Value Chain Initiatives

Research

We are focusing on three research areas (Psychiatry & Neurology, Oncology, Regenerative Medicine/Cell Therapy), while also researching infectious diseases.

- Basic research (2–3 years): We discover and create new compounds that will be the starting point for medicines.
- Non-clinical studies (3–5 years): We examine the pharmacological activity and toxicity of candidate compounds for medicines using animals and cultured cells
- We make extensive use of cutting-edge technologies that have been developed by ourselves or obtained from academia or biotech companies.

Clinical Development

Based on our global development organization, we aim to obtain the early approval by formulating strategic clinical development plans and conducting clinical development effectively.

- Clinical studies (3–7 years): Clinical studies for obtaining approval are divided into three phases[*1] and are conducted in clinical sites such as hospitals with the enrollment of healthy volunteers and patients after obtaining their informed consent.
- In parallel with clinical studies, we design products and develop processes to make pharmaceutical products that are easy to use.
- After confirming the efficacy, safety, and quality of a drug through various studies, we submit new drug applications to the Ministry of Health, Labor and Welfare for approval.

Production and Quality Control

We provide a stable supply of products under strict quality controls.

- After obtaining approval as a pharmaceutical product, we consistently produce high quality drugs under our global supply chain system that covers procurement of raw materials through to distribution under strict quality controls.
- We provide medical institutions and dispensing pharmacies all over Japan with pharmaceuticals.

➡ **Please see the following page for more information.**
Corporate Regulatory Compliance and Quality Assurance
Supply Chain

Research → **Clinical Development** → **Obtaining Approval** → **Production and Quality Control**

Corporate Regulatory Compliance & Quality Assurance / Medical Science

M&A and Alliance

Contribution to Societies / Environment

Corporate Regulatory Compliance & Quality Assurance

We assure the quality of our products and information at a global level, from the development stage through to post-marketing stage.

- We have established a quality assurance system that delivers global "A-N-SHI-N[*3]."
- We conduct integrated management of safety information, including adverse reactions, from the development stage (clinical studies) to the post-marketing stage and engage in proactive safety measures and provision of information.

➡ **Please see the following page for more information.**
Corporate Regulatory Compliance and Quality Assurance

Medical Science

We create, provide, and disseminate high-level information that is based on robust scientific evidence and that meets medical needs.

- We build up and disseminate evidence to satisfy unmet medical needs of healthcare professionals and patients.
- We respond to inquiries on the quality, efficacy, and safety of our products from patients, their families, and healthcare professionals.
- We create materials to ensure the proper usage of our products and review information and materials meant for external use.

➡ **Please see the following page for more information.**
Medical Science

M&A and Alliance

In the interest of expanding the development pipeline, Sumitomo Pharma is stepping up M&A, in-licensing, and alliance making, while also promoting alliances with outside research institutions.

- We actively promote strategic investment in acquisitions and in-licensing.
- For in-licensing, we consider a broad range of assets and alliances in our focus areas, with a priority on late-stage development assets and approved products.
- We enter into research alliances with research institutions that include universities in Japan and overseas, as well as biotech companies with innovative technologies
- We engage in an open innovation activity called PRISM through which we call for original ideas and conduct joint research to match our drug discovery research needs.

Sales and Marketing

We engage in activities tailored to the region centered on Japan, North America, and China.

- Through an information provision system capable of adapting to market changes, we provide healthcare professionals with information on proper use of pharmaceutical products.

Innovation today, healthier tomorrows

Value Delivered to Society

1. By continually creating solutions, primarily innovative pharmaceutical products, we not only treat patients, but also contribute to improving the quality of life (QOL) for patients and their families.
2. In addition to a stable supply of high quality pharmaceutical products, we provide information for the proper use of pharmaceutical products and the correct understanding of diseases to healthcare professionals, patients and their families in an appropriate manner.
3. We contribute to scientific advancement by elucidating disease mechanisms and developing new modalities such as regenerative medicine/cell therapy based on our research and development activities, and open up new possibilities for prevention and treatment.

Contribution to Societies

Sumitomo Pharma is working on offering solutions to problems in society, by listening to expectations and requests, and reflecting them in our business operations and social contribution activities.

- We promote R&D activities through industry-academia collaboration in infectious diseases and vaccines such as malaria.
- We support the development of healthcare infrastructure in developing countries such as educating healthcare professionals.
- We strive to further improve the disease-related awareness of patients, their families, and society.
- We conduct community contribution activities such as those to support the development of the next generation, and social contributions and donations.

Environment

Sumitomo Pharma is aware of its responsibility for its own environmental impact and is working to reduce environmental impact across all business activities.

- We implement initiatives to reduce our greenhouse gas (GHG) emissions to contribute to the building of a low-carbon society.
- We work to effectively use water resources and reduce waste.
- We promote dialogue with stakeholders with the proactive disclosure of environmental information.
- We implement forest conservation activities contributing to the preservation of biodiversity.

*1 Phase 1 study: testing to confirm safety and pharmacokinetics among a small number of healthy people;
Phase 2 study: testing to confirm effective and safe dose and method of administration, etc. among a small number of patients;
Phase 3 study: testing to confirm efficacy and safety among a large number of patients.

*2 Cashpoint: We sell pharmaceutical products to wholesalers, delivering the products to medical institutions and health insurance pharmacies through wholesalers which are then prescribed to patients. The method for determining the official prices for ethical pharmaceuticals (drug prices) varies according to the country.
Please see page 115 for details of basic knowledge of pharmaceuticals

*3 A-N-SHI-N: Trustworthiness, reliability, peace of mind, making people feel reassured and safe.