



# OUR PHARMACEUTICAL BUSINESS

In our pharmaceutical business, we aim to deliver innovative drugs to patients safely, securely, and 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 codes, 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 testing and managing chemical substances.

While JT focuses on R&D, our pharmaceutical subsidiary, Torii Pharmaceutical, produces and promotes drugs in Japan. Outside Japan, we do not have a sales function, but we do license drugs to other pharmaceutical manufacturers.

In 2018, we started to develop a sustainability strategy for our pharmaceutical business.

## 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.



## 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. In 2018, all of the approximately 800 employees in our pharmaceutical business completed the course.

Employees based at JT's Central Pharmaceutical Research Institute regularly attend educational programs in areas such as ethics, animal testing, managing chemical substances, and environmental management. This helps keep their skills and knowledge up to date.

## Ensuring 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 testing, 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 tests so that animals do not suffer unnecessary pain and distress. We carry out periodic in-house inspections and assessments to ensure that we comply with regulations. Our animal-testing practices are certified by the Japan Health Sciences Foundation, an external authority.

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 2018, we spent 37 billion Yen on R&D.



## Quality assurance 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. Since 2017, for our own factory and half of our contracted factories, we have been carrying out annual inspections that fully adhere to these guidelines, and there were no discrepancies in the annual inspections in 2017. In 2018, we started following our own annual inspection guidelines for the rest of our contracted factories as well.



## Transparency of contributions

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.

## Responsible promotion of drugs

Torii Pharmaceutical has its own code of practice on the ethical promotion of prescription drugs, based on the code of practice of the Japanese Pharmaceutical Manufacturers Association (JPMA). Medical Representatives (MRs) of Torii Pharmaceutical provide and gather information on drugs to/from healthcare professionals, and run monthly training programs to ensure adherence to this code. Through internal communications, 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 personnel.

