

Business

Pharmaceutical Business

● CSR Activities in the Pharmaceutical Business

With a Strong Sense of Ethics and Responsibility Involving Human Life, Contributing to Society



Noriaki Okubo

President, Pharmaceutical Business

There are still a great number of incurable diseases, and therein lies our raison d'être – to provide suffering patients with the drugs we developed. With this in mind, we are striving to fulfill our primary mission – developing world-class drugs that are unique and innovative.

The pharmaceutical business is subject to relevant laws and regulations as well as to detailed guidelines. We also have elaborate in-house regulations that set out operating procedures with the Operational Review and Business Assurance Division and the internal auditing team of the Pharmaceutical Division constituting a foolproof audit system. In addition to observing such procedures and regulations, we always need to be clear in our minds that what we are doing has a direct impact on human life. That is, we always need to have a strong sense of ethics and responsibility.

As an integral part of our CSR activities, therefore, we have been focusing on strict compliance with pharmaceutical laws and regulations and strict management of chemical substances. In FY 2007, for instance, we continued to improve the safety management system and fully comply with relevant laws and regulations while observing prescribed operating procedures. Accordingly, Torii Pharmaceutical Co., Ltd., which manufactures and distributes the JT Group's pharmaceuticals, places a premium on strict compliance with the Promotion Code and has a system in place to raise awareness of pharmaceutical issues among employees.

We feel a sense of pride and challenge in taking up the development of world-class innovative drugs as our corporate mission. Our goal is to have patients and medical professionals think that "We could not have done without JT's drugs."

CSR Promotion Plan for the Pharmaceutical Business

Development and offering of new drugs based on the highest safety standard, strong sense of responsibility and high ethical standard

- Strict compliance with pharmaceutical-related laws and regulations
 - Strengthening appropriate control of chemical substances
 - Strict compliance with Promotion Code
- Activities to raise awareness in the medical field

CSR Activities in the Pharmaceutical Business

◆ Developing and Offering New Drugs with the Highest Safety Standard, Strong Sense of Responsibility and High Ethical Standard

● Strict Compliance with Drug-related Laws and Regulations

A number of laws and regulations apply to new drug development, some of which include verification of the safety of drug candidate compounds at the preclinical stage and assurance of safety of trialists during clinical development. In addition to improving the system in compliance with related laws and regulations, JT controls the safety of its drugs through strict in-house audits to check if the prescribed operating procedures are appropriately followed.

In fact, the Helsinki Declaration, the Pharmaceutical Affairs Law and a ministerial ordinance (GCP) based on the law stipulate that the rights of research subjects to safeguard their integrity must always be respected when conducting clinical trials. Accordingly, an independent committee of experts such as outside physicians examines the ethical and scientific grounds of clinical trials and sees to it that subjects are briefed on and agree to them in writing and that subjects' privacy is protected. In addition, a division independent from clinical trials conducts in-house audits (GCP audits) to see if the operating procedures are appropriately followed – that is, compliance of clinical trials with GCP. In FY 2007, JT strictly abided by relevant laws and regulations as we did in the previous year.

At the same time, a variety of measures are in place to provide patients with drugs in an effective and safe manner, based on data for their efficacy and side effects.

● Strict Management of Chemical Substances

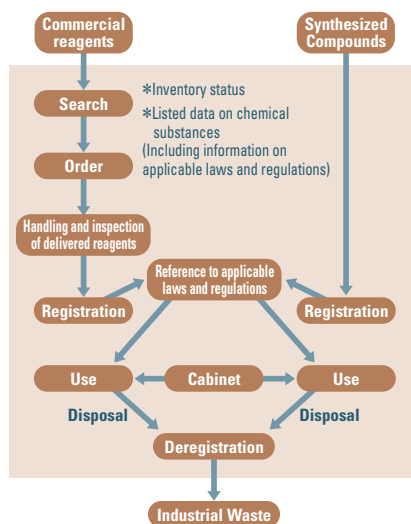
JT continues to comply with a variety of laws and regulations concerning the management of designated chemical

substances, with rigorous in-house regulations and systems in place to educate employees on safety management.

The Central Pharmaceutical Research Institute, which spearheads JT Group new drug development, is striving to improve its chemical substance management system. In FY 2007, for instance, the institute reviewed and strengthened the self-checking function of its laboratories at three locations.*

* Four laboratories in Takatsuki City (Osaka), the Pharmaceutical Frontier Research Laboratories (Yokohama City, Kanagawa) and the Toxicology Research Laboratories (Hadano City, Kanagawa).

Chemical Substance Management System (The Central Pharmaceutical Research Institute)



In accordance with relevant regulations and procedures, Torii Pharmaceutical Co., Ltd. manages chemical substances in a systematic manner, setting up management categories based on the characteristics of each chemical substance. In FY 2007, for instance, the company established risk assessment procedures recommended by the Industrial Safety and Health Law, surveyed the use of volatile organic compounds and adopted a system to manage chemical substances used for the production of investigational new drugs.

● Strict Compliance with the Promotion Code

Medical representatives (MRs) – who provide, collect and convey information

on pharmaceuticals – play a vital role in appropriate drug use. Meanwhile, the Japan Pharmaceutical Manufacturers Association (JPMA) sets forth the “JPMA Promotion Code for Prescription Drugs,” a code of conduct for pharmaceutical companies in promoting medical supplies and prescription drugs, thereby strictly prohibiting drug abuse.

Torii Pharmaceutical Co., Ltd., tasked with the JT Group's MR activities, is educating and training qualified MRs, given the nature of their duties, while holding study sessions and seminars to strictly comply with its code of conduct.

In FY 2007, the company held such seminars at 14 branch offices, with each branch having its own study sessions to raise awareness of MR activities and help MRs develop technical expertise.



At a seminar

◆ Awareness Raising Programs in the Medical Care Field

A variety of programs are in place to raise public awareness of the medical care. In particular, Torii Pharmaceutical Co., Ltd. disseminates health information through brochures, the Internet, and other media.



Health information is posed on the website

Brochure

Torii Pharmaceutical's website
URL www.torii.co.jp/

Services of the Customer Support Dept. (Torii Pharmaceutical Co., Ltd.)

The customer support dept. of the Torii Pharmaceutical Co., Ltd. answers all inquiries (primarily by telephone) from physicians, pharmacists, customers, JT's MRs, and others in a quick, accurate and detailed manner, acting as a liaison between customers and the field staff.

In particular, patient and medical expert opinions on products are always taken into account and immediately passed on to the relevant divisions.

The center staff, meanwhile, participate in study sessions to improve their skills. In addition, the MR Support System is in place to share information and ensure appropriate and speedy services for the benefit of customers. Inquiries from medical institutions are duly recorded and



passed on to the MRs in charge.

Inquiries are also handled on the website, with product information disseminated through the Internet and other means.



Yuko Kariya

General Manager, Customer Support Dept.
Torii Pharmaceutical Co., Ltd.

The customer support dept. handles inquiries from various sources such as patients (and their families), physicians, pharmacists and pharmaceutical dealers. When communicating with these people, our focus is on putting ourselves in the place of those on the other side of the line. While there are cases where we need to tell callers that this is what we can afford, we always see to it that we accommodate their requests as much as possible.

We continue to value the opinions of customers and convey their comments to the relevant divisions in an effort to improve our products.

Ethical Considerations to Animal Experiments

Animal experiments, an essential part of pharmaceutical development, play a vital role in determining the safety and efficacy of drugs. When conducting animal experiments, we always examine their scientific rationality, respect the lives of experimental animals and take into account the concept of animal welfare.

The Central Pharmaceutical Research Institute set in-house regulations for animal experiments in accordance with the Law of Humane Treatment and Management of Animals (Law 105, instituted in 1973 and revised in 2005) and its relevant guidelines (Notification 0601005, issued by the Ministry of Health, Labour and Welfare in 2006) to properly manage animal experiments and breed experimental animals. Specifically, the animal experiment committee is in place to examine and ensure that experiments are conducted in accordance with the 3R concepts*.

* 3R Concepts

Replacement: Where possible, opt for alternative test methods using no experimental animals

Reduction: Minimize the number of animals used for experiments

Refinement: Do not let experimental animals suffer unnecessary pain

Ethical Considerations to Human Genome / Gene Analysis

Likewise, the Ethics Review Committee on Human Genome /Gene Analysis is in place to examine the ethical and scientific validity of human genome and genetic sequencing research programs in accordance with the Ethical Guidelines Human Genome /Gene Analysis (Notification 1, issued by the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare and the Ministry of Economy, Trade and Industry in 2001, revised in 2004 and partially revised in 2005).