# Pharmaceutical business

## Overview

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

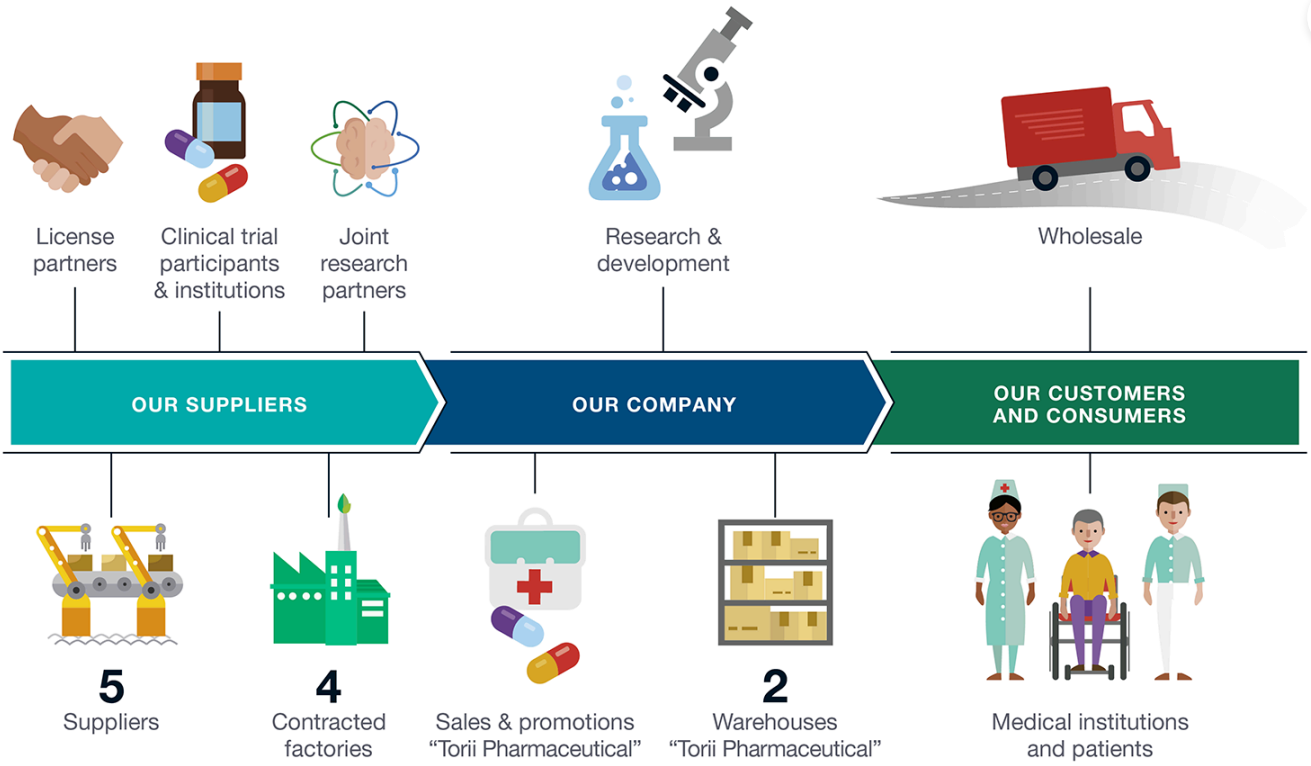
As this business has a direct impact on human health and life, we not only strictly comply with all laws, regulations, and industry standards, but are also guided by a strong sense of ethics and responsibility. This is particularly the case in areas such as clinical trials and promoting drugs, as well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

We operate our pharmaceutical business based on our business Purpose , “Respecting science, technology and people, we will contribute to patients’ lives.”

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.

# Sustainability of the Pharmaceutical Business

We selected five JT Group Materiality topics as priority issues for the Group to work on above all else. Based on the JT Group Materiality regime we set JT Group Sustainability Targets as specific goals to achieve and initiatives to undertake. The following are examples of this special focus in the pharmaceutical business.

| Materiality | Target items | Targets |
|---|---|---|
| **Value creation that exceeds consumer expectations** | Create first-in-class drugs | We will continue our efforts and investments in R&D activities for innovative drugs in specific therapeutic areas. |
| **Living with the planet** | Emissions reduction | By 2030, we commit to reduce Scope 1 and 2 GHG emissions by 47% in line with a 1.5°C reduction pathway against a 2019 base year. Along the way we help the JT Group achieve its goal of net-zero GHG emissions across the entire value chain. |
| **Investing in our people and supporting their growth** | Diversity, equity & inclusion | We promote the creation of an organizational culture where diverse talents can thrive, contributing to the achievement of JT Group's target of increasing the ratio of female managers. |
| **Good governance** | Foster ethical awareness | To cultivate personnel with a sense of mission and ethical awareness aimed at 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." |
| | Provide information responsibly | We continue training our medical representatives to provide medical professionals with latest, appropriate information on pharmaceutical products. |

# Progress with Sustainability Initiatives in the Pharmaceutical Business to 2023

## Sustainability strategy of pharmaceutical business

| Four 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**<br>We will continue our efforts and investments into research and development activities of innovative drugs in specific therapeutic areas. | In June 2023, Shenzhen Salubris Pharmaceuticals Co., Ltd., our license partner, received regulatory approval of enarodustat in China and in July 2023, LEO Pharma A/S, our license partner, has submitted a marketing authorization application for delgocitinib in Europe. In September 2023, we have filed a manufacturing and marketing approval application in Japan for in-licensed JTE-061 (tapinarof).<br>In 2023, we spent 32.2 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**<br>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." | We provide opportunities for our employees to consider drugs needed on the healthcare front lines from the patient standpoint. Recently, we carried out interviews with health professionals and representatives of healthcare corporations and children's hospices, and also organized dementia experiential sessions using VR internally, led by the 11 employees who took part in our "For the Patients Project" as facilitators. | |
| | | **Community Investment***<br>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 invested USD 500 million in our communities and employees volunteered 218,070 hours on company time.<br>2015 — 2023: 218,070 — 2030: 300,000<br>Hours spent volunteering | |
| **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**<br>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 an e-learning course once a month to keep their skills and knowledge up-to-date. A recent training subject was designed to assist in understanding and complying with laws and industry rules, such as Guidelines for Sales Information Provision Activities for Ethical Drugs and JPMA Promotion Code for Prescription Drugs. As of December 31, 2023, a total of 311 employees and contracted medical representatives have taken this training. | |
| | | **Greenhouse Gas Emissions***<br>By 2030, we will reduce emissions from our own operations (Scope1 & 2) by 47% and emissions associated with purchased goods and services (Scope3 Category1) by 28%, against a 2019 base year. | Since 2019, we have reduced Greenhouse Gas emissions from our own operations (Scope 1 and 2) by 21%, while emissions associated with purchased goods and services (Scope 3 Category 1) increased by 3%[#].<br>2019 — 2023: -21% — 2030: -47%<br>Scope 1 and 2 GHG emissions<br>2023: -3% — 2019 — 2030: -28%<br>Scope 3 GHG emissions related to materials procurement and services<br>[#] The increase in the tobacco business, the Group's leading GHG emitter, was mainly due to temporary procurement increases from Tanzania and other countries that will require more time to shift to renewable energy sources in the leaf-drying process, as a result of business scale expansion and climatic influences.<br>To shift to renewable energy sources, we have been putting effort into planting in these countries, with projected positive effects in the future. By following through on initiatives like this, we project achieving carbon-neutral operations by 2030 and net-zero emissions by 2050. | |

* Target for Community Investment and Greenhouse Gas Emission are Group-wide targets.

# Pharmaceuticals and sustainability

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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 training programs in areas including animal experiment, the ethics of research on human-derived tissue samples and information 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.

For research using human-derived tissue samples and information our Research Ethic Review Committee, which follows the Japanese government guideline “Ethical Guidelines for Medical and Health Research Involving Human Subjects” 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 quarterly clinical development status updates on our website. We invested 32.2 billion yen for research and development in 2023.

## 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

We have undertaken an initiative to incorporate patient opinions in pharmaceuticals development. (Major efforts in 2023)

- Calling this approach “patient centricity,” we continuously provide related information to employees to ensure they understand it.
- To communicate our appreciation to the participants in clinical trials*2, we send them thank-you letters.
- We are preparing a system to provide Patient Lay Summaries of the clinical results.

We will continue to incorporate patient opinions in the pharmaceuticals development process and work to make participation in clinical trials easier.

*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.