

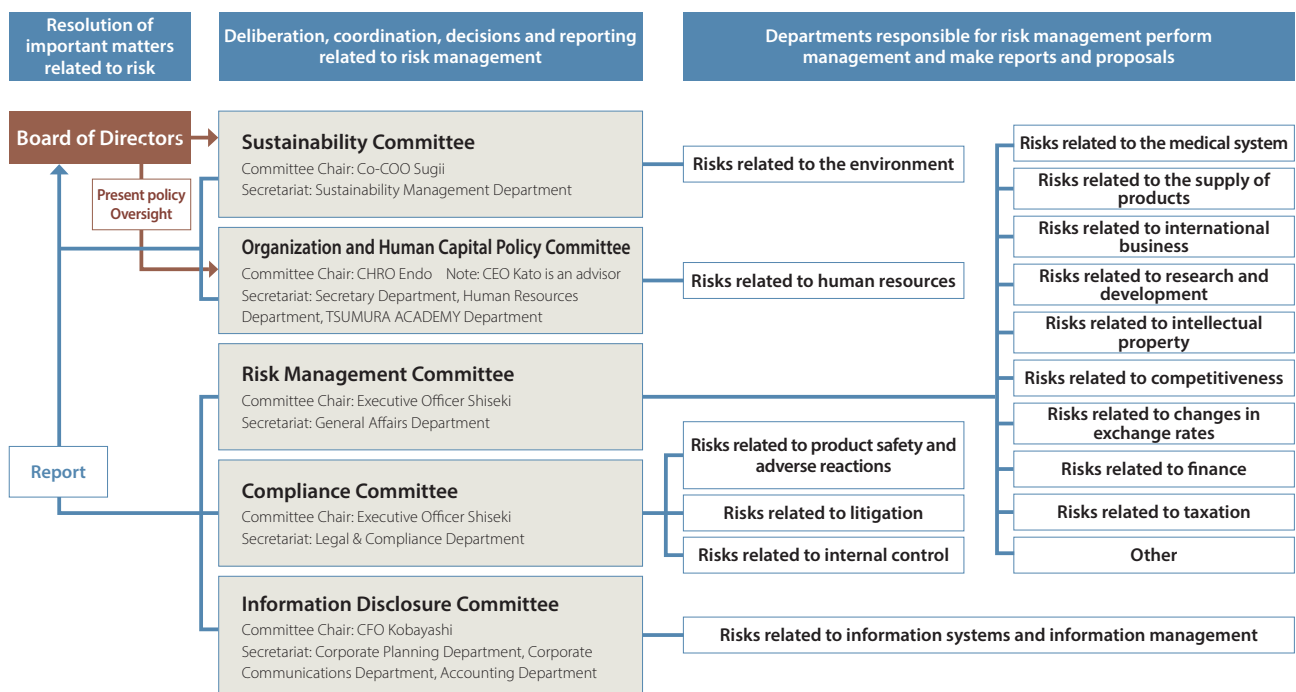
Risk Management

Risk Management Systems

The Tsumura Group recognizes that appropriately performing risk management is one of the most important issues in management, and endeavors to provide a management system headed by the Board of Directors. Pursuant to the Companies Act, the Board of Directors establishes the systems required for ensuring the appropriate execution of duties of executive officers, and all executive officers identify risks in their respective duties, and engage in the implementation of operation and management.

The Risk Management Committee is chaired by the Risk Management Officer (Executive Officer in charge of the General Affairs Department), and centrally manages significant

risks. Furthermore, in addition to performing management according to the nature of each risk after categorizing and defining risks in line with the Risk Management Regulations, the committee evaluates reports and proposals from each department responsible for risk management, and deliberates and coordinates the understanding and appropriate response to groupwide risks. The deliberation, coordination and decisions in the Risk Management Committee are periodically reported to the Board of Directors. The Board of Directors receives reports, checks the status of risk management initiatives and the effectiveness of measures, supervises these and provides necessary instructions.



Risk items	Details of significant risks	Risk mitigation measures
1 Risks related to the medical system	<ul style="list-style-type: none"> Risks related to administrative developments such as government policies to curb healthcare spending Risk of tighter domestic/overseas regulations concerning the development and manufacture of pharmaceutical products 	<ul style="list-style-type: none"> Building understanding of the value of Kampo formulations Cooperation with industry bodies and recommendations to relevant ministries and agencies Establishment of evidence of efficacy of prescription Kampo formulations Activities to raise the profile of prescription Kampo formulations
2 Risks related to the supply of products	<ul style="list-style-type: none"> Risk in the procurement of raw material crude drugs due to unforeseen weather conditions, natural disasters, etc., changes in the scope of legal restrictions on imports and exports, or unexpected changes in political and economic conditions Risk in the procurement of secondary raw materials and other materials due to sudden supply-and-demand-related distribution concerns caused by natural disasters or unstable social conditions Risk of loss of production and distribution functions due to natural disasters, fires, power outages, etc. 	<ul style="list-style-type: none"> Securing of sufficient inventory volume Expansion of range of suppliers of crude drugs domestically and overseas Continued expansion of cultivated land under own management Establishment of purchasing structure involving multiple suppliers Diversification of manufacturing sites and product supply sites Introduction of seismic isolation and earthquake-resistant structures for production facilities
3 Risks related to product safety and adverse reactions	<ul style="list-style-type: none"> Risk of occurrence of problems with product quality or safety Risk of unexpected side effects 	<ul style="list-style-type: none"> Compliance with quality control standards in the country or region Promotion of initiatives for quality of all products, including not only those manufactured in-house but also those manufactured by CMOs Thorough management of raw material crude drugs in accordance with the Regulations on the Tsumura GACP Policy Promoting proper use of products by promptly and appropriately collecting safety information on products and strengthening the dissemination of information on adverse drug reactions

Risk items		Details of significant risks	Risk mitigation measures
4	Risks related to international business	<ul style="list-style-type: none"> • Risk of the discovery of contingent liabilities or unrecognized liabilities after alliances related to the launch of operations in China, and that the expected business value and future synergies from business integration will not be realized • Risk of unexpected changes in laws/regulations or in political/economic conditions 	<ul style="list-style-type: none"> • Conduct careful due diligence concerning the financial condition, dealings, etc. of companies/businesses subject to M&A • Reinforcement of business management functions through Tsumura China Inc.
5	Risks related to research and development (R&D)	<ul style="list-style-type: none"> • Risk that future growth (globalization of prescription Kampo formulations, development of pre-symptomatic and personalized medicine) or performance cannot be maintained or improved (standardization of Kampo treatments cannot be accelerated) • Risk that standardization of Kampo treatments cannot be accelerated due to the number of Kampo products listed in treatment guidelines 	<ul style="list-style-type: none"> • [Global and Japan] Periodic verification of feasibility (return on investment and business feasibility assessment) of R&D plans • [Japan] Expansion of business target areas (beyond the medical-use domain to include the total healthcare domain)
6	Risks related to intellectual property (IP)	<ul style="list-style-type: none"> • Risk of decline in competitiveness due to IP rights infringement by third parties • Risk of disputes stemming from the infringement of third-party IP rights 	<ul style="list-style-type: none"> • Thorough information management in accordance with Company rules • Acquisition of industrial property rights such as patents and trademark rights in connection with newly developed technologies, new products, etc. • Investigation into IP rights belonging to other companies, e.g., confirmation of prior trademarks, confirmation of prior patents related to newly introduced technologies, etc.
7	Risks related to human resources	<ul style="list-style-type: none"> • Risk of being unable to secure or systematically develop the necessary human resources • Risk of a decline in societal standing due to insufficient action to tackle occupational health and safety issues, harassment, etc. 	<ul style="list-style-type: none"> • Clarification of human resource criteria and personnel numbers required for management strategy execution and establishment of recruitment techniques • Securing of global human resources for the development of operations in China and the United States • Cultivation of human resources who can conduct business based on the Group's Corporate Philosophy • Clear statement of human resource capability requirements at each level and expansion of education opportunities based on the Human Resource Development Policy • Provision of thorough labor affairs management education primarily to managers and increased opportunities for communication through the use of one-on-one meetings and other modes of communication
8	Risks related to competitiveness	<ul style="list-style-type: none"> • Risk of entry into prescription Kampo market by Japanese and foreign pharmaceutical companies • Risk of launch of new drugs by Japanese and foreign pharmaceutical companies in major markets for prescription Kampo formulations 	<ul style="list-style-type: none"> • Ensuring superiority through the stable procurement of safe crude drugs, steady supply of prescription Kampo formulations of uniform quality • Accumulation of evidence on their safety and efficacy
9	Risks related to changes in exchange rates	<ul style="list-style-type: none"> • Risk of large fluctuations in the exchange rate relevant to the import of raw material crude drugs and Kampo powdered extract from China 	<ul style="list-style-type: none"> • Stabilization of costs and cash flows over the long term through tools such as forward exchange contracts while taking into account exchange rate trends
10	Risks related to finance	<ul style="list-style-type: none"> • Risk of changes in retirement benefit obligations • Fundraising risk • Risk of price fluctuation for marketable securities 	<ul style="list-style-type: none"> • Early identification of changes in the external environment, market environment, circumstances at related companies, etc. and swift action to respond to such changes • Maintaining relationships with financial institutions, particularly the main bank
11	Risks related to taxation	<ul style="list-style-type: none"> • Risk of being charged additional tax or subject to double taxation due to differences of opinion with the tax authorities in each country 	<ul style="list-style-type: none"> • Calculation of taxation amounts and proper payment thereof in accordance with the tax laws of each country • Compliance with the transfer pricing tax regimes applied in each country
12	Risks related to the environment	<ul style="list-style-type: none"> • Risk of violating laws or regulations by causing soil contamination, water pollution, etc. • Risk of reduction in areas suitable for cultivation of crude drugs caused by changes in the natural environment • Risk of increase in procurement cost due to disasters, etc. affecting suppliers 	<ul style="list-style-type: none"> • Compliance with environment-related laws and regulations • Diversification and development of multiple crude drug production areas and production countries
13	Risks related to litigation	<ul style="list-style-type: none"> • Risk of various lawsuits being filed for, for example, side effects of pharmaceutical products including Kampo and crude drug formulations, harm to health, product liability, labor issues, infringement of IP rights, contract nonperformance, environmental pollution, etc. 	<ul style="list-style-type: none"> • Avoiding actions that could lead to lawsuits and early identification of problems by establishing a Group compliance system (rules, whistleblower system, organization, etc.) • Establishment of corporate governance structure for Group companies • Ongoing close collaboration with attorneys
14	Risks related to information systems and information management	<ul style="list-style-type: none"> • Risk of IT systems malfunctioning due to large earthquakes or other disasters such as fire, power outages, etc. • Risk of systems failing or confidential information being leaked as a result of cyberattacks by malicious third parties, carelessness or negligence by employees, etc. 	<ul style="list-style-type: none"> • Proper investment in strengthening IT systems • Formulation of a business continuity plan (BCP), implementation of drills that simulate the occurrence of an emergency, etc. • Thorough communication of internal rules concerning information management to everyone within the Company and reinforcement of information management
15	Risks related to internal control	<ul style="list-style-type: none"> • Risk of being unable to ensure the effectiveness or efficiency of operations • Risk of being unable to ensure the integrity of financial reports • Risk of unlawful conduct, fraud, etc. 	<ul style="list-style-type: none"> • Establishment and operation of internal control system • Establishment and operation of internal management standards • Periodic internal audits and internal control evaluations