Pharmaceuticals

Overview

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

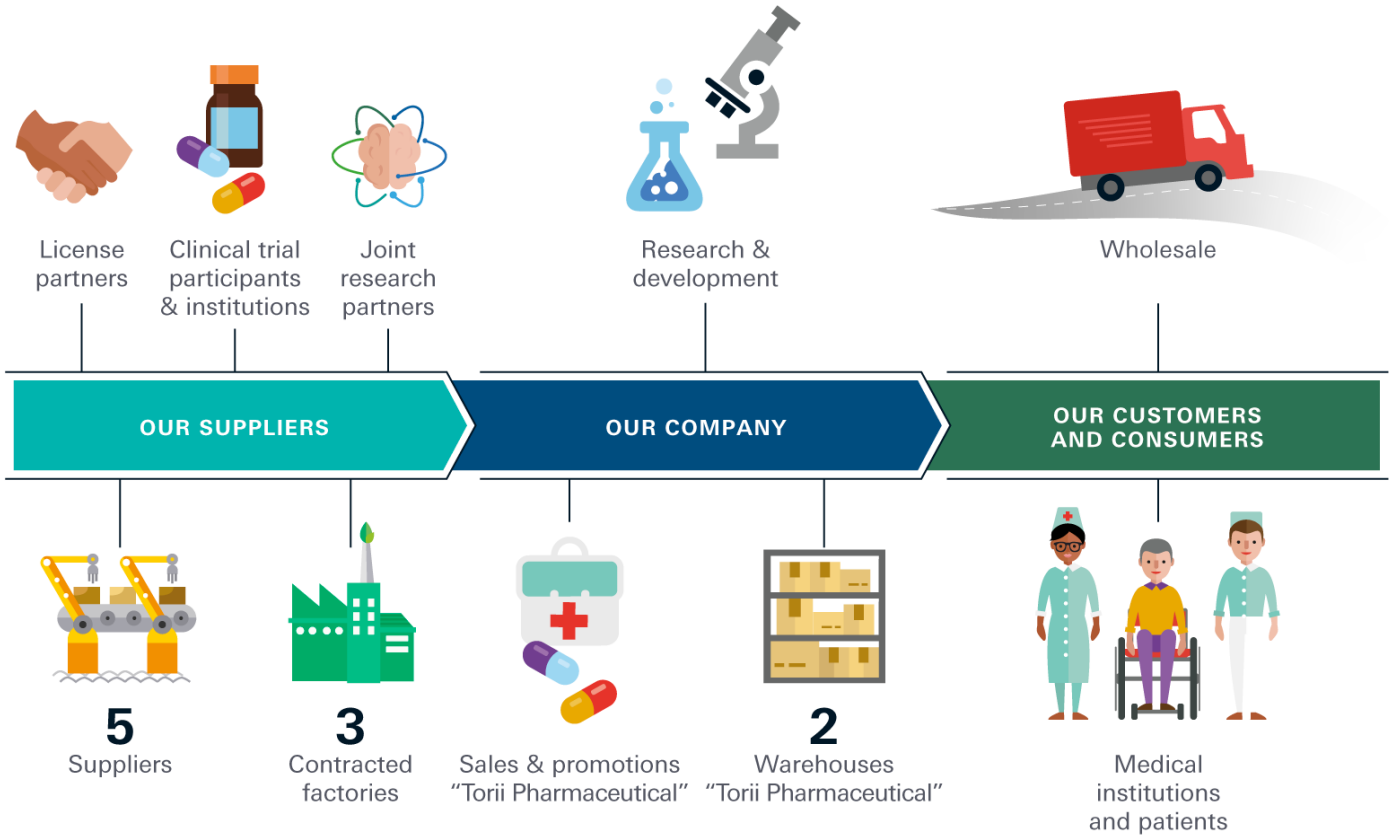
Our pharmaceutical business aims to create innovative, original drugs to support patients in the shortest time possible.

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 manufacturing, sales, and promotion in the Japanese domestic market. Outside of Japan, we do not have a sales function, but we do license drugs to other pharmaceutical manufacturers.

※Torii Pharmaceutical Co., Ltd. stopped manufacturing pharmaceutical products in its own factory in 2020, and now outsources these manufacturing operations to contracted factories.

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

Our pharmaceutical business aims to create innovative, original drugs to support patients in the shortest time possible. We are committed to the research and development of world-class, innovative drugs.

In view of this mission, in 2019, we selected the three focus areas below and set five specific targets for these focus areas. This is the first time we are reporting on our progress towards achieving these targets.

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

Strategic focus areas	Aspirational goals	Targets	Progress	SDGs
Products and services	**We will create innovative, original drugs to support patients in the shortest time possible.**	**Engaging in R&D activities** We will continue our efforts and investments into research and development activities of innovative drugs in specific therapeutic areas.	In June 2020, we launched CORECTIM® Ointment 0.5%. We then launched ENAROY® Tablets 2 mg and 4 mg in December 2020. Throughout the year, we spent 25.2 billion yen on our research and development activities.	
People	**We will strive to nurture talent development which enables us to create first-in-class (FIC) drugs.**	**Fostering ethical awareness** In order to develop talent and foster employees' ethical awareness and sense of responsibility towards saving patients, we will continue to learn more about patients' needs by engaging in dialogue with medical experts through our internal educational activity "For the Patients Project."	In 2020, five employees took part in our "For the Patients Project" as facilitators. They interviewed medical representatives and organized an internal online ethical awareness event.	
		Community investment* Between 2015 and 2030 we will invest US$600 million to help make communities inclusive and resilient, with our employees contributing 300,000 volunteering hours.	Since 2015, we have invested US$349 million in our communities and employees volunteered 137,882 hours on company time.	
Product safety and responsibility	**We will strictly comply with all relevant laws, regulations, and industry standards in order to deliver safe drugs to patients.**	**Responsible promotion of drugs** We will conduct, among others, regular training programs for our medical representatives in order to provide medical professionals with latest, appropriate information on pharmaceutical products.	After their initial training, all of our medical representatives take a mandatory e-learning course once a month to keep their skills and knowledge up-to-date.	
		Greenhouse gas emissions We will reduce greenhouse gas emissions from our own operations by 31%, between 2015 and 2030.	Since 2015, we have reduced greenhouse gas emissions from our own operations by 9.0%.	

* Target for Community investment is a Group-wide target.

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

Respecting human rights

Investing in people

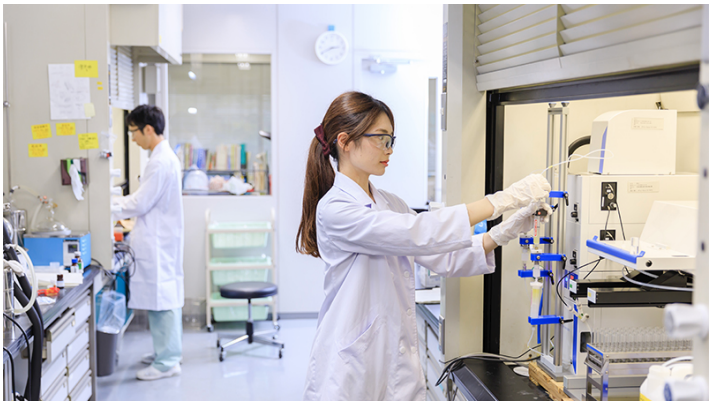
Improving our social impact

Environment

Pharmaceuticals and sustainability

The mission of our pharmaceutical business is to create innovative, original drugs to support patients in the shortest time possible.

Read more >



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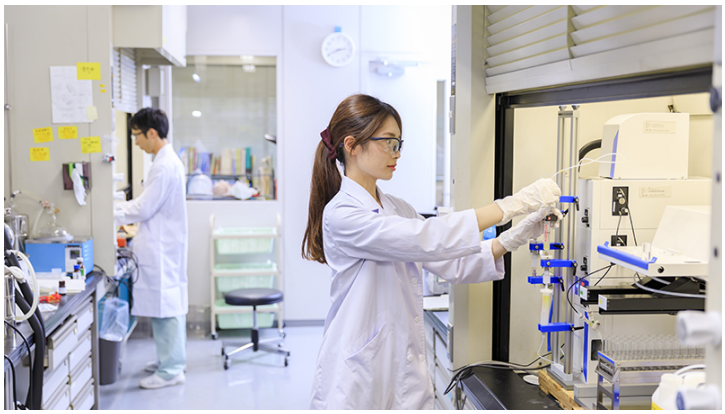
Pharmaceuticals and sustainability

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 ethics, animal experiments, 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 Health Sciences Foundation.

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.

Our chemical management system covers every aspect of the chemical handling process, from the moment we take delivery of the chemicals, through to their storage, use, and eventual disposal. It also provides employees with vital information, such as how much remains of the chemical, and the most up-to-date safety data sheet for each substance.

Employees are regularly made aware of chemical safety risks. 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 quarterly clinical development status updates on our website. In 2020, we spent 25.2 billion Yen on our R&D activities.

Quality assurance of pharmaceutical products production

We have developed our own guidelines on how to conduct annual inspections to ensure that our production methods fully comply with government recommendations. We began implementing these inspections in selected factories in 2017 and no issues were identified.

Since 2018, we have been steadily expanding the scope and now it covers 100% of our contracted factories. We will continue to operate these guidelines.

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 studies

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

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. Read more on our progress in 2020:

(1) The announcement of our patient’s satisfaction survey
We conducted a satisfaction survey[*1] for patients who agreed to participate in our clinical drug trials[*2] in 2019. We then reported the survey results at the 20th Conference on CRC and Clinical Trials 2020. This allowed us to gather a lot of feedback from medical and pharmaceutical experts who were at the conference.

*1 In 2019, we carried out a satisfaction survey among patients who had participated in our clinical drug trials. Approximately 150 patients agreed to take part in the survey.

*2 Clinical drug trials
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.

(2) Establishment of a project team in clinical development department
When it comes to clinical trials, we understand the importance listening and responding to patients’ questions and concerns. With this in mind, we established a project team in our clinical development department, which is responsible for all clinical drug trials in our pharmaceutical business. The new team will play a key role in developing and implementing these trials with a focus on patient feedback and the overall patient experience.

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.