O Pharmaceutical business

Overview

JT is committed to the research and development of world-class, innovative drugs.

We operate the pharmaceutical business based on our Purpose, "Respecting science, technology and people, we will contribute to patients' lives."

As this business has a direct impact on human health and life, we not only strictly comply with all laws, regulations, and industry standards, but are also guided by a strong sense of ethics and responsibility. This is particularly the case in areas such as clinical trials and promoting drugs, as well as animal experiments and managing chemical substances.

JT concentrates on R&D, while Torii Pharmaceutical Co., Ltd. is in charge of sales and promotion in the Japanese domestic market.

Note: Regarding manufacturing, we outsource the entire process of manufacturing operations to contracted factories. Outside of Japan, we do not have a sales function, but we do license drugs to other pharmaceutical manufacturers.

Our pharmaceutical business value chain*



* This diagram represents the value chain of products developed by JT, and sold and promoted by Torii Pharmaceutical.

Pharmaceutical business sustainability strategy

We operate the pharmaceutical business based on our Purpose, "Respecting science, technology and people, we will contribute to patients' lives." In 2019, we selected the three focus areas below and set five specific targets for these focus areas.

Focus areas	Aspirational goals
Products and services	We will create innovative, original drugs to support patients in the shortest time possible.
People	We will strive to nurture talent development which enables us to create first-in- class (FIC) drugs.
Product safety and responsibility	We will strictly comply with all relevant laws, regulations, and industry standards in order to deliver safe drugs to patients.

Sustainability strategy of pharmaceutical business



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Our pharmaceutical business is working towards five specific targets in order to meet <u>the JT Group sustainability strategy</u>.

Respecting human rights

Investing in people

Improving our social impact

Environment

Pharmaceuticals and sustainability

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Pharmaceuticals andsustainability

Educating employees

Ethical integrity Quality assurance Promotion of drugs Transparen v cy

Educating employees

We strictly adhere to specific processes to ensure that our pharmaceutical business activities are always carried out in a responsible and appropriate way. We provide e-learning to help employees understand the importance of drug safety and quality assurance. All of the employees in our pharmaceutical business complete a mandatory e-learning course every year.



Employees based at JT's Central Pharmaceutical Research Institute regularly attend educational programs in areas such as animal experiments, the ethics of research on human tissue samples, managing chemical substances, and environmental management. This helps to keep their skills and knowledge up-to-date.

R&D that ensures ethical integrity

Our research activities are carried out in an ethical manner and comply with all relevant laws, regulations, and industry standards.

We have established in-house regulations on animal experiments based on government legislation. Our Institutional Animal Care and Use Committee ensures that we follow the '3R' concept: Replacing laboratory animals with other research materials where possible; Reducing the number of animals used; and Refining experiments to prevent animals from suffering unnecessary pain and distress. We carry out periodic in-house inspections and assessments to ensure that we comply with regulations. Our practices are accredited by the Japan Pharmaceutical Information Center.

When utilizing human tissue samples, our Ethical Review Committee, which follows the relevant Japanese guidelines and consists of both internal and external members, examines the ethical justification and scientific validity of the research.

We have built a chemical management system that manages every process centrally, from the moment we take delivery of the chemicals through to their storage, use, and eventual disposal. This system allows us to manage the quantity of chemical substances and adhere to the latest regulatory and safety information. Our employees undergo regular training on chemical safety risks so that they know how to handle chemicals in an appropriate manner.

Torii Pharmaceutical separates chemicals into categories requiring different levels of management, and has specific rules and procedures according to the characteristics and safety risks of each category of chemicals.

We publish <u>quarterly clinical development status updates</u> on our website. In 2022, we spent 29.8 billion Yen on our R&D activities.

Quality assurance in the production of pharmaceutical products



We have developed our own guidelines on how to conduct annual inspections to ensure that our production methods fully comply with government recommendations. We started annual inspections in accordance with these guidelines in 2017. Since 2018, we have been operating inspections at all of our contracted factories.

Responsible promotion of drugs

We have our own standard on the ethical promotion of prescription drugs, based on the guidelines on sales information provision activities by the Ministry of Health, Labour and Welfare.

Medical Representatives of our subsidiary company Torii Pharmaceutical Co., Ltd. provide and

gather information on pharmaceutical drugs to/from medical professionals appropriately, and regularly participate in training programs to ensure adherence to these guidelines. Through internal communication, we provide relevant and detailed information to our Medical Representatives to keep them up to date with the latest guidelines. Furthermore, after completing their initial training, all Medical Representatives take a mandatory e-learning course once a month.

We also conduct training sessions, which include case studies of violations that have occurred in Japan and important points to consider when providing lectures for medical professionals.

Transparency of partnerships

In order to develop more effective drugs, we build partnerships with research institutes, universities, and medical institutions. When we make financial contributions to our partners, we strive to ensure transparency by disclosing these payments on our website.

Case study

Case study

For the Patients Project

We have an internal educational activity to foster employees' ethical awareness and sense of responsibility towards saving patients.

We offer this program continuously, both internally and externally, by engaging in dialogue with medical experts. Every year, around 10 employees participate in this program as a facilitator and learn more about patients' medical needs. Their knowledge and findings are then shared across our business operations through reporting sessions and/or internal communication.

Case study

Patient input informs clinical development - patient-centricity^{*1}

As part of our ongoing clinical development efforts, and in the spirit of continuously improving the patient experience, we gathered input from patients in the form of a 'patient's voice' program.

(1) Interactive communications

We conducted a satisfaction survey for patients and the CRC (Clinical Research Coordinator) with the aim of creating an informed consent form template to ensure that participants would fully understand the content of the clinical trial^{*2}. We then reported the survey results at the 22nd Conference on CRC and Clinical Trials 2022. We took the opportunity to gather helpful feedback from medical and pharmaceutical experts attending the conference.

(2) Key developments in 2022

- We encouraged our department to adopt a patient-centric approach and shared related information internally.
- We send a thank-you letter to clinical trial participants.
- We set up opportunities for patients from our target groups to tell us about their difficulties with disease and what they expect from the new drugs.

We want our clinical trials to be developed in line with patient feedback; this will make it easier and more satisfactory for patients who are interested in clinical trials to confidently take part.

*1 Read more about patient-centricity (patient-focused drug development) on the FDA website.

*2 Tests performed on humans at the final stage of pharmaceutical development in order to collect and/or assess data concerning the results of a clinical study, including data on efficacy and safety. Human clinical trials are mandatory for "candidate drugs" to be approved by governments.

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