

# **Corporate Governance Initiatives**

## Compliance

In fiscal 2019, the Compliance Committee (chaired by the president) met quarterly and periodically conducted education on themes including respect for human rights, e-learning about information security and the distribution of information security news, and jointly engaged in targeted email attack and other training in Japan and the United States.

Since May 2019, we have conducted monthly compliance e-learning for all employees on themes such as sexual harassment, power harassment, the mixing of



public and private affairs, and the Antimonopoly Act, with a total of 33,819 employees participating. Sawai is working to strengthen compliance by calling for thorough observance of laws and regulations.

## **Internal Reporting Process**

Sawai attempts to improve internal control and compliance by ascertaining operational status based on the "structure for ensuring proper conduct of business" then taking any necessary corrective measures. In addition, we have established a corporate ethics helpline as an internal point of contact for compliance-related reporting in an effort to facilitate the prevention, early detection and proper handling of compliance violations and other issues (Whistle-Blower System). In addition to relevant departments within the Company, we have also made it possible to select consultation with an outside lawyer, and in the aforementioned e-learning, we make it known to employees that they can consult with the corporate ethics helpline. Depending on the nature of the issue, we receive advice from various experts and consult with the Compliance Committee chaired by the president and the Internal Control Committee.

## **Risk Management Committee**

In fiscal 2019, the Risk Management Committee (chaired by the president) met two times. Each year, the committee reviews the importance and impact of risks in 18 categories by analyzing and evaluating risks faced by the Company using a risk assessment sheet, and reviewing countermeasures intended to minimize damage to Company management resources.

During discussions held in fiscal 2019, with regard to

earthquake responses, we confirmed contact methods in the event of a disaster based on a virtual scenario.

Regarding IT risks, there was a vigorous discussion about information sharing pertaining to risk avoidance mechanisms using an external server in the event of a disaster, and various information leakage risks in normal operations and their countermeasures.

Sustainability

# **Business Risks**

What Sawai considers to be its main risks are listed below. In the event that any such risks emerge, it is possible that such circumstances may have an effect on the Sawai Group's management performance and financial condition.

Types of Major Risk	Explanation of Risks
Regulatory risk arising from the Pharmaceutical and Medical Devices Law and other regulations	The Sawai Group is regulated by the Pharmaceutical and Medical Devices Law and other relevant laws and regulations and is required to obtain permits, registration and licenses, as well as submit notifications in each prefecture where we do business. Although the Group has a sufficient legal compliance system in place, in the event of a violation of laws or regulations pertaining to the licensing of our pharmaceutical manufacturing and sales business, there is a possibility that the regulatory authorities may suspend our business operations, cancel our permits or take other actions affecting the financial condition and business performance of the Group.
Changes in Japan's National Health Insurance (NHI) drug price scheme and healthcare system	In order to sell prescription drugs, which constitute the Group's main products and merchandise, they must be listed under national drug pric standards. With regard to drug prices, market price surveys are conducted, with many NHI drug prices reduced in line with drug price revision as well as in consideration of policies based on actual market price. In addition, there are ongoing discussions on drug price and medical insurance system reforms aimed at optimizing rising medical expenses Sawai pays close attention to these trends and reflects them in our management policies and strategies, however, there is a possibility that NH drug price reduction rates or changes to the system may affect the financial condition and business performance of the Group.
Lawsuits pertaining to intellectual property	The Sawai Group conducts thorough investigations into intellectual property rights, including patents, designs and trademarks related to substances, applications, manufacturing methods, crystal formations, usage methods, dosages and formulations. We also make every effort to develop products in careful observance of the Unfair Competition Prevention Act. However, many generic drugs marketed by the Group have multiple active patents related to manufacturing methods, crystal formations, usage methods, dosages or formulations even after the expiration of the original drug substance and usage patents, thus there is a possibility of litigation based on these patents. Such circumstances have the potential to affect the financial condition and business performance of the Group.
Effects of competition and other factors	Products sold by the Sawai Group become unprofitable due to frequent drug price reductions, and in order to avoid being forced to halt sales, we make an effort to sell at prices that ensure appropriate profit. However, when many manufacturers enter the generic drug market, intense competition easily causes prices to drop. Furthermore, original drug manufacturers make efforts to respond to declines in market share after patents expire through the introduction of authorized generics among other measures, and because of this trend, it is possible that Sawai canno achieve its sales targets. Additionally, although our strength lies in our R&D capability of launching several generic drugs every year ahead of other companies, the risk from competition is increasing due to the improvement of competitors' R&D capabilities which has the potential to affect the financial condition and business performance of the Group.
Product recalls and suspension of sales	The efficacy and safety of active ingredients used in the generic drugs sold by the Sawai Group have been confirmed over a set period of time based on the usage history of the original drug. In addition, drugs undergo reexaminations and reevaluations so that the risk of developing unknown and serious side effects is, in principle, extremely small. However, in the event of unexpected new side effects, contamination of the product with impurities or the establishment of new or stricter inspection standards, we may be forced to recall and/or discontinue product sales and depending on the severity of the circumstances, may be held liable for damages caused by the product, all of which have the potential to affect the financial condition and business performance of the Group.
Temporary suspension and delays in production due to natural disasters	With regard to natural disasters such as earthquakes, storms and floods, as well as other serious health risks including COVID-19 and other pandemics, The Sawai Group formulates and maintains Business Continuity Plan (BCP), crisis management protocols and other measures in order to continue engaging in business with respect for human life as our first priority. With production bases located in Fukuoka Prefecture, Hyogo Prefecture, Osaka Prefecture, Chiba Prefecture, Ibaraki Prefecture and the United States, the Group aims to reduce the risk of suspended operations through a decentralized factory network and standardized manufacturing equipment. However, if factory operations are halted due to natural disasters, technical or regulatory issues, or other problems, there is a possibility that the supply of products manufactured at the impacted production bases will be suspended, which may affect our business results. Furthermore, in terms of important raw materials, Sawai attempts to manage and respond to supply chain risks including multi-source purchasing, but as some materials are supplied by specific business partners, if purchases are suspended due to natural disasters or other factors and it is difficult to source replacements, this may affect the financial condition and business performance of the Group.
Global business development	In anticipation of slowing growth in the Japanese market due to an increase in the share of generic drugs, the Sawai Group has been considering overseas expansion, capital tie-ups, corporate acquisitions and other means of targeting sustainable growth. Although we strive to thoroughly examine business profitability as well as related laws and political and economic conditions, in some cases, unexpected changes in circumstance or investment outcomes beyond our initial expectations may affect the financial condition and business performance of the Group.
Company acquisitions	On April 20, 2017, we agreed to acquire Upsher-Smith for U.S. \$1.05 billion, with the acquisition completed on May 31, 2017. Also, on November 13, 2017, Sawai sold a 20% stake in its U.S. subsidiary, Sawai America INC. (hereinafter, "SAI"), the parent company of Upsher-Smith, to Sumitomo Corporation of Americas (hereinafter, "SCA"), entering into an equity transfer agreement with SCA that was completed on January 3, 2018 (SAI changed its name to Sawai America, LLC, after transitioning to a Limited Liability Company in December 2017). Moreover, in accordance with the acquisition of Upsher-Smith, goodwill of Y38.636 billion yen was recorded on the consolidated statement of financial position for the fiscal year ended March 31, 2020. Sawai believes that the acquisition of Upsher-Smith, which is one of the leading companies in the U.S. generic drug market, will greatly contribute to the rapid establishment of a foundation in the US market, which is the world's largest generic drug market, and we are working to create synergies through collaborations that leverage the strengths of Sawai and Upsher-Smith. However, if the expected results of this acquisition are not achieved due to changes in the Upsher-Smith business environment or business activities, delays in the progress of integration, issues not discovered in due diligence or for other reasons, there is a possibility that goodwill impairment or other accounting treatments may affect the financial condition and business performance of the Group.
Information management	The Sawai Group retains possession of personal information from within and outside the Company, trade secrets and a substantial amount of other important information. In addition to establishing internal regulations, implementing IT security measures and saving data at multiple locations, including external data centers, the Group has established an Information Security Committee to conduct education and awareness activities, among other efforts, to ensure thorough information management. However, in the event of information leaks, falsification, loss or other incidents caused by system failure or accident, there is a possibility this may affect the financial condition and business performance of the Group
Other	In addition to the above, there are various risks involving financial market and exchange rate fluctuations, risks related to corporate governance including compliance, risks related to climate change and other environmental problems, and short-term labor shortages due to low birthrates and an aging population. Thus, the risks described herein are not inclusive of all risks facing the Sawai Group. The Risk Management Committee chaired by the representative director, meets twice a year to discuss necessary risk responses and countermeasures, including discussions aimed at narrowing down particularly important risks in terms of frequency of occurrence and the degree of impact on business. Related topics are considered in greater detail separately by the Compliance Committee and CSR Committee, etc. In addition, we are working to reduce the ris of executives and employees violating laws and regulations or violating social norms by implementing regular educational initiatives and awareness-raising activities that utilize tools such as e-learning.

Financial Section/Data

# **Board of Directors**



Chairman, Representative Director

### Mitsuo Sawai

Jan.1989	Joined the Company
Jun.2000	Director, Deputy Vice President of Sales Division,
	and General Manager of Sales Planning Department
Jun.2002	Managing Director, Vice President of Sales Division, and General Manager of Sales Planning Department
Jun.2005	Senior Managing Director, Vice President of Sales
Jun.2008	President, Representative Director
Jun.2020	Chairman, Representative Director (incumbent)

Mr. Mitsuo Sawai has thorough knowledge of the generic medicines business and works to build strong relationships with business partners and other stakeholders to lead the enhancement of corporate value in accordance with Sawai's management philosophy. He serves as President of the Japan Generic Medicines Association and contributes to the sustained development of the industry.



President, Representative Director

#### Kenzo Sawai

Apr.1995	Joined Sumitomo Pharmaceuticals Co., Ltd.
	(currently Sumitomo Dainippon Pharma Co., Ltd.)

- Apr. 2001 Joined the Company Jun.2010 Director, Vice President of Corporate Strategy
- Department Jun.2013 Director, Senior Executive Officer, Vice President of
- Corporate Strategy Department, and Deputy Vice President of Sales Division
- Jun.2017 Director, Senior Managing Executive Officer, Vice President of Corporate Strategy Department and Supervisor of Sales Division President, Member of the Board of Sawai America LLC (incumbent) Chairman of the Board of Upsher-Smith Laboratories, LLC (hereinafter referred to as "Upsher-Smith") (incumbent)
- Jun.2018 Director, Senior Managing Executive Officer, Vice President of Corporate Strategy Department and Supervisor of Research & Development Division
- Jun.2020 President, Representative Director (incumbent)

Mr. Kenzo Sawai is well-versed in the generic drug business. The Company appointed him to utilize his strategic planning and implementation abilities to support the Sawai Group's growth, medium- to long-term business plans overseas strategies, alliances and advertising efforts.



Director, Senior Executive Officer, and Senior Vice President of Corporate Administration Division

#### Kazuhiko Sueyoshi\*

Apr.1980	Joined The Sumitomo Bank, Limited (currently
	Sumitomo Mitsui Banking Corporation)
Apr.2012	Joined the Company
	General Manager of Controller Department
Jun.2017	Executive Administration of the Board of
	Upsher-Smith (incumbent)
Feb.2018	Executive Officer,
	Deputy Vice President of Corporate Administration
	Division, and General Manager of Controller
	Department
Jun.2018	Director, Senior Executive Officer, and Vice
	President of Corporate Administration Division
	(incumbent)
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Mr. Kazuhiko Suevoshi has expertise in finance and accounting. Mit. Accurring Subject in the experiment in finance and accounting, and the Company appointed him to contribute deep insights into corporate management based on his extensive experience and being well-versed in compliance, CSR and all other aspects of corporate governance.



Director, Senior Executive Officer, Senior Vice President of Reliability Assurance Division

### Toru Terashima\*

	Joined Sumitomo Chemical Company, Limited Joined Sumitomo Pharmaceuticals Co., Ltd.
	(currently Sumitomo Dainippon Pharma Co., Ltd.)
Jan.2016	Joined the Company
Jun.2016	Corporate Officer, and Vice President of Reliability
	Assurance Division
Jun.2017	Director, Corporate Officer,
	Vice President of Reliability Assurance Division
Jun.2018	Director, Executive Officer, Vice President of
	Reliability Assurance Division, and General Marketing
	Compliance Officer (incumbent)
Jun.2019	Director, Senior Executive Officer, Vice President of Reliability Assurance Division

Mr. Toru Terashima is in charge of general manufacturing and sales. The Company appointed him to provide professional knowledge and business experience in the research, development, and production of, and regulatory affairs related to, pharmaceuticals.



External Director

## Masatoshi Ohara

- Apr.1979 Registered as a lawyer at Osaka Bar Association Joined Kikkawa Sogo Law Offices (currently Kikkawa Law Offices) (incumbent)
- Law Offices) (incumbent) Aug.1886 Attorney admitted in the State of New York, the U.S. Apr.2004 Member of the Board of Directors for the Kinki Federation of Bar Associations Apr.2017 The President of Osaka Bar Association, and the Vice President of Japan Federation of Bar Associations Jan.2018 External Director of Teijin Frontier Co., Ltd. (incumbent)

- (incumbent) Jun.2019 External Director of the Company (incumbent)

Mr. Masatoshi Ohara has extensive experience and professional knowledge as a lawyer in the United States and Japan. The Company appointed him to utilize his experience as an external director at other companies to provide beneficial advice from an independent perspective.



## Nawomi Todo

Jun.1984 Obtained Medical License	9
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- Jul. 1984 Staff Doctor at Osaka University Hospital Jul. 1987 Staff Doctor at Osaka Police Hospital, Association of Osaka Police Foundation
- Jul.1990 Staff Doctor at Nissay Hospital Jan.2002 Staff Doctor at Osaka-tetsusho Health Insurance Society (incumbent)
- Jan. 2007 Obtained Certified Occupational Physician
- Qualification of Japan Medical Association Jun.2015 External Director of the Company (incumbent)

Ms. Nawomi Todo has extensive professional knowledge and experience as a medical doctor. The Company appointed her to continue providing beneficial advice to patients and physicians from an independent perspective.

# **Auditors (Audit & Supervisory Board Members)**



Standing Statutory Auditor

### Tadao Tsubokura

Jul.2008	Joined the Company
	General Manager of Controller Department
Apr.2012	General Manager of General Affairs Department
Jun.2018	Standing Statutory Auditor
	(incumbent)

Mr. Tadao Tsubokura conducts audits drawing on his experience as the leader of the Company's business management and genera affairs departments, participates in the Audit & Supervisory Board . ement and general as a Standing Statutory Auditor, and serves as the contact point for the Board of Directors



External Auditor

#### Takanobu Tomohiro

Apr.1991	Registered as an attorney Joined Kogoshi Takizawa Law Office
Apr.1994	(currently, Kobe-Kaito Law Office) Partner of Kobe-Kaito Law Office (incumbent)
lup 2016	Extornal Auditor

Apr.2020 Chairman, HYOGO-KEN BAR ASSOCIATION (incumbent)

Mr. Takanobu Tomohiro has a wealth of expertise and experience as a lawyer, and provides useful advice and auditing from an independent standpoint as an External Auditor.



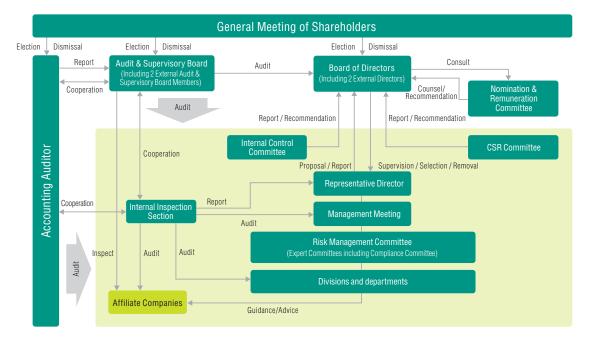
External Auditor

#### Junichi Hirano

- Jul. 2013 Director, Co-ordination Division, Second Large Enterprise Examination Department, Osaka Regional
- Taxation Bureau District Director, Higashi Yodogawa Tax Office Jul.2014 District Director, Higashi Yodogaw Jul.2015 District Director, Himeji Tax Office
- Aug.2016 Established a Certified Tax Accountant Office (incumbent) Jun.2017 External Auditor (incumbent)

Mr. Junichi Hirano opened a tax accountant office after serving as the District Director of the Himeji Tax Office. He has considerable knowledge of finance and accounting, and provides useful advice and audits from an independent standpoint.

### **Corporate Governance Structure**



## **Governance Reforms**

The Sawai Group is implementing various governance reforms. From fiscal 2018, we incorporated Environmental, Social and Governance (ESG) performance in terms of risk and compliance into the elements of performance-linked remuneration for executives, with the lead independent outside director as the Nomination and Remuneration Governance Committee chairman.

## Evaluating the Effectiveness of the Board of Directors

The Sawai Group conducts analyses and evaluations to ensure the effectiveness of the Board of Directors. We have a strong reputation for providing meticulous explanations and reports, as well as engaging in frank and open discussions of important matters.

At the same time, we continue to strengthen the effective use of outside directors and the training of other executives.