

# Risk Management

The Daiichi Sankyo Group defines “risks” as those factors that may prevent it from achieving its goals and targets and that can be predicted in advance. We take appropriate measures against risks inherent in our corporate activities through retaining, reducing, avoiding, and transferring these risks; should risks materialize, we promote risk management to minimize impacts on people, society, and the Group itself.

## Promoting Risk Management

We have established a risk management system that provides for appropriate responses to risks inherent in our corporate activities. As the Risk Management Officer (RMO), the Chief Financial Officer (CFO) is responsible for overseeing Group-wide risk management and promotes risk management in line with an annual cycle of formulating and executing business plans.

The heads of each unit independently manage risks to aid the achievement of their unit’s goals and targets. To this end, they identify risks; carry out assessments to evaluate the likelihoods and potential impacts of these risks; formulate and implement countermeasures, and provide information, training, and education related to their unit’s risk management.

The RMO assesses the risks reported by each unit and identifies those that could potentially have a major impact on the Group’s

corporate management as Material Risks at the Executive Management Committee (EMC) Meeting and the Board of Directors. (See the Conceptual Diagram of the Group’s Risk Level Classification below.) An individual is assigned responsibility for each Material Risk and coordinates with relevant organizations to ensure appropriate measures are carried out. If signs of a Material Risk occurrence are detected, the individual is instructed to swiftly provide relevant information to the RMO, who will then report to the CEO. In addition, the progress of countermeasures against Material Risks is monitored twice a year and risk measures are reviewed as necessary. If potential new Material Risks requiring urgent action are identified, they will be added to the list of Material Risks after the review by the EMC and the Board of Directors, under the supervision of the RMO.

Conceptual Diagram of the Group’s Risk Level Classification

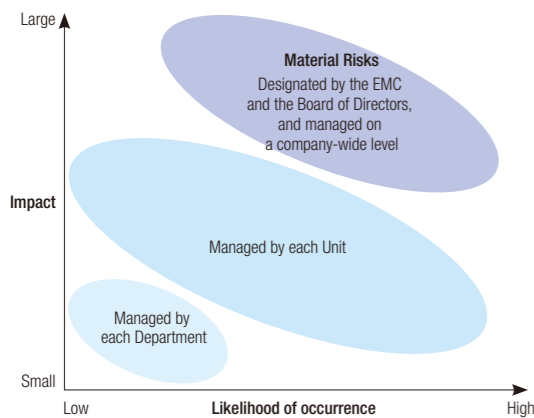
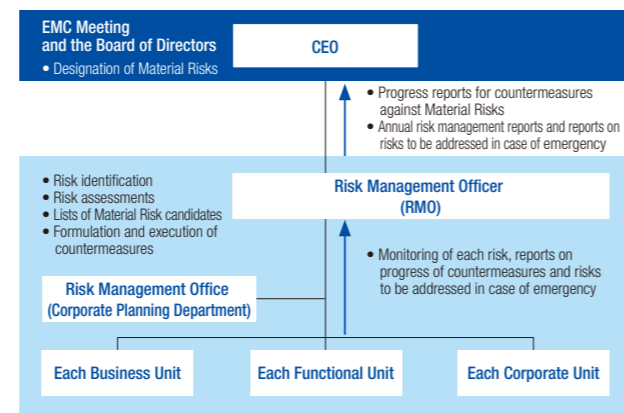


Diagram of Risk Management System



## Overview of Risk and Crisis Management

Risk Management Under Normal Circumstances	Materialized Risks and Emergency Events
<p><b>Risk Management</b></p> <p>Definition of “Risk”:  <b>Factors that prevent the achievement of business goals</b></p> <p>Proper response to assess and analyze risks and then contain the risks within acceptable limits</p>	<p><b>Crisis Management</b></p> <p>Definition of “Crisis”:  <b>When risks have materialized and require emergency responses, or when risks have an extremely high likelihood of materializing</b></p> <p>Preparations to minimize impact and damage in the event of a crisis, and comprehensive response from occurrence to resolution</p>
<p><b>Business Continuity Plan (BCP)</b></p> <p>Definition of BCP:  <b>Plans to ensure that, in the event of unforeseen circumstances, critical business operations are either not disrupted or, if they are disrupted, are swiftly restored</b></p> <p>Examine the management resources required to continue critical business operations, establish recovery procedures, and ensure that plans are maintained and improved</p>	

## Crisis Management

Under our Global Crisis Management Policy, we define “Crisis” as a collective term both for business risks that have materialized and that require immediate response, and for business risks that have an extremely high likelihood of materializing. Basic matters related to Crisis Management with the aim of minimizing losses caused by such events have been established. Our basic policy is as follows: “Upon the occurrence of a crisis, the Daiichi Sankyo Group shall respond immediately and precisely based on the following principles: ensuring the safety of the lives and communities of Daiichi Sankyo Group employees and related personnel; and fulfilling the responsibilities as a life science company. The Group shall endeavor to minimize human, social, or corporate losses and strive for business continuity and quick recovery.”

We have established a system that enables us to respond flexibly according both to the type of crisis—disasters and accidents; incidents including terrorism, scandals, and legal violations; information management issues; and product issues—and to the degree of impact

of the crisis. See the “Initial Response to Crisis” diagram below. In the event of a crisis, we will endeavor to prevent its escalation and to resolve it as soon as possible through swift and appropriate initial responses. We have clearly specified the reporting criteria and reporting line and established the Crisis Management Officer (either the CEO or a person designated by the CEO) and the Crisis Initial Response Officer (the Vice President of Corporate Affairs & Procurement). For crises with significant global impact requiring a Group-wide response, the Group will also share all relevant information with the Risk Management Officer (CFO). After the crisis has been resolved, we conduct an ex-post analysis to prevent its recurrence and improve crisis countermeasures.

To combat the effects of COVID-19, we have established a COVID-19 Emergency Response Headquarters, headed by the CEO, and coordinate continuously with relevant departments. Through this system, we intend to ensure both the safety of our employees and to maintain a stable supply of pharmaceuticals.

Initial Response to Crisis



## Business Continuity Plan (BCP)

### Daiichi Sankyo Group BCP Policy

In April 2022, we established the “Daiichi Sankyo Group BCP Policy,” a new global policy for formulating and implementing BCP. Based on this policy, we plan to establish systems that ensure a stable supply of pharmaceuticals of assured quality and secure the continuity of our research and development activities in order to respond to societal demands even in times of emergency. In addition, in response to the diversification of crises and the globalization of our business in recent years, we are engaged in a Group-wide review of our BCP. The review focuses on management resources and seeks to promote advance preparations and clarification of business continuity procedures.

### BCP Measures in the Supply Chain

We revised our BCP in 2012 following the experiences in the aftermath of the Great East Japan Earthquake. Since then, we have continued to improve the BCP to ensure effective response measures are taken in the event that a risk materializes; to this end, we have reviewed the list of drugs for which supply should be prioritized and updated disaster plans at our production sites, in line with revisions to national disaster response plans and prevailing societal

needs. We are also working to implement continuous improvements that enable us to cope with the growing complexity and globalization of production and logistics systems. Our list of pharmaceuticals for which supply should be prioritized includes those that are used by a large number of patients, that are needed in emergencies, or that cannot be substituted by other drugs and is reviewed on a regular basis to ensure a system that can provide a continuous and appropriate supply of necessary drugs when risks occur.

To realize a continuous and stable supply of pharmaceuticals by tracing back the manufacturers of our products accurately and selecting appropriate suppliers with BCP in our mind, we carry out manufacturer surveys and supplier assessments every three years, with the previous surveys and assessments completed in FY2020. In FY2021, we commenced manufacturer surveys to check the traceability of the raw materials procured by our overseas Group companies. We will use the results of these surveys to identify issues, carry out improvements, and establish robust supply chains.

## Major Risks and their Management

The table below lists the Major Risks identified by the Group's Material Risks and management risks at each unit and department management level. In identifying these risks, we have taken into consideration the potential impact they may have on investment decisions.

Area	Material Risk	Risk Summary	Status of Risk Management
Research and Development / Alliances with Partner Companies	✔	For new drug candidates, risks include: the suspension of research and development—in particular for trastuzumab deruxtecan (T-DXd / DS-8201; anti-HER2 ADC; product name: <i>Enhertu</i> ®) and datopotamab deruxtecan (Dato-DXd / DS-1062; anti-TROP2 ADC), on which we are collaborating with AstraZeneca; changes to approval review criteria resulting in failure to obtain approval; and changes to the terms and conditions of our R&D alliances, or their termination	<ul style="list-style-type: none"> <li>Establish a Joint Executive Committee with AstraZeneca, create a unified vision between the two companies for each area of collaboration, and use this vision to formulate and manage the progress of strategies</li> <li>Ensure constant communication with pharmaceutical regulatory authorities in each country, as a means of managing and reducing pharmaceutical risks</li> </ul>
Pharmaceutical Side Effects and Quality Issues	✔	Pharmaceutical products may be recalled or withdrawn from the market due to quality issues or unforeseen side effects; significant expenses may be incurred due to resulting allegations of injury and other matters of liability.	<ul style="list-style-type: none"> <li>Perform objective assessments, reviews, and analyses of safety management information—including information on side effects—collected from both Japan and around the world, and share this information with health care professionals in an appropriate manner</li> <li>Provide all employees with annual training in safety management information</li> </ul>
Overseas Business Expansion	✔	Operations overseas may be impacted by a number of factors, including: political instability; deterioration of economic circumstances; contraventions of local laws and regulations; and worsening labor-management relations	<ul style="list-style-type: none"> <li>Appoint risk management officers at group companies outside of Japan, and collect and share information on a regular basis</li> <li>When a problem occurs, the risk management officer serves as a hub for coordinating with local Group companies, aiding prompt problem resolution</li> </ul>
Manufacturing and Procurement	✔	Risks affecting manufacturing and procurement activities may include damage to Group-owned facilities, impairment of social infrastructure, and technical issues	<ul style="list-style-type: none"> <li>Establish systems to rapidly restore operations in the event of an emergency and to ensure stable supplies of pharmaceuticals with assured quality for the continued provision of medical services</li> <li>Ensure distribution of manufacturing and logistics bases, and install private electricity generators</li> <li>Strengthen IT foundations, such as by ensuring redundancy in core systems</li> </ul>
Environment and Safety		Risks include exposure to chemical substances for people both internal and external; adverse impacts on the environment through soil and air pollution; fragmentation of supply chains for pharmaceuticals due to extreme weather disasters, global warming, and other phenomena related to climate change; and rising manufacturing costs negatively affecting the stable supply of pharmaceuticals	<ul style="list-style-type: none"> <li>Establish and ensure continuous monitoring of independent management standards that are more rigorous than those set by local authorities</li> <li>Disclose information according to recommendations of the Task Force on Climate-related Financial Disclosures (TCFD)</li> </ul>
Intellectual Property Rights	✔	Third party claims of patent infringement or other intellectual property claims against the Group, which could interrupt the Group's business or result in legal action; the Group itself may initiate legal action if a third party is found to have infringed Group-owned intellectual property rights	<ul style="list-style-type: none"> <li>Maximize value and minimize risks for the creation and protection of intellectual property</li> <li>Establish systems to minimize the impact of intellectual property disputes on business by working together with internal and external parties</li> </ul>
Litigation	✔	Lawsuits may arise over pharmaceutical side effects, product liability, labor and employment, and fair trade-related litigations, among others, may arise	<ul style="list-style-type: none"> <li>Minimize legal risks and maximize business opportunities from the perspective of laws and regulations, contracts, and dispute prevention and resolution</li> <li>Maintain and enforce preventive measures against compliance violations</li> </ul>
Laws and Regulations and Regulatory Trends to Limit Healthcare Expenses	✔	Negative impact may arise from administrative measures related to drug price revisions, the healthcare system, and health insurance	<ul style="list-style-type: none"> <li>Revise wholesale prices and rebates in light of NHI drug price system reforms and distribution improvement guidelines</li> <li>Monitor drug price policies across the world</li> <li>Draw up and implement appropriate sales conditions</li> </ul>
Legal Violations	✔	There is the risk of serious legal violations at the individual level, including personal misconduct of executives and employees	<ul style="list-style-type: none"> <li>Monitor business operations to detect inappropriate activities as early as possible</li> <li>Prevent violations through strict compliance with laws and regulations and through educational and awareness-raising activities</li> </ul>
Financial Market and Exchange Rate Fluctuations	✔	Negative impact may result from sluggish stock markets, interest rate trends, and exchange rate fluctuations	<ul style="list-style-type: none"> <li>Reduce cross holdings</li> <li>Implement mid-term reviews of pension fund asset allocations</li> <li>Execute currency hedging transactions</li> </ul>
IT Security and Information Management	✔	Network virus infections and cyberattacks may result in system shutdowns or leakages of personal data and other confidential information	<ul style="list-style-type: none"> <li>Appoint CIO*1 and CISO*2 to establish global organizational system in the field of information</li> <li>Provide employees with training in information management</li> <li>Establish security systems with defense functions and infringement-detection and countermeasure functions</li> <li>Strengthen and improve operation of information security infrastructure</li> </ul>
Recoverability of Deferred Tax Assets	✔	Negative impact may result from reductions in taxable income, deductible temporary differences due to tax reforms, and reassessment of tax loss carryforwards	<ul style="list-style-type: none"> <li>Review future tax income as appropriate in light of changes to business environment</li> </ul>
Securing Talent		Increasingly competitive job markets may result in an inability to secure either sufficient talent in IT-related fields or employees with the high levels of expertise required for various roles	<ul style="list-style-type: none"> <li>Secure talent by strengthening systematic recruitment activities and incorporating diverse approaches</li> <li>Develop and secure talent through internal training programs</li> <li>Promote both One DS Culture and Inclusion &amp; Diversity(I&amp;D), and analyze and improve employee engagement through global engagement surveys</li> </ul>
Impact of COVID-19	✔	Delays of goods in the supply chain caused by the spread of COVID-19 may affect the stable supply of products; delays to ongoing clinical trials and protocol violations resulting from disruptions to clinical settings may harm future product value	<ul style="list-style-type: none"> <li>Maintain COVID-19 Emergency Response Headquarters</li> <li>Ensure stock of pharmaceuticals</li> <li>Continue and modify clinical trials with the highest priority on the safety of participants</li> </ul>

\*1 Chief Information Officer

\*2 Chief Information Security Officer

## Information Management and Security Initiatives

### Establishing and Strengthening Information Governance Structures

We are endeavoring to build an information security management system based on ISO/IEC27001 at all Group companies, to provide our customers with a stable supply of products and information. We have appointed a Chief Information Officer (CIO) to oversee global specialized functions in the field of information; we have also appointed a Chief Information Security Officer (CISO), who is responsible for overseeing management of confidential information and promoting information security measures. In this way, we are promoting the establishment of policies and rules related both to new digital technologies and to new laws and regulations. To ensure information security as part of our business strategy for both the entire Group and each organization, we are working with the CIO to further strengthen our measures. In addition, through regular employee training, we are seeking to improve the information literacy and information-related ethics of all our employees so they can properly understand information security and behave accordingly.

### Strengthening Cyber Security Measures

The Computer Security Incident Response Team (CSIRT), whose purpose is to respond appropriately to the cyber threats that have been increasing in recent years, is operated under the leadership of the CISO and monitors security 24 hours a day with the cooperation of external security partners. We set a system in place where incidents are promptly handled when they occur.

We believe employee awareness is critical to protecting our information assets from security threats. We therefore are continuously raising awareness and alerting our employees by carrying out educational trainings which are tailored to individual Group companies on the subject of information security such as targeted email attacks and other techniques used by cyber criminals. When it comes to the threat of cyberattacks, we also believe it is vital to work together with other organizations both inside and outside the life science industry. We collaborate with external security teams, such as specialist organizations and CSIRTs at other companies, to collect cyber security information, and we use this information to formulate security measures for our Group. By building cooperative relationships with external parties, we are continuing our work centering on the CSIRT to contribute to the improvement of cyber security not only within the Group but also in society.

### Measures against Cyberattacks

We are working to strengthen our information security infrastructure, including defense functions and breach detection/response functions, and improvements in information security operations in order to enhance our global countermeasures against cyberattacks on our IT systems.

In FY2021, we began measuring our security level using the security rating service. We identify assets that are vulnerable to attackers and strengthen our response to vulnerabilities that could be exploited by attackers. We are also conducting desktop drills for response and recovery functions, detecting and identifying potential issues with our incident response, and working to strengthen and improve these issues globally.

### Personal Information Security Initiatives

We have established the "Daiichi Sankyo Group Privacy Policy" to clarify globally uniform standards for the protection of personal information. We conduct ongoing employee education and monitoring of this policy. In FY2021, in response to the Amendments to the Act on the Protection of Personal Information, which came into effect in April 2022, including mandatory disclosure of records related to the provision of personal information to third parties in Japan and tightened regulations on the provision of personal data to third parties overseas, we and our Group companies in Japan updated legal compliance systems by revising our policies and procedures for handling personal information and updating notices related to personal information published on our corporate websites in Japan. In addition, we and our Group companies in Japan are endeavoring to improve awareness of how to handle personal information appropriately: training programs for executives by external lecturers to increase their understanding of the Act and to have them learn about points to consider as members of executive management; information sessions on the subject of amendments both to laws and Group regulations are also held for persons in charge of personal information security. At overseas Group companies, we also have implemented training sessions to improve employee understanding of personal information security. In order to prevent serious compliance violations of the Act on the Protection of Personal Information, we will continue to engage in continuous risk reduction initiatives and early detection initiatives.

## Responses to Geopolitical Risks

With economic friction, conflicts, and other geopolitical risks on the rise, we seek to swiftly grasp and minimize any impact on our business. Also, we pay close attention to changes in such risks, so that we can meet the expectations of our stakeholders and fulfill our responsibilities to society.

We are engaged in R&D, manufacturing and sales activities across the world, and collaboration with numerous overseas business partners is essential to carry out our business activities. Risk management officers at our Group companies and other organizations in Japan and overseas regularly collect and share information, enabling us to respond promptly to any risks that have the potential to impact our business activities.

While we have measures in place against political instability and worsening economic conditions, we are working to further strengthen our measures in numerous fields, including R&D and alliances with other companies; pharmaceutical side effects; overseas business expansion; and manufacturing and procurement. To manage geopolitical risks pertaining to the Ukraine-Russia situation, we quickly established an emergency response team headed by the CEO to assess its impact on the entire Group. We intend to carry out crisis management should events occur requiring urgent responses, while our Risk Management System is executing and monitoring measures against potential subsequent risks.