

Risk scenario, impacts on corporate value, and progress of countermeasures, on each items

Assessment points	Risk scenario	Impacts on corporate value	Relevant issue(s) of ESG materiality*1	Current progress of Santen's countermeasures
Global compliance	<ul style="list-style-type: none"> <li>Violations of social norms, laws, regulations, etc.</li> </ul>	<ul style="list-style-type: none"> <li>Decline in public trust and brand image</li> <li>Damage to corporate value due to a stock price decrease</li> <li>Decline in Santen's business performance or difficulty in business continuity due to decrease revenue, compensation payments, etc.</li> </ul>	3	<ul style="list-style-type: none"> <li>Formulated the Global Compliance Policy and systemically enhancing global compliance</li> <li>Introduced and operates a systematic global education program for all employees</li> <li>Fosteres awareness of compliance and strengthened legal and regulatory compliance by designating a month for emphasizing the Santen Code of Practice, supported by messages from the CEO and regional senior management</li> <li>Integrates Group-wide systems (global whistleblowing system, etc.) to identify issues and ensure appropriate follow-up are in place and operational</li> </ul>
Production and supply	<ul style="list-style-type: none"> <li>Suspension of operation at a specific plant (the Noto, Shiga or Suzhou Plants, in particular) or external contractor, or the suspension of raw material supply from a supplier due to a pandemic, natural disaster, fire or other factor</li> </ul>	<ul style="list-style-type: none"> <li>Adverse impacts of disruption or suspension, etc. of production activities on stable product supply, and on Santen's business performance and financial condition</li> </ul>	1	<ul style="list-style-type: none"> <li>Creates processes, systems and other mechanisms to ensure stable supply</li> <li>Remains abreast of actual conditions and responded to issues by planning, monitoring execution, and assessing risk</li> <li>Structures product manufacturing and supply for compatibility with rigorous logistics regulations in Europe</li> <li>Visualizes and centralizes global inventory management and production planning</li> <li>Establishes and strengthens the contract manufacturer management system and backup supplier system</li> </ul>
Investment	<ul style="list-style-type: none"> <li>Failure to realize the expected effects of or profits from investments proactively made with the aim of sustainable global growth in the ophthalmic field, due to unfavorable changes in the external environment or other circumstances</li> </ul>	<ul style="list-style-type: none"> <li>Impairment loss on tangible or intangible assets and adverse impacts on Santen's business performance</li> </ul>	1,3	<ul style="list-style-type: none"> <li>Implements investment decisions in line with internal evaluation criteria based on cost of capital</li> <li>Established the Corporate Strategy Committee to discuss key strategic issues; organically coordinated discussions of medium-to-long-term strategy, businesses and development portfolio with individual projects for submission to the Board of Directors; clarified the position of individual projects in overall strategy and lay out issues for discussion</li> <li>Introduced a framework for regular, ongoing monitoring of matters the Board of Directors has resolved to support steady results</li> </ul>
IT security and information management	<ul style="list-style-type: none"> <li>Malfunction of IT systems used in business activities</li> <li>Cyberattacks, computer virus infection, etc.</li> <li>Leakage of personal or other kinds of information</li> </ul>	<ul style="list-style-type: none"> <li>Adverse impacts of suspension of or delays in business activities, decline in public trust, etc. on Santen's business performance</li> </ul>	3	<ul style="list-style-type: none"> <li>Operates and maintains an information security management system that meets the ISO/IEC 27001 standard</li> <li>Established the Global Data Privacy Policy, the Global Information Security Policy, the Document Management Policy, and other policies to address cyber security risks</li> <li>Enhances security governance through personnel and organizational measures centered around security training and drills and through technical measures (provided global anti-phishing training as one of the measures to enhance cyber security)</li> <li>Ensures appropriate risk management not only within the Santen Group but also throughout its supply chain and at its business partners</li> <li>Established a system by which the Chief Digital &amp; Information Officer (CDIO) serves as the Chief Information Security Officer (CISO), who is in charge of formulating and implementing global information security strategies and reports directly to the CEO and the Board of Directors</li> </ul>
Pharmaceutical regulatory trends	<ul style="list-style-type: none"> <li>Drug price revisions beyond the scope of those predicted, mainly in the Japanese market</li> <li>Other revisions to healthcare insurance systems</li> <li>Measures by governments or revisions to pharmaceutical insurance systems to encourage the use of generic drugs, such as the Volume-Based Purchasing in China, and other companies' launch of generic drugs</li> </ul>	<ul style="list-style-type: none"> <li>Adverse impacts on Santen's business performance and financial condition</li> </ul>	1	<ul style="list-style-type: none"> <li>Accelerates the development of new drugs with high added value</li> <li>Pivotes from long-listed products to a portfolio centered on new drugs</li> <li>Expands sales channels to include markets for treatments that are not listed under healthcare insurance systems, etc.</li> <li>Helps ensure drug approval and fair pricing by strengthening global regulatory and market access capabilities</li> </ul>
Research and development	<ul style="list-style-type: none"> <li>Suspension of or delays in development, refusal of submitted drug approval applications, failure to obtain expected efficacy, etc.</li> <li>Unexpected side effects, leakage of personal information, etc. during clinical trials</li> </ul>	<ul style="list-style-type: none"> <li>Difficulty in achieving sales commensurate with research and development investment costs</li> <li>Decline in public trust and adverse impacts on Santen's business performance</li> </ul>	1,3	<ul style="list-style-type: none"> <li>Enhances development functions, mainly in the U.S. and China</li> <li>Prioritizes and optimizes the development pipeline</li> <li>Consults closely with authorities to refine clinical trial design and improve the process for selecting institutions where clinical trials are conducted</li> <li>Established and holds meetings of the Research Ethics Committee as a deliberating body to ensure scientifically and ethically appropriate research and development</li> <li>Implements necessary measures to ensure patients' participation in clinical trials of their free will, with their fully informed consent, and with the protection of their personal information ensured</li> </ul>
Global operation	<ul style="list-style-type: none"> <li>Revisions to laws or regulations in the countries where Santen operates</li> <li>Political instability and/or economic uncertainties</li> <li>Cultural differences in business practices</li> </ul>	<ul style="list-style-type: none"> <li>Difficulty in achieving initially expected effects and/or profits</li> </ul>	1,2,3,4	<ul style="list-style-type: none"> <li>Strengthens the crisis management system through global collaboration</li> <li>Established global policies and operational rules</li> <li>Ensures continued monitoring</li> </ul>
Environment	<ul style="list-style-type: none"> <li>Occurrence of environmental issues, such as environmental pollution</li> <li>Legal measures or obligations to pay damages due to revisions to environmental laws or regulations, or other circumstances</li> <li>Accelerated shift to low-carbon energy</li> <li>Mandatory or regulatory shift to bioplastic or biomass plastic in materials for eye drop bottles and other packages</li> <li>Decline in the supply of plant-based materials</li> <li>Floods or drought at major production bases due to changes in rainfall patterns, and resulting delays in or suspension of product supply</li> </ul>	<ul style="list-style-type: none"> <li>Adverse impacts on Santen's business performance</li> <li>Incurrence of countermeasure costs</li> <li>Increase in capital investment, procurement costs, etc.</li> </ul>	4	<ul style="list-style-type: none"> <li>Operates an environmental management system that not only complies with environmental laws and regulations but also meets higher in-house standards</li> <li>Formulated the Environmental Vision, set environmental targets, and implements the action plan based thereon (including promoting the use of biomass plastic as a material for eye drop bottles)</li> <li>Plans capital investments necessary to realize a low-carbon society, including investments in installing hydrogen boilers and hydrogen fuel storage facilities</li> </ul>

\*1: 1 Development and stable supply of socially significant products and services ("Happiness with Vision"); 2 Encouragement of an organizational culture that promotes value creation; 3 Strengthening governance, contributing to the realization of a fair and equal society; 4 Conservation of the global environment