

Changes in the Environment Surrounding Pharmaceutical Companies

Backcasting to identify future changes in the environment

The changes which are expected in the overall social environment include the advancement of the Fourth Industrial Revolution, demographic aging and the shrinking of the working population, and the relatively lower positioning of Japan and Europe due to the rise of China and other emerging countries.

In the pharmaceutical and healthcare industry to which the Sumitomo Dainippon Pharma Group belongs, further aging society and pressure on healthcare costs are expected to become major issues. In addition, the elucidation of disease mechanisms and the enhancement of preventive and interventional measures may lead to a shift from treatment to prevention and the discovery of new treatment methods for diseases that were previously untreatable.

In the area of pharmaceuticals, the options offered by new modalities such as antibody drugs, nucleic acid drugs, gene therapy, and regenerative medicine and cell therapy are expanding beyond the previous focus on small

molecule drugs. In addition, advances in the use of big data and AI across the value chain from drug discovery to marketing are expected to shorten development time, reduce costs, and enhance the probability of success.

In the future, it is expected that pharmaceuticals will continue to be the mainstay of treatment as the solution to unmet medical needs while non-pharmaceutical treatments and preventive medical care using digital technology will become more widely available.

We believe that due to these changes in the environment the pharmaceutical industry will face a Time for Change which will require the establishment of non-conventional new business models. Based on this belief, in April 2019, Sumitomo Dainippon Pharma formulated a new vision and the Mid-term Business Plan 2022 (fiscal 2018 to fiscal 2022) covering the five years starting in fiscal 2018 in order to contribute to solving social issues in a changing healthcare environment.

Anticipated changes by 2033

Society

- Acceleration of the 4th Industrial Revolution
- Aging society with fewer working population
- Rise of China and other emerging countries, relatively lower positioning of Japan and Europe
- Increasing corporate social responsibilities for contribution to global health



Healthcare/ Healthcare System

- Further aging society
- Higher pressure on healthcare costs
- More disease-prevention measures available and more diseases treatable
- Realization of new modalities such as regenerative medicine
- Greater use of big data and AI technologies



Healthcare Industry

Solution to unmet medical needs

- Pharmaceutical products remain at the core of solutions
- Digital technologies become available
- Preventive medical care becomes available



Opportunities and Risks

Identifying and responding to opportunities and risks in the value chain

Sumitomo Dainippon Pharma recognizes opportunities and risks in the value chain, which includes research and development, production and quality control, sales, marketing, corporate regulatory compliance & quality assurance and medical science, and takes measures to reduce risks, including for M&As and alliances. The direction of our responses for each area is as below.

→ Please see page 95 for details on the significant risks that could negatively impact the operating results, cash flow and financial position of Sumitomo Dainippon Pharma Group.
 → Please see page 169 for details on our value chain initiatives

● Opportunities ▲ Risks ■ Direction of responses

<p>Research and development</p>	<ul style="list-style-type: none"> ● There are high unmet medical needs in the three focus areas (psychiatry & neurology, oncology, and regenerative medicine/cell therapy) with significant impact on healthy life expectancy ● Open innovation with academia and biotech companies is gaining momentum. ● Support from regulatory authorities, public institutions, governments and others can be actively utilized. ▲ The focus areas of psychiatry & neurology and oncology are areas with a higher degree of uncertainty and difficulty in research and development. As regenerative medicine/cell therapy is a new field, the rules on regulatory approval and drug price listing are not completely in place. ▲ If clinical development fails, there are significant losses due to soaring research and development expenses. ▲ Non-pharmaceutical disease prevention and treatment methods are emerging (which is an opportunity for Frontier business). ■ We will expand our pipeline by leveraging our competitive technology and know-how and focusing on research and development in our three focus research areas. ■ We will establish a strategic development plan under our global development framework to implement efficient clinical development. ■ We will manage our R&D portfolio appropriately by reviewing research and development policy as is appropriate to match the timing of development stage transitions.
<p>Production and quality control</p>	<ul style="list-style-type: none"> ● We have built a stable supply structure by strengthening our global supply chains in collaboration with partners in Japan and overseas. ▲ The stable supply of products can be impacted by supply chain disruptions caused by natural disasters, such as a major earthquake or flooding, unforeseen accidents, or pandemics. ▲ Product quality issues can lead to product recalls, administrative penalties, and loss of social trust. ■ To ensure stable and safe procurement, we use multiple suppliers and consider alternative products and stockpiling. We secure safe inventory of products based on risk. ■ We use audits of our suppliers to check on quality, the environment, and safety, and to request improvements. ■ We have established a global quality assurance system which complies with the laws and regulations of each country. ■ We are making efforts to prevent the occurrence of counterfeit pharmaceuticals.
<p>Sales and marketing</p>	<ul style="list-style-type: none"> ● Unmet medical needs are increasing due to the aging of the population and responses to rare diseases. ● Treatment opportunities are growing to meet the need for early detection and prevention. ▲ There is a global policy trend to control drug prices to reduce healthcare costs. ▲ Changes in the competitive environment, such as the emergence of major competing products, could lead to delays in market penetration and decrease in revenue. ■ We will expand our pipeline to enable contribution to revenue at an early stage. ■ We will commercialize healthcare solutions that provide new value to society with a focus on areas where synergies with our pharmaceutical business are expected.
<p>Corporate Regulatory Compliance & Quality Assurance / Medical Science</p>	<ul style="list-style-type: none"> ● We can identify unmet medical needs by collecting information from patients, their families, and healthcare professionals. ● Global standardization of pharmaceutical regulations and quality assurance is making progress. ● There is increasing use of real world data and digital technology. ▲ There can be unexpected adverse reactions after a product is launched. ▲ There is an increasingly high level of management due to the diversifying supply chain. ▲ The demands of patients and medical institutions are becoming more sophisticated. ▲ The level of evidence for medical science information is becoming more diverse and advanced. ■ We evaluate safety information collected from Japan and overseas through centralized global database management. ■ We will plan the necessary measures to ensure the safety and proper use of pharmaceuticals, and implement safety measures in a timely manner. ■ We will create and disseminate information of an advanced scientific level to meet needs.
<p>M&A and alliance</p>	<ul style="list-style-type: none"> ● We can maximize profit and reduce business risk by partnering on a global basis. ● We can acquire development pipeline leveraging our solid marketing base. ▲ The acquired development pipeline products may be delayed or terminated. ▲ Acquired pipeline products may fall short of revenue contribution forecasts after launch. ■ Through strategic investment, we will acquire pipeline in late-stage development which can be expected to contribute to early revenue generation. ■ We will improve profitability by selling products that have reached loss of exclusivity and R&D assets.