



Corporate Governance and Compliance

Sawai is developing a fair and highly transparent management structure based on the recognition that corporate governance is the management platform for the fulfillment of corporate social responsibility.

Corporate Governance

Basic Policy on Corporate Governance

One of the Company's most important management priorities is to develop a management system that can ensure prompt, appropriate decision-making and business execution in response to changes in the external environment and practice highly fair and transparent management in order to realize the basic management policy of enhancing corporate value through profitable growth and maximizing shareholder interests from a long-term perspective.

To cultivate and maintain high ethical standards as a company that affects people's lives through the provision of medical drugs, in keeping with the "Patients first" corporate philosophy, Sawai will engage in business activities in accordance with the Company's code of conduct and internal regulations.

Sawai has adopted the corporate auditor system, which it considers the optimal corporate governance structure in view of its size and management style.

Description of Management Organization

The Company has a comparatively small management organization consisting of eleven directors and five corporate auditors (including three external corporate auditors). In view of its size and management style, Sawai has for some time employed the corporate auditor system. The three external corporate auditors have no business connections with the Sawai Group.

The corporate auditors are specialists in accounting, taxation, legal affairs and other disciplines. They attend meetings of the Board of Directors and express necessary opinions from an objective perspective. The Company has prepared Board of Auditors Regulations, Audit Standards and Internal Audit Regulations. It encourages close collaboration between the Board of Auditors and the Internal Inspection Section, and is undertaking reinforcement of the corporate audit function. In addition, the full-time corporate auditor shares information with the external corporate auditors by attending the Management Conference and other important meetings and reporting to the Board of Auditors.

The Company strives to demonstrate management flexibility through vitalization of the Board of Directors, the Management Conference and the Conference of Head Office General Managers and promotes ethical standards and information sharing appropriate to a pharmaceutical company that affects people's lives.

The Board of Directors convened for a total of fourteen regular monthly meetings and extraordinary meetings in the year under review, and the Company has a small management organization that allows for a close exchange of views and reciprocal checks on a regu-

lar basis. The Company's Articles of Incorporation provide for a maximum of fifteen directors. In addition, the Company seeks to ensure rigorous auditing and supervision company-wide through means including business site audits conducted by the Board of Auditors and the Internal Inspection Section. The Internal Inspection Section has a staff of four and conducted audits at 27 business sites during the previous business year.

To ensure the appropriateness and efficiency of business operations throughout the Group, the Company ensures adherence to the corporate philosophy and management policies at Group companies and provides direction and guidance on matters related to the day-to-day execution of business. The Group's consolidated subsidiaries undergo accounting audits required for consolidated auditing performed by the Company's independent accounting auditors as well as internal audits performed by the Company's Board of Auditors and Internal Inspection Section.

The Company obtains advice concerning issues related to corporate management and day-to-day business operation as necessary from several attorneys and other specialists, and refers to the advice when making business decisions. In addition, the Company submits matters, depending on their nature, to the Compliance Committee or the Internal Control Committee for deliberation. These committees are chaired by the president and consist of involved directors and the full-time corporate auditor.

With regard to risk management, the Company has prepared and implemented Risk Management Rules and other rules and regulations. It also concentrates channels for information, including insider information, on the Corporate Administration Division director who constitutes the Board of Directors, and ensures the rapid, accurate gathering and processing of information.

Decisions on directors' remuneration are made principally by the representative directors in accordance with internal regulations, within the total amount determined by a resolution of the General Meeting of Shareholders.

With regard to the appointment of independent executives, the purpose for the appointment and registration of independent executives is explained in advance at a meeting of the Board of Auditors and, after their prior approval of independent executive candidates, the matter is deliberated at a meeting of the Board of Directors. After the process above, two of the three external corporate auditors were designated as independent executives in this fiscal year.

Internal Controls and Compliance

Basic Policy on Internal Control Systems

To prevent the occurrence of corporate scandals and to realize appropriateness, efficiency and transparency in management and business operations, the Company has established a basic policy concerning the development of internal control systems.

With regard to the establishment of standards of conduct, the Company engages in activities to ensure appropriate awareness of the Sawai brand on the part of each employee in accordance with three activities policies: 1) the conduct of activities to inculcate the corporate philosophy among all Group employees, 2) the conduct of group-wide activities and training by the General Affairs Department together with an M1 Project committee to ensure that the corporate philosophy and code of conduct are firmly instilled, and 3) rigorous assurance of compliance with the corporate philosophy and code of conduct in business operations and of legal compliance on the part of all executives and employees.

With regard to the establishment of corporate governance systems, the Company firmly adheres to the corporate governance systems it has developed and announced to the public and constantly strives to enhance those systems.

Concerning the monitoring and verification system, the Company is reinforcing the Internal Inspection Section to perform internal control audits and undergoes rigorous audits performed by the corporate auditors and independent accounting auditors. When a corporate auditor requests an assistant, a member of the Internal Inspection Section is assigned to provide assistance.

To forestall improper conduct by the Board of Directors, we have set up a reporting mechanism for employees to report directly to the Audit Office (currently to a corporate auditor) as stated in the regulations concerning the corporate ethics help line.

Compliance System

Concerning the development and establishment of the business execution system, 1) the Company systematically observes and implements approval and authority regulations to prevent the occurrence of misconduct, while maintaining a balance between delegation of authority and checks and balances. Also, 2) the Company has prepared the Document Management Regulations and appropriately retains for the prescribed retention periods documents whose retention is prescribed by law, as well as minutes of important meetings, approval documents pertaining to important matters, important contracts and other information pertaining to the directors' execution of duties (including electronic records) whose retention is prescribed by internal regulations. 3) The Compliance Committee convenes regular and special meetings to deliberate on compliance-related matters and engages in compliance education and awareness activities for executives and employees. The Compliance Committee is made up of the directors, standing statutory auditors, and members of the Corporate Administration Division and maintains a secretariat in the Compliance Section. 4) With regard to risk management systems,

the Reliability Assurance Division is the organization responsible for product quality and safety. It performs rigorous quality and safety supervision based on GQP (Good Quality Practice) and GVP (Good Vigilance Practice) standards. In accordance with the Risk Management Rules, the General Affairs

Department supervises the monitoring of risks pertaining to business operations as a whole and accident and disaster prevention measures, and the director of the Corporate Administration Division is the chief risk management officer.

When serious accidents or disasters occur, a crisis management headquarters is set up immediately and the president takes up the chief position of it, and an emergency response team is dispatched to the disaster site.

With regard to information management, the Company takes all possible measures to control material facts and confidential information learned in the course of business in accordance with the Insider Trading Control Rules and Information Security Management Rules. The Company also strives to ensure the timely and appropriate disclosure of IR information and other important information to be disseminated outside the Company. The Company ensures the appropriate operation of the corporate ethics help line and rigorously implements measures to prevent and deal with sexual harassment and moral harassment.

With regard to the exclusion of anti-social forces, the Company rigorously ensures open and aboveboard business operation and bans dishonest business dealings. The Company has a resolute attitude against antisocial forces and cooperates with the police and other concerned public authorities and attorneys on matters involving anti-social forces or groups that pose a threat to public order or safety.

Operational Risks

The following matters, among others, may have a material impact on the decisions of investors concerning the Company's overall business condition, financial situation, management performance, and future prospects.

Regulation Under the Pharmaceutical Affairs Law and Other Laws

The Sawai Group is subject to regulation under the Pharmaceutical Affairs Law and other relevant laws and regulations. In addition it is required by law to comply with permission, registration, designation, licensing and notification in the prefectures in which the Group has business offices. Although the Group has implemented a sufficient legal compliance system, a violation of the law with respect to drug manufacturing and marketing approval could result in the suspension of business or revocation of approval by the authorities and have an adverse impact on the Company's business results.

Changes to the Drug Price System and Medical Care System

The marketing of ethical drugs, the Sawai Group's mainstay prod-

ucts, requires listing in the drug price standards established by the government. Studies of the market prices of drugs are conducted, and the prices of nearly all items are reduced in drug price revisions conducted once every two years. Reviews of the medical insurance system are also conducted for the purpose of curbing expanding healthcare costs. Future implementation of major changes to the drug price system or policies to reduce healthcare costs could have an adverse impact on the Group's business results.

Litigation Concerning Intellectual Property Rights

The Sawai Group conducts rigorous examinations of intellectual property rights, focusing on substance, use, process and formulation patents, design and trademark and engages in product development that reflects consideration of the Unfair Competition Prevention Law.

Nevertheless, in many cases, multiple patents pertaining to process, crystal form, dosage and administration, or formulation remain in force with respect to the original drugs on which the generic drugs sold by the Sawai Group are modeled, even after the expiration of substance or use patents, and at times, lawsuits are filed based on these patents. Such legal action could have an adverse impact on the Group's financial position or business results.

The Impact of Competition

To avoid unprofitable business and the unavoidable discontinuation of products resulting from frequent price reductions, the Sawai Group strives to sell its products at prices that ensure fair profits. Nevertheless, many generic drug manufacturers are entering the market, and intense competition causes price deterioration.

Furthermore, original drug manufacturers are devising measures to secure market share even after the expiration of patents. These trends could prevent achievement of the Company's planned sales, which could have an adverse impact on the Group's business results.

Product Discontinuation and Recall

Since the active ingredients in the generic drugs sold by the Sawai Group have a proven record of effectiveness and safety in use confirmed over fixed periods of time and have been reexamined, in principle, the risk of occurrence of unknown, severe side effects is extremely low. Nevertheless, the occurrence of unforeseen new side effects or accidents such as contamination from impurities would make product discontinuation and recall unavoidable, and cause product liability depending on the nature of the accident which could have an adverse impact on business results.

Production Disruption or Delays due to Disasters, etc.

The Sawai Group disperses its production sites in Fukuoka, Hyogo, Osaka, Chiba, and Ibaraki Prefectures. Nevertheless, the shutdown of operation at a manufacturing site due to the occurrence of a natural disaster, technical problem, or regulatory problem could result in the disruption of supply of certain products, which could have an adverse impact on business results.

Also, the Group is dependent on specific sources of supply for important raw materials. A supply interruption resulting from a disaster or any other reason could have an adverse impact on business results.

The Group suffered no human loss from the Great East Japan Earthquake of March 11, 2011. Damage to production facilities was limited to minor damage to the Kanto Plant, and the disaster had no impact on plant operation. Although the Sendai Branch, which incurred partial building damage, was forced to relocate, it has resumed normal business operation. Nevertheless, additional damage could be identified, and the impact of the disaster could increase due to the electric power supply situation.

Crisis Management Headquarters

Sawai has put in place a system for establishing a crisis management headquarters and responding in the event an accident, disaster or other crisis occurs. When the Great East Japan Earthquake struck on March 11, 2011, on the same day, we set up a crisis management headquarters under the direction of the president and confirmed matters including the safety of the employees and their families, the state of damage to buildings and facilities, the inventory situation and damage incurred by our business partners. Fortunately, the disaster caused only minor damage to Sawai and had nearly no impact on operation at our factories. However, more than a few of our business partners incurred extensive damage. Accordingly, we immediately considered assistance measures. Even after completion of the initial response to the disaster, the Corporate Administration Division that serves as the secretariat of the crisis management headquarters is coordinating information sharing concerning examination of issues, such as planned alternative redundancy of business partners, a complementary production system to distribute production of products among the factories and power-saving measures.

In addition, as an outcome of the disaster we are conducting a review of our current crisis management structure. Sawai recognizes that the rapid establishment of a crisis management headquarters is of critical importance no matter what crisis may arise in the future and will strive to ensure preparedness for various crisis situations.