O Pharmaceuticals

Overview

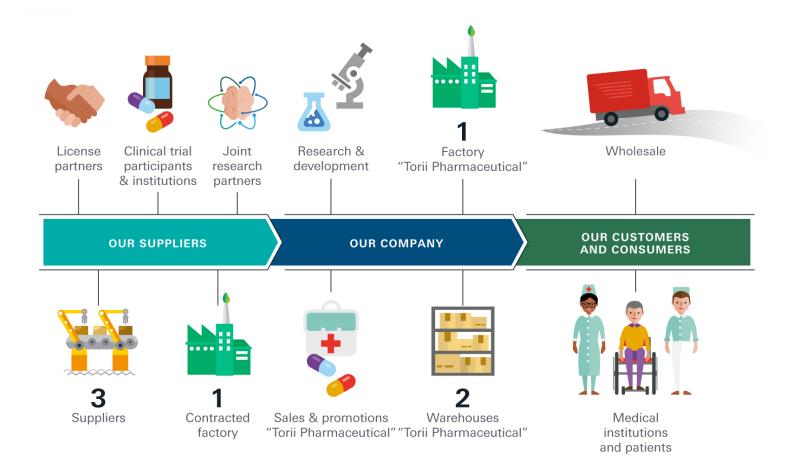
JT is committed to the research and development of world-class, innovative drugs.

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.

Our pharmaceutical business value chain*



* This diagram represents the value chain of products manufactured and/or developed by JT, and sold and promoted by Torii Pharmaceutical. In 2020, the JT Group will stop manufacturing operations of its pharmaceutical products in its own facilities and outsource all of them to contracted factories.

Pharmaceutical business sustainability strategy

Throughout 2019, our pharmaceutical business held numerous discussions on sustainability and set out three focus areas. The mission of the pharmaceutical business is to create innovative, original drugs to support patients in the shortest time possible. In view of this mission, we have selected 'products and services' and 'product safety and responsibility' as our focus areas. As talent development of our employees is essential to first-in-class drug discovery, we have selected 'people' as our focus area. In total, we have set five specific targets for these pharmaceutical business focus areas.

These will provide a solid basis for measuring and benchmarking our sustainability performance, and support the sustainability of the JT Group. We will be updating our progress regularly, as we strive to contribute and fulfill our commitments that we have made to our stakeholders and to ourselves.



Pharmaceutical business sustainability strategy - Focus areas, aspirations and targets

Read more about the <u>JT Group sustainability strategy</u>.

Read more about our Group-wide initiatives in the Investing in people and Environment sections.

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

Ethical integrity Quality assurance ✓✓Of

Promotion of drugs Transparen 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 elearning 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 \Box , an external authority which lists all accredited facilities on its <u>website</u> \Box .

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 <u>quarterly clinical development status updates</u> on our website. In 2019, we spent 33.2 billion Yen in 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 own factories* and contracted factories. We will continue to operate these guidelines.

*In 2020, the JT Group will stop manufacturing operations of its pharmaceutical products in its own facilities and outsource all of them to 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, Labor and Welfare.

Medical Representatives (MRs) 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 MRs to keep them up to date with the latest promotional guidelines.

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 will then be 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, we gathered input from patients in the form of a 'patient's voice' program, and in the spirit of continuously improving the patient experience. We conducted a survey among patients who had participated in our clinical drug trials* to measure their satisfaction. In 2019, approximately 150 patients agreed to take part in the survey.

The survey consisted of a face-to-face interview and a questionnaire. The interview was designed to evaluate the patient experience and gauge how patients felt during the clinical trials. For example, we asked about the quality of guidance delivered at the beginning of the trial and about the usability of any patient tools they had used, e.g. informed consent form and patient reported outcomes. The questionnaire asked about their expectations of the medical experts in charge of the trials and what information they had needed or requested before the trial started.

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.

* Clinical 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.