

# Risk Management

## Major Risks and Corresponding Responses

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. 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.

For details on our risk management system, crisis management, and BCP (Business Continuity Plan), please click [Here](#)

Areas	Material Risks	Risk Summary	Status of Risk Management
Research and Development & Alliances with Partner Companies	○	The potential of discontinuation of research and development, failure to obtain approval due to changes in approval review criteria, or changes or termination of contract terms related to collaborations in the development of new drug candidates. This includes Trastuzumab Deruxtecan (T-DXd/DS-8201: Anti-HER2 ADC, product name: ENHERTU®) and Datopotamab Deruxtecan (Dato-DXd/DS-1062: Anti-TROP-2 ADC) in partnership with AstraZeneca, as well as Patritumab Deruxtecan (HER3-DXd/U3-1402), Inatamab Deruxtecan (I-DXd/DS-7300), and DS-6000 (R-DXd) in partnership with Merck.	Establish a Joint Committee with AstraZeneca and Merck, 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; Ensure constant communication with pharmaceutical regulatory authorities in each country, as a means of managing and reducing risks; Ensure distribution of manufacturing and logistics bases, and install private electricity generators; Strengthen IT foundations, such as by ensuring redundancy in core systems
Pharmaceutical Side Effects and Quality Issues	○	Pharmaceutical products may be recalled or withdrawn from the market due to quality issues or unforeseen side effects; significant expenses may be incurred due to resulting allegations of injury and other matters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.	Consistent quality assurance through the enhancement of management systems compliant with GMP and GDP standards; Regular audits of group company facilities and business partners are conducted; Perform objective assessments, reviews, and analysis of safety management information (e.g., information on side effects) globally collected; and share this information with health care professionals in an appropriate manner; Provide all employees with training in safety management information every year
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	Appoint risk management officers at group companies outside of Japan, and collect and share information on a regular basis; When a problem occurs, the risk management officer serves as a hub for coordinating with local Group companies, aiding prompt problem resolution
Manufacturing and Procurement	○	Risks affecting manufacturing and procurement activities may include damage to Group-owned facilities, impairment of social infrastructure, and technical issues	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; Continuously improve BCP by reviewing operations and organizational structure related to priority supply items, etc.; Periodically review list of priority supply items
Environment & 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.	Establish and ensure continuous monitoring of independent management standards that are more rigorous than those set by local authorities; Disclose information according to recommendations of the TCFD
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.	Maximize value and minimize risks for the creation and protection of intellectual property; Establish systems to minimize the impact of intellectual property disputes on business by working together with internal and external parties
Litigation	○	Lawsuits may arise over pharmaceutical side effects, product liability, employment/labor issues, and fair trade-related litigations, among others.	Minimize legal risks and maximize business opportunities under applicable laws and regulations, contracts, and dispute prevention and resolution
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.	Revise wholesale prices and rebates in light of NHI drug price system reforms and distribution improvement guidelines; Draw up and implement appropriate sales contracts; Monitor drug price policies in each country
Legal Risk	○	There is always legal risk the Group is cognizant of, including the serious risk associated with illegal conduct by executives and employees.	Monitor business operations to detect any inappropriate activities as early as possible; Prevent violations through strict compliance with laws and regulations and through educational and awareness-raising activities; Establish measures to prevent compliance violations and take strict action when violations occur
Financial Market and Exchange Rate Fluctuations	○	Negative effects may result from stock market behavior, interest rate trends, or exchange rate fluctuations.	Reduce cross holdings; Implement mid-term reviews of pension fund asset allocations; Execute currency hedging transactions
IT security and information management	○	Network virus infection, cyber-attacks, and other similar events may result in a system shutdown or leakage of confidential information including personal data.	Under the leadership of the CDXO, promoting measures related to information management and security, and establishing policies and rules; Provide employees with continuous information management training; Establish security systems with defense functions and infringement detection and countermeasure function; Strengthen information security infrastructure and improve its operation; Regular monitoring of personal information management practices
Securing Talent	○	Increasingly competitive job markets may result in an inability to secure sufficient talent with the high levels of expertise required for various roles.	Strengthening planned recruitment activities and fostering and securing talents through diverse approaches; Establishment and implementation of a globally unified HR system and human resource information system; Promote both One DS Culture and Inclusion & Diversity (I&D), and analyze and improve employee engagement through global engagement surveys

## Initiatives for Information Management and Security

Our Group has established a global information security policy to ensure the stable supply of products and the provision of reliable information to our customers. Under the leadership of the Head of Global Information Security, we are implementing information security measures on a global scale. Additionally, the Chief Digital Transformation Officer (CDXO), the chief officer in the digital domain with information management functions, supervises digital transformation for the entire organization and oversees the conduct of its operations.

Our information and system assets referred to in the information security policy include information on our business units, as well as our business partners and customers, and data, media, information systems, and industrial systems that include the information. We have standardized information management measures among Group companies in Japan and are continuously assessing them to ensure thorough information management. In information security, we have established the Daiichi Sankyo Group Information Security Standard to enhance the level of security measures globally. We assess compliance with these standards and implement continuous improvements based on the results. Furthermore, since FY2023, we have transferred the information security function to the digital transformation management department, “Global DX”, to further strengthen information security across the entire group. To protect information resources from security threats, raising awareness among all employees is crucial. As part of our information security awareness activities tailored to the specific circumstances of each company, we educate employees about cyber-attacks and targeted e-mails, etc. on an ongoing basis.

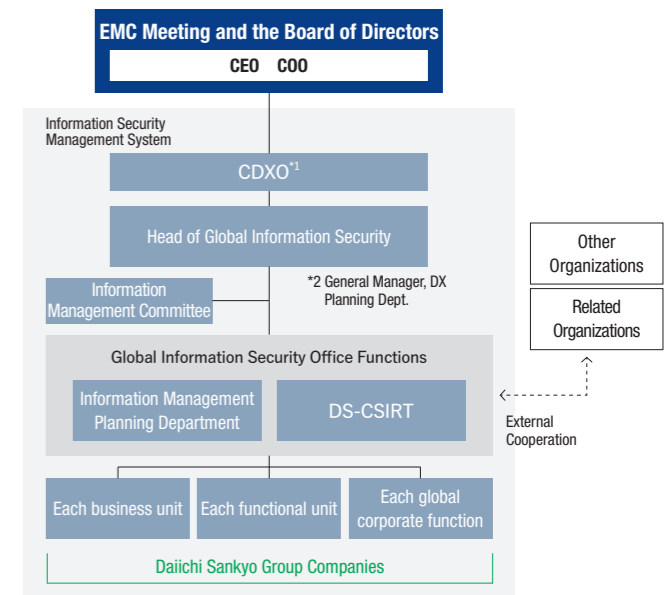
Moreover, under the leadership of the Head of Global Information Security, we operate a Computer Security Incident Response Team (CSIRT)<sup>2</sup>, which conducts 24-hour security monitoring with the support of external security partners. To effectively counter cyberattacks, collaboration with other organizations is essential. We work closely with external expert organizations and other CSIRTs to gather information and develop and promote security

measures. By building such cooperative relationships, we contribute not only to the security within our Group but also to the overall enhancement of security in society.

Furthermore, to address the risk of cyberattacks on control devices and systems involved in the pharmaceutical manufacturing process, we are actively promoting Operational Technology (OT) security measures. Specifically, we are advancing security measures by designing a standard model that organizes recommended security technologies, as well as processes for evaluating and managing OT security risks. With these measures, we minimize risks related to quality control and stable supply, thereby contributing to the provision of pharmaceuticals to patients.

<sup>\*1</sup> Abbreviation for Chief Digital Transformation Officer

<sup>\*2</sup> A framework for dealing with incidents relating to computer security in enterprises



## Strengthening the Management System for Safety and Quality Assurance

To deliver safe and high-quality products that patients can use with confidence, we have established and strengthened a management system that complies with Good Manufacturing Practice (GMP) for pharmaceutical manufacturing and quality control, as well as Good Distribution Practice (GDP) for ensuring the quality of pharmaceuticals during transportation and storage. This comprehensive quality assurance approach covers the entire process, from the procurement and storage of raw materials to pharmaceutical manufacturing and distribution. In addition, we conduct regular audits of our global company sites and business partners to ensure the maintenance and

enhancement of an appropriate quality management system, as well as to reduce risks.

Regarding safety, we have established a system that enables us to conduct safety monitoring activities on a global scale. We promote activities aimed at minimizing risks on patient safety by evaluating, reviewing, and analyzing safety information (such as side effect information) collected from around the world and promptly providing the results to healthcare professionals. Additionally, we conduct annual training on safety information for all employees, striving to foster a strong awareness of Patient Safety.