activities involving product promotion and advertising, and ensure they are conducted ethically and appropriately.

We also strive to engage in appropriate corporate activities as a pharmaceutical company in line with the letter and spirit of relevant codes, including the Corporate Code of Conduct, Compliance Program Guidelines, and Promotion Code for Prescription Drugs set out by the Japan Generic Medicines Association (JGA), as well as the Sawai Group Holdings Corporate Philosophy and Code of Conduct.

Moreover, to increase transparency in our business relationships with medical institutions, we have established our own guidelines based on the JGA's Guidelines on Transparency in Corporate Activities Business Relationships with Medical Institutions, as well as publishing information on payments and funding for medical institutions on a dedicated page. We also disclose information for Medisa Shinyaku Inc. and Kaken Shoyaku Co., Ltd. on the same page.

WEB Transparency Guidelines  
<https://www.sawai.co.jp/company/transparency/>

### WEB

### Sawai Pharmaceutical

- Commitment to formulation
- Quality management in factories
- Attention to detail in packing design and design
- Feeling of responsibility about product improvement
- Research and development initiatives
- Production initiatives
- Quality initiatives

### Upsher-Smith

Upsher-Smith's business standards include several policies on proper promotion of products and medical interactions with healthcare professionals.

The company has explicitly adopted the PhRMA Code on Interactions with healthcare professionals, and its sales representatives are trained on appropriate product promotion activities that comply with the PhRMA Code and the applicable laws and only use approved product promotion items.

Upsher-Smith sales representatives receive further training to identify and avoid inappropriate interactions with healthcare professionals which could arise from the provision of other items of value in exchange for the use of the company's products.

Total financial loss incurred as a result of legal proceedings related to corruption and bribery

Sawai Pharmaceutical: 0 / Upsher-Smith: 0

Total financial loss incurred as a result of legal proceedings related to false statements involving marketing

Sawai Pharmaceutical: 0 / Upsher-Smith: 0

## Product ingenuity

### Sawai Pharmaceutical

Sawai endeavors to design products that incorporate features that take into consideration how the patient takes the dose.

In fiscal 2020, we received approval for the first orally disintegrating (OD) tablet as an azilsartan, amlodipine combination drug, as well as for a regular tablet. In order to improve identification, the name of ingredients and the content are printed on both sides of the tablets. The OD tablet has a film coating designed to improve stability.



## Providing drug information

### Sawai Pharmaceutical

Sawai Pharmaceutical believes that delivering accurate information promptly is one aspect of quality. MRs (drug information staff), the Medical Information Center (inquiry helpdesk), and the corporate website, which are the three points of contact for the provision of information, work together to meet the expectations of healthcare professionals and patients seeking peace of mind.

#### Provision of information by MRs

Approximately 380 MRs work to provide information, endeavoring to communicate more accurate information more quickly. In addition, information on the side effects and safety of drugs is collected and compiled led by the Pharmacovigilance Department. We ensure the proper use of drugs by feeding details of this information back to medical institutions.

#### Medical Information Center

We established the Medical Information Center which is open 24 hours a day, 365 days a year to respond immediately to inquiries from medical institutions even at night and on holidays. The center receives around 4,000 inquiries a month about product characteristics, usage, and safety.

#### Website for healthcare professionals

We disseminate the latest product information and information that can be used for treatment and medication guidance through Sawai medical site, our comprehensive information site for healthcare professionals. We were the first in the industry to introduce chatbots, a bilateral communication tool, to guide users quickly to the information they want on the website.



Sawai medical site

#### Website for patients

Sawai Pharmaceutical's corporate website provides information that is useful for patients to manage their health. In addition to basic information on generic



Sawai Kenko Suishinka

drugs and quality initiatives, we have posted a variety of healthcare-related information, including information on pre-disease and preventive measures, disease awareness, and health promotion through pages called Sawai Kenko Suishinka, Zutsu Online and others.

## Social contribution activities

### Sawai Pharmaceutical

#### Dementia Supporter Training Course

In September 2020, we were registered as an Orange Partner company, which indicates a company that is working to support people with dementia. We completed our registration after being invited to become an Orange Partner company by the Orange Team representatives from the Osaka Yodogawa Ward Eastern District Comprehensive Support Center, which provided the Dementia Supporter Training Course attended by 185 Sawai Pharmaceutical employees held at the Head Office / Research Laboratories.

Going forward, we will continue working together as a company that supports people with dementia and their families.



Orange Partner sticker

**Osaka City Council of Social Welfare**  
[https://www.osaka-sishakyo.jp/orangepartner\\_list/](https://www.osaka-sishakyo.jp/orangepartner_list/)

#### Supporting the Pink Ribbon Campaign which donates to cancer patients

In February 2021, we renewed some of our vending machine contracts and changed them to a type that donates to Pink Ribbon activities. Five vending machines have been installed at the Head Office/Research Laboratories, the Development Center, and the Osaka Branch. The Pink Ribbon machines feature a pink wrap.

A portion of the sales will be donated to the Hohoemi (Smile) Foundation\* to support activities aimed at reducing the number of people suffering from breast cancer.



A vending machine with the Pink Ribbon wrap

\* Hohoemi (Smile) Foundation: a foundation operated by the Japan Cancer Society with the aim of decreasing the number of people suffering from breast cancer even if only by one person. The foundation supports activities to eliminate breast cancer such as promoting screening, raising awareness of early detection, training doctors and radiologists, and supporting patients.

## Producing and donating posters that raise awareness of infectious disease prevention to elementary schools

In collaboration with *The Yomiuri Shimbun*, which publishes *The Yomiuri KODOMO Shimbun* newspaper as an educational project aimed at elementary school students, we produced a poster to raise awareness of preventing COVID-19 and donated posters to around 300 elementary schools with approximately 115,000 students in Osaka City, which is the home of Sawai Pharmaceutical. It is our hope that the COVID-19 pandemic will be brought under control as soon as possible so that students can relax and work hard at their studies.



Poster to raise awareness of preventing infection

## Human resource initiatives

### Sawai Pharmaceutical

#### Development of personnel systems

Sawai Pharmaceutical has developed a variety of personnel systems, which include systems for the evaluation and treatment of employees, a career development statement system, training systems, and a childcare leave system, to ensure that our employees continue to work with a high level of motivation.

Last year, Sawai Pharmaceutical, the Group's core company, undertook personnel system reforms and established a new remuneration system to ensure that employees with high performance are properly rewarded. In addition, in order to facilitate the stable development and supply of generic drugs in the future amid a falling birthrate, aging population, and declining labor force, we have made our factory workers into regular employees and newly established a contract employee system that enables those

#### Main Initiatives in 2020

- Optimizing working hours and ensuring work-life balance and time for living
- Expanding the age range of eligibility for subsidized gynecological screening for employees from those aged 35 or older to those 18 or older
- Anti-smoking measures (no smoking on premises and no smoking during work hours, financial assistance for treatment and smoking cessation aids, etc.)
- Infection control measures (full subsidization of influenza vaccines for employees, development of telecommuting environment, etc.)



**Sawai Group Holdings**  
 • ESG Data  
 • Social-related data

**Sawai Pharmaceutical**  
 • Providing drug information  
 • Information provision initiatives

who want to continue working up until the age of 70.

In this way, we are developing a working environment that allows our employees to be motivated and challenged to achieve results and growth while also focusing on the establishment of a safety net so that employees can continue to work for us with peace of mind. We believe that our human resources are human "assets," and we will aim to be a company that is worth working for going forward.

#### Health and Productivity 2021 certification

Sawai was selected for Health and Productivity 2021 certification, recognized by the Ministry of Economy, Trade and Industry (METI) and Nippon Kenko Kaigi as an enterprise engaging in efforts to advance health and productivity management.

In accordance with the corporate code of conduct that "better drugs are born from workplaces that are both mentally and physically healthy," we assign dedicated public health nurses to each worksite who strive to coordinate occupational health activities aimed at promoting safe and hygienic workplaces.

#### Message from the Sawai Group Workers Union

**Toshitaka Niiyasu**  
 Sawai Group Workers  
 Union Central  
 Executive Committee Chairman



Without the development of the Company, there can be no happiness for employees and their families. And without the growth (activity) of each employee, the Company cannot develop, which is to say, the Company cannot enhance corporate value. The Company recognizes that our union is an important stakeholder, and we continue to maintain sound labor management relations based on the union shop system (in principle, all employees are union members).

Last year, Sawai Pharmaceutical undertook personnel system reform, and we were able to have in-depth discussions with the Company looking ahead to what Sawai should be like in the future.

The union has changed its name and form in response to the establishment of Sawai Group Holdings. However, based on an unchanging policy of labor-management cooperation, we hope to contribute to the development of the Company and the happiness of employees by improving the job satisfaction of our members through our union activities, constantly thinking about what is best for both employees and the Company.