# **Risk Management**

The Daiichi Sankyo Group identifies factors that may prevent the Group from attaining its organizational goals and targets and that can be predicted in advance as risks. The Group is promoting risk management by taking steps to address risks inherent in corporate activities by retaining, reducing, avoiding, or eliminating these risks. In addition, we seek to minimize the impacts of risks on people, society, and the Group should they occur. Specifically, in addition to establishing the risk management system that defines steps to address risks inherent in corporate activities, the Group has a business continuity plan (BCP\*) that enables it to continue to operate even in the event of a disaster, etc., that may affect its business, as well as a crisis management system to minimize loss should a risk greater than expected occur.

Regarding the spread of COVID-19 since the last fiscal year, we assessed its impact on our business and took necessary measures from two perspectives: preventing the spread of infection and continuing our business. We are still monitoring the status of COVID-19 cases while considering additional measures against a possible relapse of the pandemic.

\*Business Continuity Plan

### **Risk Management**

In promoting the risk management of the Group, the chief financial officer (CFO) oversees Group-wide risk management as the risk management officer (RMO) and operates the risk management system in conjunction with an annual cycle of formulating and implementing business plans.

In addition, the heads of units autonomously manage risks to aid the accomplishment of their units' goals and targets. To this end, they extract risks, formulate and implement countermeasures, and provide employees with information on underlying risks in the organization, education, and insight concerning risk management.

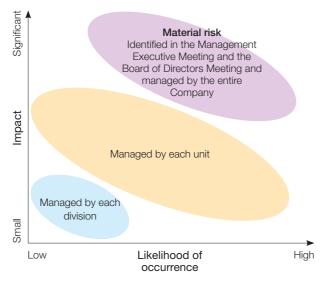
The Risk Management Office (Corporate Business Management Department) assesses the risks extracted in each unit from the aspects of their impact and probability.

### Overview of the risk management structure



Risks with the potential to significantly affect the management of the Company are identified as material risks by the Management Executive Meeting and the Board of Directors Meeting (see the conceptual diagram below on the Group's risk level classification). In addition, responsible persons are appointed for each material risk identified and they implement risk countermeasures in cooperation with relevant organizations. The progress of the risk countermeasures is checked through risk monitoring twice a year and the countermeasures are corrected or improved upon as necessary. Should precursors of the potential occurrence of a material risk be detected, related information will quickly be assembled for the RMO and reported to the CEO.

### Conceptual diagram of the Group's risk level classification



### Major Risks and Their Management

The table below summarizes Major Risks extracted from the Group's material risks and management risks at each unit/ division. In extracting the risks, the possibility of impact on investment decisions and other similar matters were considered.

Area	Risk Summary
Research and Development/ Alliances with Other Companies	For new drug candidates, in particular, tras deruxtecan (DS-8201), potential risks inclu discontinuation of the collaborative researc development (R&D) project with AstraZene to approval review criteria and other similar result in failure or delay to obtain approval, terms and conditions of the R&D alliance a may be amended or terminated, among ot
Side Effects and Quality Issues of Pharmaceuticals	Pharmaceutical products may be recalled of from the market due to quality issues or un side effects. Significant expenses may be in connection with liability for health damage of similar matters.
Manufacturing / Procurement	There is the potential for adverse risk with a suspension, or other similar issues in manu and procurement due to damage to the Co facilities, impairment of social infrastructure reasons, among others.
Litigation	Lawsuits may arise over pharmaceutical sic product liability, labor issues, and fair trade among others.
Laws, Regulations, and Regulatory Trends to Limit Healthcare Expenditures in Japan	Adverse effects may be caused by adminis measures related to NHI drug price revision system, and health insurance.
Breaches of Laws	There is the risk that serious breaches of la regulations, including personal fraud by exe employees
Financial Market and Foreign Exchange Rate Fluctuations	Adverse effects may result from a sluggish market, interest rate trends, or exchange ra fluctuations.
IT Security and Information Management	Network virus infection, cyber-attacks, and events may result in a system shutdown or confidential information, including personal
Impact of Spread of COVID-19	Delays of goods in the supply chain and ott issues caused by the spread of COVID-19 the stable supply of products. In addition, or ongoing clinical trials and protocol violation from the uncertainty in clinical settings due whicih may also impact product approval.
Overseas Business Development	Overseas business operations may bring ris political instability in regions, adverse econo conditions, conflicts with laws, regulations, requirements, and worsened labor-manage relations, among other risks.
Environment / Safety	There is the possibility that people, both int external, may be exposed to chemicals. Th possibility that the Group's operations may air, and other environmental pollution, and I have adverse effects on climate change.
Intellectual Property Rights	If a third party asserts that the Group's ope infringed the party's patent or other intellect rights, the Group may face a lawsuit or it m the business. If a third party infringes Daiich intellectual property rights, a lawsuit may be
Recoverability of Deferred Tax Assets	Decrease in the amount of taxable income, temporary differences due to tax reform or reasons, and reassessment of tax loss carr may have adverse effects.

\*1 Chief Information Officer \*2 Chief Information Security Officer

	Status of Risk Management
stuzumab ide the ch and cca, changes r matters may and the agreement ther risks.	<ul> <li>Establish a joint executive committee between the Group and AstraZeneca regarding <i>DS-8201</i> to formulate a vision and strategy and to manage progress, among others</li> <li>Manage and reduce pharmaceutical risks through constant communication with the applicable authorities</li> </ul>
or withdrawn npredicted incurred in or other	<ul> <li>Perform objective assessments, reviews, and analysis of safety management information (e.g., information on side effects) collected both in Japan and from around the world; and deliver information, as appropriate, to the authorities and/or healthcare practitioners.</li> <li>Provide all employees with training in safety management information every year</li> </ul>
a delay, ufacturing ompany's e, or technical	<ul> <li>Put systems in place to restore operations quickly in the event of an emergency and to ensure a steady supply of pharmaceutical products with assured quality to help support the continued provision of medical services</li> <li>Disperse manufacturing and distribution sites, and introduce private electricity generators</li> </ul>
de effects, issues,	<ul> <li>Minimize legal risks and maximize business opportunities from the perspectives of laws and regulations, contracts, and dispute prevention and resolution</li> <li>Establish preventive measures against compliance violations as well as strong remediation to address any such violations</li> </ul>
strative ns, healthcare	<ul> <li>Revise wholesale prices and rebates in light of NHI drug price system reforms and distribution improvement guidelines</li> <li>Establish and implement appropriate sales contracts</li> </ul>
aws and ecutives and	<ul> <li>Strictly comply with laws and regulations and implement measures to prevent breaches and raise awareness through education, ongoing training, and other similar activities</li> <li>Monitor and auditing of business operations to detect any inappropriate activities as early as possible</li> </ul>
stock ate	<ul> <li>Reduce cross-shareholding shares</li> <li>Review the pension fund asset allocation during the period</li> <li>Enter into currency hedging transactions</li> </ul>
d other similar r leakage of l data.	<ul> <li>Appoint the CIO<sup>*1</sup> and the CISO<sup>*2</sup> to establish a global organization structure in the information field</li> <li>Provide employees with training in information management</li> <li>Strengthen the Group's information security infrastructure and improve its operation</li> </ul>
ther similar may affect delays in ns resulting to COVID-19	<ul> <li>Set up the COVID-19 Emergency Headquarters</li> <li>Ensure the stock of pharmaceuticals</li> <li>Continue to manage clinical trials with the highest priority on the safety of subjects and also modify our clinical trials, as needed, due to impact of COVID-19.</li> </ul>
isks of iomic , or other ement	<ul> <li>Appoint persons in charge of risk management at overseas subsidiaries, and collect and share information on a regular basis</li> <li>When a problem arises, the persons serve as a hub for solving the problem promptly in cooperation with local subsidiaries</li> </ul>
ternal and here is the / result in soil, may also	<ul> <li>Established SOPs to manage chemical substances which is including stricter criterion than regulatory standards, and undertake continued monitoring.</li> <li>Disclose information in accordance with the Recommendations of the Task Force on Climate-related Financial Disclosures (TCFD)</li> </ul>
erations have ctual property nay impact hi Sankyo pe filed.	<ul> <li>Create and protect intellectual property to maximize values and minimize risks</li> <li>Establish a system to minimize the impact of any intellectual property dispute in cooperation with internal and external parties</li> </ul>
e, deductible rother ryforwards	<ul> <li>Review future taxable income as appropriate in light of changes in the business environment and other factors</li> </ul>

## Risk Management

### **Business Continuity Plan**

The Daiichi Sankyo Group has formulated a business continuity plan (BCP) in preparation for four major threats to business continuity: natural disasters, facility accidents, pandemic influenza and other infectious diseases, system failures and cyberattacks. Based on this plan, systems are in place to quickly restore operations in the event of an emergency and to ensure a stable supply of pharmaceutical products with assured quality to support the continued provision of medical services.

### Business Continuity Plan Measures in Supply Chain

Based on its experiences following the Great East Japan Earthquake, we revised our BCP in 2012. Since then, we have continued to improve upon the BCP through such means as reviewing the list of priority supply drugs for which supply should be prioritized and the disaster response plans at our production sites based on revisions to national disaster response plans and social needs. In this manner, we strive to ensure effective response measures are taken in the event that a risk occurs.

For the stable supply of pharmaceutical products, we have prepared a BCP for each production site in Japan in

Business Continuity Plan Measures in Supply Chain

consideration of its functional and regional characteristics by estimating the recovery time based on the damage from the largest earthquake expected. As shown in the table below, BCP measures are taken for necessary management resources such as facilities, logistics/ inventory, personnel, and information from four viewpoints: implementing preventive measures, ensuring diversity, ensuring support measures, and ensuring alternative measures. For example, our measures for facilities include reinforcing buildings and facilities, operating multiple sites, and securing emergency power. Measures for logistics/inventory include ensuring backup inventory of priority supply drugs, decentralizing their storage, and other actions that combine measures to mitigate risks in advance.

In addition, we have developed and regularly revise the list of priority supply drugs that are used by a large number of patients, that are needed in emergencies, or that cannot be substituted by other drugs. In this way, we have established a system to supply necessary drugs continuously and appropriately when risks occur.

### Implementing Preventive Measures Ensuring Alternative Measures Management Ensuring Diversity Ensuring Support Measures Resources Operating multiple sites Securing spare items and repair parts, Reinforcing buildings/ Moving facilities Facilities Operating multiple securing standby machines and facilities Alternative processes facilities emergency power Alternative Ensuring multiple Ensuring backup Logistics/ transportation Emergency procurement agreement channels Inventory Shipping from alternative inventory Distributed inventory sites Operating at multiple Preparing manuals Personnel Dispatching support personnel from other sites Securing backup Education and training personnel Distributed facilities Considering alternative Information (Ex: distributed server Parallel operation Data backup processes system, etc.) Reconstructing data

### Pandemic Influenza Action Plan

To prepare for a global outbreak of pandemic influenza, the Group formulated the Pandemic Influenza Action Plan in 2009 for the purpose of ensuring the safety of employees and their families and continuing the supply of pharmaceuticals. In addition, Daiichi Sankyo is a designated public corporation under the Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response and has the responsibility to cooperate with measures taken by national and local administrative organs. We work to fulfill our corporate social responsibilities by contributing to

maintaining the healthcare system through the continued supply of pharmaceuticals.

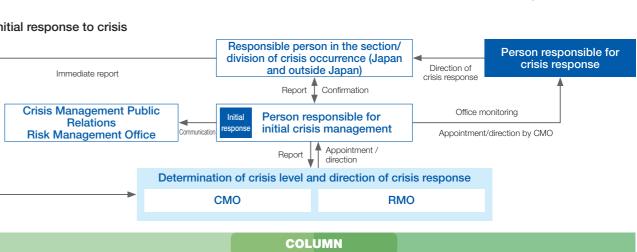
The Pandemic Influenza Action Plan prescribes operations that need to be continued in the event of an outbreak or spread of the disease, and defines an action plan for each operation according to the stage of the outbreak. In response to the recent outbreak of COVID-19, we have taken flexible measures in accordance with the Action Plan, and, based on the knowledge gained through this experience, we will review the Action Plan to make it more practical.

### **Crisis Management**

The Group's Global Crisis Management Policy collectively defines crises as events that have occurred and require immediate response and other events with extremely high likelihood of occurrence, among potential risks in business activities. For the purpose of minimizing loss due to the occurrence of a crisis, the policy stipulates basic items related to crisis management. The policy stipulates that "In the event of a crisis, crisis management shall be conducted promptly and certainly to minimize the impact on people, society, and the company with the principle of securing the lives of Daiichi Sankyo Group employees and related parties and the safety of the local community, and fulfilling the responsibilities of a company that is engaged in a business that affects human lives, and making efforts to ensure business continuity and early recovery from the crisis."

The Group also has a structure to respond flexibly to crisis depending on the type (disaster/accident, incident including terrorism, scandal, breach of laws, information management-related problem, product-related problem)

### Initial response to crisis



### Information Security

### Information Management Initiatives

Amid the rapid increase in sophisticated cyber attacks in recent years, the information management environment has changed significantly, including the strengthening of information-related laws and regulations in each country. In April this year, the Group strengthened its information management structure led by the CISO,\*1 and established the Information Security Policy. This Policy applies not only to electronic information, but to all information including paper-based and oral information. In addition, it covers external information such as those of our business partners and other related parties as well as internal information. Moreover, the Group is working on enhancing employee education and developing necessary regulations, among others, in order to

\*1 Chief Information Security Officer \*2 Computer Security Incident Response Team. An organization that deals with computer security in an enterprise or the like.

or the degree of impact of the crisis (see the figure below). We have clearly defined the reporting criteria and channels and established the crisis management officer (CMO), either the CEO or an officer appointed by the CEO, and the person responsible for the initial crisis management (the vice president of the General Affairs and Procurement). For a crisis with a global impact requiring company-wide response, we strive to prevent the situation from escalating and to resolve it by sharing the relevant information with the RMO (CFO) and through guick and appropriate initial response. After the crisis has been resolved, we conduct ex-post analysis to prevent a recurrence of the crisis and improve our response.

In response to COVID-19, we established the COVID-19 Emergency Headquarters headed by the CEO at an early stage, and work together with different departments to ensure the safety of employees as well as the stable supply of pharmaceuticals.

For details of actions against COVID-19, refer to page 43.

maintain an environment where each and every employee handles information properly.

### Countermeasures against Cyber Attacks

Under the leadership of the CISO, the Group has established the CSIRT<sup>\*2</sup> to promote information security measures. Specifically, the CSIRT collects information on cyber security from the Group companies in Japan and overseas, and develops security measures for the Group based on the information obtained. The CSIRT also promotes initiatives aimed at dealing with the threat of cyber attacks in cooperation with other organizations in the same and other industries. The goal of the CSIRT is to contribute to improving security not only within the Company, but throughout society.