



Special Issue

Aiming to Be a Global Research-Driven Pharmaceutical Company that Truly Contributes to Patients

Mitsubishi Tanabe Pharma Corporation (MTPC) was established in October 2007 through the merger of Tanabe Seiyaku Co., Ltd., and Mitsubishi Pharma Corporation. Since this merger, rather than pursuing economies of scale our focus has been on seeking to take advantage of the two former companies' drug discovery technologies. This approach allows us to do our utmost to develop new pharmaceuticals that will assist in the earliest possible treatment of ailments from which patients suffer. Mitsubishi Tanabe Pharma seeks to continue doing its best for patients. This has always been the starting point of our business.

Drugs that Help with Information that Assists

● Pursuing R&D in Priority Fields

Mitsubishi Tanabe Pharma Corporation (MTPC) intends to maximize the expanded management resources made available through its merger to contribute to the health of people throughout the world by creating and supplying superior pharmaceuticals. The company has designated the metabolic and circulatory systems as priority R&D fields. Within these domains, we are placing the highest priority and concentrating management resources on diabetes and stroke patients. In diabetes, our research includes metabolic risks and complications arising from obesity and lipid disorder. We are studying strokes over the period from acute onset to recovery and maintenance, as we aim to create pharmaceuticals from the viewpoint of total care, from prevention to post-onset care.

● Providing Drugs that Help Society

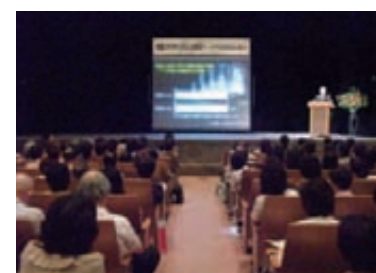
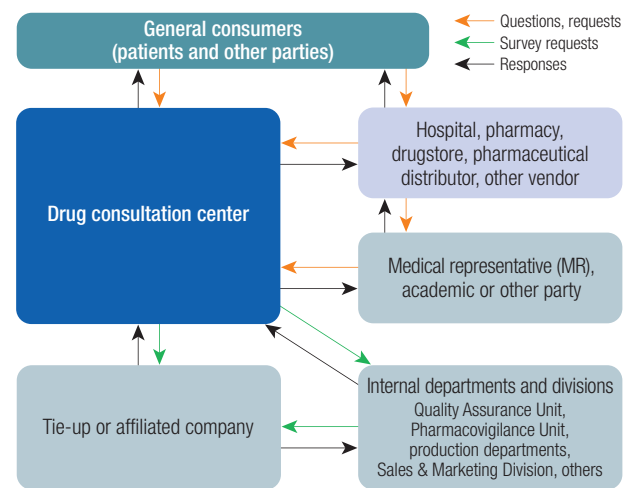
MTPC provides blood plasma derivatives, which are essential pharmaceuticals in clinical situations, as well as vaccines for disease prevention and various drugs with specific characteristics, such as mental and nervous system treatments and medical narcotics. We are developing the OTC pharmaceutical business, which helps provide safe medications. We also are making a full-fledged effort to enter the business of generic pharmaceuticals under the "reliable generics" concept. By extending and enhancing our operations in these ways, we aim to raise our level of contribution to medical care in Japan.

● Disseminating Information to Support the Appropriate Use of Drugs

To promote the appropriate use of pharmaceuticals, MTPC has established a Drug Consultation Center to communicate directly with patients; hospitals, dispensaries, insurance pharmacies and other medical institutions; as well as drugstores and distributors. This center provides information on various products, including data on the safety and efficacy of non-prescription drugs and quasi-drugs. Its aim

is to present accurate and easy-to-understand product information quickly and courteously. The center incorporates feedback that enables us to develop better products and provide information more appropriately.

Flow of Communications with Drug Consultation Centers



Courses for the General Public
We collaborated with a course sponsored by Nihon Keizai Shimbun, Inc., providing a variety of material to help educate members of the general public about disease and prevention.



Crohn Frontier Website



Ruimachi21.info

Mitsubishi Tanabe Pharma has established this website to provide people suffering from Crohn's disease, rheumatoid arthritis, strokes, sleep disorders, hemorrhoids and other complaints with information about symptoms, diagnoses and treatments. Specialists supervise information that is included on the website.

Drug Efficacy with a High Degree of Safety

● Ensuring Quality, Safety and Efficacy

To ensure that medical institutions and patients use pharmaceuticals with complete peace of mind, MTPC has created high-quality drug production and supply systems spanning the stages from raw material procurement through to production and distribution.

At the procurement stage, we perform acceptance testing on raw materials procured from Japan and overseas. At the production stage, we test manufactured drug substances and products and perform spot checks in accordance with pharmaceutical production management and Good Manufacturing Practice (GMP). We integrate the results of research conducted by our Chemistry Manufacturing and Control (CMC) Research Center into each manufacturing process, from drug substances to tablets and injections.

At the distribution and transportation stage, we maintain

careful control over warehouse temperatures and cleanliness. Our warehouse management systems allow product and shipping management by product type and lot number.

Pharmaceutical Reliability Assurance System



- 1 Good Laboratory Practice (GLP): standard for non-clinical testing related to pharmaceutical safety
- 2 Good Clinical Practice (GCP): standard for conducting clinical tests of pharmaceuticals
- 3 Good Quality Practice (GQP): quality management standard for pharmaceuticals, quasi-drugs, cosmetics and medical equipment
- 4 Good Vigilance Practice (GVP): safety standard for pharmaceuticals, quasi-drugs, cosmetics and medical equipment following manufacturing and sale

Focus Initiatives in the Area of Blood Plasma Derivatives

Plasma derivatives and blood transfusion products are pharmaceuticals made from the blood of well-intentioned donations. Plasma derivatives, which contain various proteins purified from liquid components separated from blood, come in various types¹. These are indispensable pharmaceuticals for patients because each has a vital function that cannot be substituted by other substances.

However, products manufactured from human blood have the potential to transmit viruses, and the risk of infectious disease cannot be eliminated completely. Therefore, careful consideration of safety is required when manufacturing, supplying and using such products.

Upon reflection of the health damage caused by the introduction of human immunodeficiency virus (HIV) and the hepatitis C virus (HCV) through its plasma derivatives in the past, MTPC established the Benesis Corporation in October 2002 to ensure the stable supply of safer plasma derivatives.

In accordance with the Act on Securing a Stable Supply of Safe Blood Products (Blood Law) enacted in 2003, Benesis strives to fulfill its mission as a licensed marketer providing a "stable and appropriate supply of safe blood products, developing technology, and collecting and providing information to improve safety" in strict compliance with the Blood Law.

One of these initiatives involves the quality risk management system that Benesis employs to centrally manage quality risks related to its products. This system evaluates quality-related risks on an ongoing basis at a variety of stages, from research and development through to sales, and promotes various countermeasures to reduce these risks.

Furthermore, Benesis retains MRs specializing in plasma derivatives to promptly provide medical institutions and patients with the appropriate information.

In addition, MTPC has established the Quality and Safety Coordination Council to strengthen its communications with Benesis. This channel serves as a backup to ensure that safety is the top operational priority.

MTPC and Benesis maintain more stringent standards for plasma derivatives than are required for typical pharmaceuticals under the Blood Law and the Pharmaceutical Affairs Act. In the future, we aim to raise this level of safety even further. In addition, we are working to research and develop new plasma derivatives, as we seek to make further improvements to patients' quality of life.

¹ Albumin products are used when the patient has suffered trauma including burns or shock. Immunoglobulin products are utilized when the patient's immune function has declined, for the prevention and treatment of serious infectious diseases, the treatment of acute phase Kawasaki disease and autoimmune disorders. Blood coagulation factor products are indispensable for the treatment of blood coagulation abnormalities and for sustaining life.





Strengthening CSR

Compliance

To ensure that its business is conducted in a sound manner and based on the highest sense of ethics and spirit of compliance, the Mitsubishi Tanabe Pharma Corporation (MTPC) Group has created a compliance promotion system centered on the Compliance Promotion Committee.

The Group conducted the following activities in fiscal 2008.

(1) Compliance Promotion Committee

The committee convened two regular and one special meeting, reported its promotion activities and deliberated its activity plans and important topics.

(2) Liaison meetings for people in charge of compliance promotion

Liaison meetings were held twice for personnel in charge of compliance promotion in the workplace, offering opportunities to provide necessary information related to compliance promotion and conduct training. (Meetings were held in April and December, with a total of 224 people participating. An outside instructor was invited to conduct training at the December meeting.)

(3) Compliance training

Conducted according to an annual plan, by level and content.

(4) Surveys on the status of compliance promotion

We regularly conduct surveys to confirm the status of compliance promotion, and reflect survey results into future promotion activities. A survey was conducted targeting all Group employees in Japan, including contract staff. (Respondents: 6,289, response rate: 71.5%)

(5) Human rights awareness initiatives

A meeting of the Human Rights Promotion Committee was held, chaired by the president, to deliberate the planning and promotion of companywide measures. In addition to conducting human rights awareness training, the committee solicited human rights awareness slogans.

Risk Management

In accordance with the MTPC Group's Risk Management Policy, the president chairs the Risk Management Committee, which meets regularly (twice per year) and on additional occasions, if necessary.

The Risk Management Committee periodically monitors Group companies in Japan and overseas, identifies the risks faced by individual divisions and companies and conducts spot checks on that basis. At the same time, the committee responds to thematic risks across the Group, as necessary.

In times of crisis, the committee acts in accordance with the Risk Management Policy and the Emergency Response Standards as it seeks to enact measures to minimize damages. At such times, the committee serves as a companywide countermeasure headquarters, optimizing the Group's overall response and conducting risk management efficiently.

Together with Employees

Work-Life Balance

MTPC seeks to create an environment in which all employees can experience such important and proud life events as childbirth, childrearing and nursing care with peace of mind while continuing to work at their jobs with a sense of self-achievement. The company's childcare leave system exceeds legal requirements, and we work to provide parental support, as well. Accordingly, in 2007 the company was certified as confirming to standards for general employers in accordance with the Law for Promoting Measures to Support the Development of the Next Generation.

Fiscal 2008 activities that were planned in accordance with this law included (1) loaning mobile PCs to employees on childcare or nursing care leave to smooth their re-entry into the workplace and (2) reviewing the way employees work, and requiring all employees to leave the office at the end of regular work times four times per year. After having put these plans into effect, in 2009 we expect to earn certification under this law again.

To ease the uncertainties that employees might feel when taking leave before and after childbirth and for childrearing and to provide procedural support, we have prepared a manual concerning these activities and publicized the existence of the Follower (consultation desk). To reduce overtime working hours, we have implemented a system that encourages employees to plan consecutive holidays and have implemented a system requiring people to leave the office at the end of regular work times.



Kurumin certification of confirming to standards for general employers

Occupational Safety and Health Initiatives

In fiscal 2008, MTPC's objective was to have zero facility-related accidents and zero occupational accidents. Although no facility-related accidents occurred, accidents accompanied by one or more days of lost time occurred five times at the company's plants and research laboratories. Consequently, the lost time injury frequency¹ was 0.66. (By comparison, in 2008 the average lost time injury frequency for the pharmaceutical industry was 1.06). Looking at causes, these accidents mostly resulted from chemical injuries, falls or drops, or being caught. We conclude that risk prediction and safety confirmations are insufficient, and that these incidents stem from lack of education and training.



Training Experience Highlighting the Fear of Chemical and Thermal Injuries
Through practice with piping, we help workers experience the fear of chemical and thermal injuries, which is linked to accident prevention.

Given this situation, to create a workforce that encourages people to think before acting we have expanded safety training, and to heighten safety awareness we have introduced risk prediction training, training experience highlighting the fear of chemical and thermal injuries and naze naze analysis training. Such training, which takes workplace characteristics into account, is designed to eliminate occupational accidents.

¹ Lost time injury frequency: Number of lost time injury accidents per million working hours

Together with Society

MSC Volunteer Salon Operation

Since 1968, we have encouraged volunteer interaction through lectures and mini-concerts held on alternate months at the Maker, Seller and Consumer (MSC) Volunteer Salon in Ginza, Tokyo. Lifestyle and health-related themes during fiscal 2008 included "The Story of Medicine's Birth" and a "Talk on Walking and Shoes." During the Christmas season, international aid associations' activities were introduced, and products were exhibited and sold.



Scene from "the Story of Medicine's Birth," held in June

Together with the Global Environment

Environmental Safety Risk Management

We strive to recognize the greenhouse gases emitted through our business activities, as well as the leakage and release of chemical substances into the atmosphere, water and soil, as well as the accompanying health hazards, ecological impact and other environmental safety risks. We then work to prevent such risks. We have prepared the Environmental Safety Risk Management Bylaws to define the procedures to follow in the event that a risk materializes, and we provide education and training on their application.

When building the new drug substance production wing at Mitsubishi Tanabe Pharma Onoda Plant that was completed in fiscal 2008, we anticipated issues resulting by production processes and chemical substances that would be handled and introduced countermeasures against such potential problems as atmospheric pollution, water contamination, foul smells, sound and waste. Our environmental assessments sought to predict the extent of such issues. We compiled our findings into a report, which we explained to the Sanyo Onoda City Environmental Commission, resulting in their approval.

Creation of Eco-Promotion System

MTPC has introduced electric vehicles for use on sales routes as part of its proactive efforts toward an environmentally friendly system for eco-promotion. We are conducting other types of environmentally conscious corporate activities, as well.

We will also introduce electric vehicles for MRs to use when they visit medical institutions. In summer 2009, we had 50 of these vehicles for such visits in Tokyo, Kanagawa, Kyoto and Osaka prefectures. Compared with the gasoline-powered vehicles used in the past, electric vehicles emit no CO₂ during operation.

We will continue to convert fleet vehicles to hybrid or low-emission vehicles and revise the assumption of having one vehicle per MR. For MRs responsible for university hospitals in urban areas, we will encourage car sharing and the use of the use of public transport. Through such methods, we expect to change our style of sales and reduce the number of sales vehicles required.



Electric vehicles introduced for use on sales routes
Vehicles sport two-tone blue and white corporate colors

Issue of Medway Injection Test Data Exchange

MTPC learned that Bipha Corporation, a consolidated subsidiary, intentionally exchanged some authentic test data with irrelevant data when preparing a data package submitted with an application for manufacturing and sales approval of Medway Injection 5%, a recombinant human serum albumin preparation jointly developed by MPTC and Bipha, manufactured by Bipha and marketed by MPTC. Upon learning of this exchange, in March 2009 MTPC applied for the withdrawal of its manufacturing and marketing authorization and voluntarily recalled Medway Injection 5% and Medway Injection 25%.

MTPC sincerely regrets this occurrence. In response to this situation, MTPC is reinforcing its training and quality assurance systems and has created an overall management review and enhancement program. Through such measures, the company is working to restore its GMP compliance and confidence in the data accompanying its applications, and is implementing thorough compliance measures related to other pharmaceutical-related regulations. Through the establishment of the Bipha GMP System Monitoring Committee, MTPC will redouble its supervision and support of Bipha.

Through the steady implementation of such efforts, MTPC is striving to recover trust among its stakeholders.