Mitsubishi Tanabe Pharma Corporation

# CSR Report 2012





Mitsubishi Tanabe Pharma Corporation will grow with the universal values of protecting the health of people and contributing to comfortable lifestyles through the creation of new pharmaceuticals.

We strive to be a global research-driven pharmaceutical company that is trusted by communities.

#### **Philosophy**

## We contribute to the healthier lives of people around the world through the creation of pharmaceuticals.

Mitsubishi Tanabe Pharma's philosophy expresses the importance and purpose of the Company's existence and reaffirms its roots as a creator of pharmaceuticals.

#### **Vision**

## We strive to be a global research-driven pharmaceutical company that is trusted by communities.

Mitsubishi Tanabe Pharma's vision lays out the future direction for the Company based on its philosophy.

#### **Corporate Behavior Charter**

We will maintain high ethical standards, place priority on fairness and integrity in all activities, and act in accordance with the following guidelines.

#### Pride and Sense of Mission

As people involved in the creation of pharmaceuticals, we will work with pride and a sense of mission as we endeavor to research and develop pharmaceuticals that are needed by society and to ensure product safety and quality.

#### Trust and Teamwork

Through free and open communication, we will promote mutual understanding and respect, and will emphasize teamwork as we strive to maximize our results based on a strong relationship of trust.

#### Challenge and Innovation

With acute sensitivity and a broad perspective, we will focus on our future direction, decisively take on the challenge of meeting higher goals, and strive to create innovative value.

#### Harmonious Coexistence with Society

We will work to achieve harmonious coexistence with society by acting with consideration for local communities and the environment.

Based on the Company's philosophy and designed to realize its vision, the Corporate Behavior Charter sets the highest standards of behavior for all of Mitsubishi Tanabe Pharma's directors and employees.

#### **Editorial Policy**

This report is intended to provide a wide variety of information on the Group's CSR activities carried out in fiscal 2011 to stakeholders, including patients, medical professionals, shareholders, investors, local communities, and employees.

Editors sought to present specific initiatives in various areas taken in relation to the Company's philosophy of contributing to the healthier lives of people around the world through the creation of pharmaceuticals.

Third party verification on environmental performance data included in this report was performed by Bureau Veritas Japan Co., Ltd. to ensure objective and independent verification of the data. The Company wishes to acknowledge the valuable review performed by Ms. Chika Saka, Professor of Accounting at the School of Business Administration of Kwansei Gakuin University. The Company thanks this knowledgeable scholar, who gave constructive views and suggestions concerning the Company's CSR activities.

Explanations of medical and pharmaceutical terms appearing in this statement are included at the end of the report.

#### **About the Mitsubishi Tanabe Pharma Corporation CSR Report 2012**

■ This report covers the period from April 1, 2011 to March 31, 2012.

In addition, certain activities and policies undertaken after this period are included.

■ This report covers Mitsubishi Tanabe Pharma Corporation and its Group companies both within and outside Japan. Some included information may be different in scope.

#### Applied Guidelines

Environmental Reporting Guidelines, 2007 Version, published by the Ministry of the Environment of Japan; Global Reporting Initiative (GRI) Sustainability Reporting Guidelines, 3rd Version

■ Issued: August 2012

Issuance of next report: Scheduled for August 2013

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#### CONTENTS

Message from the President	04
Business Overview of Mitsubishi Tanabe Pharma Group	06
Major Products of Mitsubishi Tanabe Pharma Group	08
Creating Pharmaceuticals	
Research and Development	10
Manufacturing and Supply Chain	14
Providing Comprehensive Information	18
Assuring the Reliability of Drugs	22
Management	
Corporate Governance	24
Risk Management	26
Compliance	28
Employee Relations	
Training Human Resources and Promoting Work-Life Balance	30
Ensuring a Safe and Fair Working Environment	32
Social Contribution Activities	,
Participating in the Community	34
Relationship with the Global Environment	
Environmental Management	38
Overview of Environmental Impact	40
Energy Conservation and Global Warming Mitigation	42
Waste Reduction	45
Proper Management of Chemical Substances	46
Promotion of Environmental Communications	47
Independent Verification Report	48
Third-Party Opinion	49
Explanation of Terms	50



Reaffirming our mission as a pharmaceutical company, we contribute to society through our business activities.

Message from the President

## Striving to bring new drugs to patients as quickly as possible

Guided by the key concept of "new value creation," we commenced our Medium-Term Management Plan in April 2011. In the first fiscal year of the plan, Mitsubishi Tanabe Pharma worked to transform itself into a company that could continuously create new value, and succeeded in launching a series of new products designed specifically for unmet medical needs.

One of these products was Imusera, a multiple sclerosis treatment that Mitsubishi Tanabe Pharma developed and launched in November 2011. In the past, therapies for multiple sclerosis had been limited to injections. However, Imusera was the world's first oral medicine for this disease. The Company also released Telavic, a chronic hepatitis C treatment with a new mechanism of action. Its therapeutic efficacy has been recognized in patients who have not experienced sufficient treatment effectiveness through the conventional methods.

Mitsubishi Tanabe Pharma implemented strict controls to ensure the safety of these products while promoting their appropriate usage, so we are confident that they will be beneficial in treating a greater number of patients in

Along with these new products, indications have multiplied for Remicade, an intravenous drip infusion formulation launched in 2002. Remicade is now benefiting treatments of intractable illnesses including Crohn's disease, Behcet's disease, and rheumatoid arthritis, which is a type of autoimmune disorder. In September 2011, we also launched Simponi, which features also a subcutaneous injection formulation for the treatment of autoimmune disorders, offering another treatment option to meet the needs of people suffering from rheumatoid arthritis.

For many years, Mitsubishi Tanabe Pharma has been selling vaccines developed and produced by the Research Foundation for Microbial Diseases of Osaka University in an effort to ensure a stable supply of vaccines in Japan. We intend to continue helping society prevent infections by providing these vaccines in collaboration with the foundation.

Looking ahead, we are committed to providing drugs with value along with accurate information to offer more beneficial treatments for people suffering from disease.

## Revitalizing our raison d'êre to contribute to people's health around the world

With the goal of retaining society's trust as an international pharmaceutical company, we are focusing on establishing a business platform outside of Japan to provide drugs with value worldwide. For the markets of advanced countries in North America and Europe, Mitsubishi Tanabe Pharma is pursuing in-house development in the fields of kidney disease and critical orphan diseases such as autoimmune disease. Moreover, in emerging markets, we are working to rapidly launch products that have been approved in Japan, the United States, and Europe.

In the future, we recognize that for Mitsubishi Tanabe Pharma to further contribute to people's health around the world, all employees must make active efforts to broaden their outlook and strengthen their resolve, without falling back on conventional practices. With a spirit of challenge and innovation, each and every employee should promote a corporate culture built on mutual trust, while aiming to make Mitsubishi Tanabe Pharma a pharmaceutical company that is admired worldwide.

Providing products with value around the world answers the wishes of people suffering from disease, and also fulfills the ambitions of every member of Mitsubishi Tanabe Pharma, beginning with our medical representatives, researchers, and production staff. As such, we take great pride and gratification in our efforts to conduct business activities that enable products to be provided to medical patients. At the same time, we continually ask ourselves what purposes we can create drugs for and how we can provide the most useful information as we strive to revitalize our raison d'êre as a pharmaceutical company.

## Recognizing anew the importance of a stable supply of drugs in a time of disaster

More than one year has now passed since the Great East Japan Earthquake, a disaster that made us recognize anew that a stable supply of drugs is vital no matter what the circumstances. A number of the Mitsubishi Tanabe Pharma Group's business sites were damaged in the regions affected by the disaster; however, operations quickly resumed owing to the united efforts of employees to implement repairs and recovery work. During the time business was suspended, the Group worked together with wholesales to steadily supply drugs without running out of stock, thereby realizing

its mission to guarantee business activities that people's lives depend on.

We regularly conduct thorough examinations of risks that are particularly consequential for the Company's ongoing business activities. To ensure that Mitsubishi Tanabe Pharma can continue its operations going forward, it is essential for all employees to make advance preparations on a routine basis so that we can deal with risks on both an individual and organizational basis. Each and every employee is raising his or her awareness of relevant risks in order to respond to the initial stages of an emergency situation, in recognition of the importance of the measures laid out in our business continuity plan.

## Fulfilling our corporate responsibilities with pride and a sense of mission

Mitsubishi Tanabe Pharma aims to develop medical products that respond to unmet medical needs from the perspective of patients. Moreover, we hope to be regarded as a dreaminspiring company by quickly developing and delivering new medicines wished for by people suffering from disease. Every time I have the opportunity to visit a medical institution, I make an effort to listen directly to the opinions of people involved in medical care. I sense that they have greater expectations for Mitsubishi Tanabe Pharma than ever before. Therefore, I ask the Group to work toward meeting the expectations of these medical professionals with pride and a sense of mission.

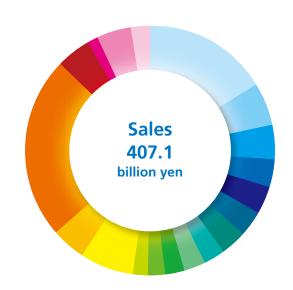
October 2012 will mark the fifth anniversary of Mitsubishi Tanabe Pharma Corporation, which was established through a merger. While it is true that this merger increased the scale of our business, this was not our main objective. Rather, we intended to expand our capabilities for continuously developing useful pharmaceuticals for patients and ensuring their stable supply. At Mitsubishi Tanabe Pharma, helping improve the quality of life of people suffering from disease through our business activities is the essence of our social mission. From this standpoint, Mitsubishi Tanabe Pharma will continue working daily to contribute to realizing a more comfortable society, as a core healthcare company of the Mitsubishi Chemical Holdings Group. As we pursue our endeavors, we ask all stakeholders of the Mitsubishi Tanabe Pharma Group for their continued support and understanding.

Michihiro Tsuchiya President and Representative Director Chief Executive Officer

Michi Tuchiy

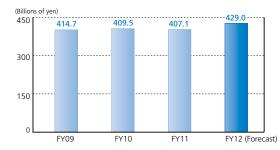
## **Business Overview of Mitsubishi Tanabe Pharma Group**



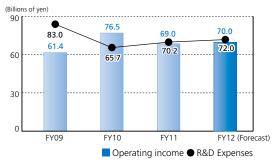


	(billions of yen)
Domestic Sales of Ethical Drugs	355.4
<ul><li>Remicade</li></ul>	66.3
<ul><li>Radicut</li></ul>	22.4
<ul><li>Ceredist</li></ul>	18.0
<ul><li>Anplag</li></ul>	15.2
<ul><li>Urso</li></ul>	14.4
<ul><li>Maintate</li></ul>	13.6
<ul><li>Talion</li></ul>	13.3
<ul><li>Kremezin</li></ul>	11.6
<ul><li>Depas</li></ul>	10.9
<ul><li>Venoglobulin IH</li></ul>	10.6
<ul><li>Herbesser</li></ul>	8.6
<ul><li>Tanatril</li></ul>	8.3
<ul><li>Vaccines</li></ul>	28.8
<ul> <li>Tanabe Seiyaku Hanbai-handled produ</li> </ul>	cts <b>17.4</b>
<ul><li>Other pharmaceuticals</li></ul>	96.0
Overseas Sales of Ethical Drugs (Herbesser, etc.)	18.4
• OTC	5.4
<ul> <li>Royalties for Pharmaceutical Technologies</li> </ul>	18.2
<ul><li>Other</li></ul>	9.5

#### Consolidated Net Sales



## Operating Income and R&D Expenses



#### Corporate Data

Company Name Representative Paid-in Capital

Mitsubishi Tanabe Pharma Corporation President and Representative Director Michihiro Tsuchiya

50 billion yen

Number of Employees 9,180 (as of March 31, 2012)

(consolidated) Headquarters

2-6-18 Kitahama, Chuo-ku, Osaka 541-8505, Japan

October 1, 2007

Date of Merger **Business Activities** 

Manufacture and sales of pharmaceuticals

#### Network

Headquarters Sales Network Osaka Headquarters, Tokyo Head Office Hokkaido, Tohoku, Kita-Kanto, Koushinetsu, Tokyo, Chiba, Saitama, Yokohama, Tokai,

Kyoto, Osaka, Kobe, Chugoku, Shikoku and

Kyushu branches

Research Centers Toda, Kazusa, Yokohama and Kashima offices

Overseas Network Shanghai Office

#### Group Companies in Japan

Mitsubishi Tanabe Pharma Factory Ltd. Tanabe Seiyaku Yoshiki Factory Co., Ltd. **Benesis Corporation** Bipha Corporation **API** Corporation Yoshitomiyakuhin Corporation

Tanabe Seiyaku Hanbai Co., Ltd. Choseido Pharmaceutical Co., Ltd. Hoshienu Pharmaceutical Co., Ltd. Tanabe R&D Service Co., Ltd. Tanabe Total Service Co., Ltd. MP-Logistics Corporation

#### ■ Group Companies Overseas



#### Europe

Tanabe Europe N.V. Mitsubishi Pharma Europe Ltd. Mitsubishi Pharma Deutschland GmbH Synthelabo-Tanabe Chimie S.A.

Tianjin Tanabe Seiyaku Co., Ltd. Mitsubishi Pharma (Guangzhou) Co., Ltd. Mitsubishi Pharma Research & Development (Beijing) Co., Ltd. Guangdong Tanabe Pharmaceutical Co., Ltd. Taiwan Tanabe Seiyaku Co., Ltd. Tai Tien Pharmaceuticals Co., Ltd. P.T. Tanabe Indonesia Mitsubishi Tanabe Pharma Korea Co., Ltd.

#### **United States**

Mitsubishi Tanabe Pharma Holdings America, Inc. Tanabe Research Laboratories U.S.A., Inc. Mitsubishi Tanabe Pharma Development America, Inc.

Mitsubishi Tanabe Pharma America, Inc. Tanabe U.S.A., Inc.

MP Healthcare Venture Management, Inc.

## **Major Products of Mitsubishi Tanabe Pharma Group**



Anti-human-TNF- $\alpha$ monoclonal antibody Remicade

Remicade is used in the treatment of rheumatoid arthritis and other inflammatory conditions. It eases inflammation and ameliorates symptoms by suppressing the action of tumor necrosis factor alpha (TNF- $\alpha$ ), which is regarded as the cause of immune abnormalities. Since its launch in Japan, Remicade has been used to treat more than 50,000 patients with rheumatoid arthritis and a total of more than 80,000 patients for all indications combined.



Oral spinocerebellar degeneration treatment

Ceredist

Ceredist is used to lessen the severity of ataxia in spinocerebellar degeneration, which affects routine actions such as walking, eating, talking, and so forth. Ceredist activates neurons through the enhanced release of the neurotransmitters acetylcholine and dopamine, stimulation of metabolic turnover, and neurotrophic factor-like action.



Selective histamine H1 receptor antagonist anti-allergy drug **Talion** 

Used in the treatment of allergic rhinitis, hives, and itching accompanying skin disorders, Talion reduces sneezing, nasal congestion, and other sinus conditions as well as skin irritation by suppressing the generation and action of histamine in the body, which is the cause of allergic symptoms.



Selective  $\beta_1$ antagonist **Maintate** 

Maintate has proven effective against conditions such as hypertension, angina pectoris, and chronic heart failure. It shows antihypertensive, antianginal, antiarrhythmic, and anti-heart-failure effects by easing excess action of the heart. It does this by blocking  $\beta_1$  receptors that transmit sympathetic nerve impulses to the heart.



Cerebral neuroprotective drug (free radical scavenger)

Radicut

During treatment in the acute phase of cerebral infarction (stroke), Radicut protects the brain by eliminating harmful free radicals that increase where blood flow has become poor. This lowers the chance of paralysis and numbness in the extremities and impairment in movement in daily life, which are symptoms of cerebral infarction.



5-HT<sub>2</sub> blocker **Anplag** 

Anplag inhibits blood clotting and improves blood flow by suppressing platelet aggregation and vascular contraction through antagonistic action to serotonin receptors in platelets and vessels. This ameliorates symptoms such as pain, feeling cold, and ulcers of the limbs resulting from disturbance of peripheral circulation.



Multiple sclerosis treatment **Imusera** 

Imusera is prescribed to patients with multiple sclerosis. It suppresses nerve inflammation by restraining lymphocytes, including autoreactive T cells that attack one's own cells, from emerging from lymph nodes and other secondary lymphatic tissue.



#### Antiviral drug **Telavic**

Telavic has therapeutic efficacy against chronic hepatitis C, as it acts to suppress the proliferation of the hepatitis C virus. Its antiviral abilities increase when used in combination with pegylated interferon alpha-2b (recombinant) and ribavirin.



Human TNF- $\alpha$ monoclonal antibody **Simponi** 

**Vaccines** 

Simponi is prescribed when existing treatments of rheumatoid arthritisincluding the prevention of structural damage to the joints-have been inadequate. Simponi ameliorates rheumatoid arthritis symptoms by suppressing the action of TNF- $\alpha$ , which is thought to be one of the main causative agents of inflammation.



Selective serotonin reuptake inhibitor (SSRI)

#### Lexapro

Lexapro can help patients with depression and depressive syndromes, as it increases the concentration of serotonin by selectively inhibiting the reuptake of serotonin that exists in the brain. This smoothes neurotransmission and eases feelings of depression and anxiety.



Mearubik

Vaccines are agents made from weakened or killed forms of pathogens or their toxins. Being inoculated with a vaccine causes the body to produce antigens specific to the pathogen in the vaccine. Thus, the body's immunity against infection by the pathogen is strengthened.



Over-thecounter drugs

Flucort f

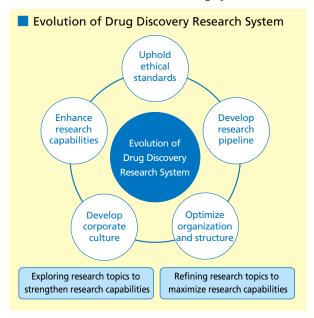
Over-the-counter (OTC) drugs are available at pharmacies and drug stores without a doctor's prescription. These OTC drug products allow users to manage their personal health and treat simple physical ailments.

## **Research and Development**

#### **Contributing to Healthier Lives of People around the World**

Guided by its philosophy of "contributing to the healthier lives of people around the world through the creation of pharmaceuticals," Mitsubishi Tanabe Pharma selects targets for innovative drug development in order to respond to unmet medical needs. It utilizes its medicinal chemistry, HTS, and antibody screening technologies to actively pursue development candidate compounds that will lead to the creation of pharmaceuticals that will be of value to its patients. The Company's focus in these efforts is on strengthening drug discovery research at its laboratories, bolstering its portfolio by green-lighting the appropriate number of research projects, and fostering close, cooperative ties between its Research Division and the Corporate, CMC, and Development divisions. Mitsubishi Tanabe Pharma's researchers are encouraged to participate in a free and open exchange of their opinions and findings, to create synergy between various fields of expertise and resolve issues that arise in the process of drug discovery.

The Company also works at times with other corporations in the industry, as well as with government and academic institutions. This approach boosts the level of its own drug discovery research and helps ensure that research projects achieve their intended results. At Mitsubishi Tanabe Pharma, the research structure is grounded in a corporate culture that upholds high ethical standards, and fosters a spirit of collaboration, so that we can obtain highly reliable data.



#### **Ethical Considerations in Research**

Research using donated human tissue and cells has contributed in recent years to a better understanding of the pathology of diseases, and this type of research is expected to lead to the discovery of new drugs in the future. Whenever samples of human origin are involved, however, ethical issues such as the informed consent of donors and the protection of their personal information must be given serious and careful consideration. The Mitsubishi Tanabe Pharma Ethics Review Committee meets nearly every month to deliberate the ethics and scientific validity of any research using human samples. In an effort to ensure that its decisions are balanced and incorporate differing views, the committee includes members from outside the Company to promote objectivity, impartiality, and transparency.

Animal testing is also essential to new drug research. The Company requires that all proposed research be approved by its Animal Experiment Committee, which deliberates the validity of proposals based on international standards for animal testing and ensures that all research is conducted with a high regard for the animals' welfare.

#### **Human Rights and Bioethical Considerations in Clinical Trials**

All Mitsubishi Tanabe Pharma clinical trials are subject to strict standards. The Company follows the guidelines set by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use/Good Clinical Practices (ICH-GCP), based on the Declaration of Helsinki. It also upholds the laws and regulations of the country in which the studies are conducted, as well as its own standards and clinical trial protocol. All volunteer participants in the trials give their informed consent to do so. The Company's highest priority is to ensure the safety of its subjects, protect their human rights, and safeguard their personal welfare.

Mitsubishi Tanabe Pharma's Clinical Trial Protocol Review Committee includes members from outside the Company and medical experts who are well-versed in clinical trial ethics. Before a trial is allowed to begin, the committee investigates the proposed study to confirm its ethical and scientific validity. Once trials are underway, the Company's clinical trial management system is employed to verify that studies are being properly administered. Inspections are also conducted as needed, to ensure that the trial data is reliable.

#### **Strengthening Capabilities to Create New Drugs Autoimmune Diseases**

Autoimmune diseases are caused when the immune system, which is supposed to eliminate pathogens, attacks normal cells and tissues. The treatment of rheumatoid arthritis and multiple sclerosis, both autoimmune diseases, may have advanced tremendously with the introduction of Remicade, Simponi, and Imusera; however, there are still many autoimmune diseases for which no effective treatments have been found. These diseases are a major impediment in patients' lives, as they are accompanied by systemic manifestations including pain. Mitsubishi Tanabe Pharma will contribute to the further improvement in patients' QOL (quality of life) by creating new drugs to satisfy unmet medical needs through the investigation of pathophysiological mechanisms.

#### Remicade

Out of the approximately 30,000 Crohn's disease patients in Japan, at present more than 12,000 are being treated with anti-human TNF- $\alpha$  monoclonal antibody Remicade. However, the Company was receiving requests to change the recommended dosage, as some patients were not obtaining sufficient benefit with the conventional amounts prescribed. In response to these requests, the Company conducted clinical trials and confirmed that administering increased doses of Remicade to patients who did not have a significant response to the usual dosage was both safe and efficative. In August 2011, partial changes in the recommended dosage were approved.

#### Simponi

Mitsubishi Tanabe Pharma launched human anti-TNF-lphamonoclonal antibody Simponi in September 2011 under a joint marketing agreement with Janssen Pharmaceutical K.K. Simponi was developed as a treatment for inflammatory autoimmune diseases such as rheumatoid arthritis. Since receiving approval in the U.S. in 2009, the product has been approved in more than 40 countries worldwide. Simponi can decrease the need for patients to visit the hospital, since the drug is administered once every four weeks. Moreover, a clinical trial of Simponi conducted in Japan gave unprecedented evidence of a subcutaneous injection preventing structural damage in the joints.

#### **Strengthening Capabilities to Create New Drugs Diabetes and Kidney Disease**

Diabetes is a disease in which the concentration of glucose in the blood increases to a pathologic level. It is estimated that the number of diabetes patients in Japan, including those with borderline diabetes (pre-diabetes), is over 20 million and is forecast to increase in the future.

Diabetes is a known trigger in the progression of chronic kidney disease. Consequentially, chronic kidney disease is increasing along with the increase in diabetes. Progression of chronic kidney disease not only leads to renal failure and the need for dialysis or a kidney transplant, it is also known to carry a high risk of complication with cardiovascular disease from a relatively early stage. Mitsubishi Tanabe Pharma is aiming to create breakthrough chronic kidney disease treatments by pushing forward with the search for new drug discovery target molecules. In order to do so, it is enthusiastically cooperating with academic institutions in its clinical research

#### Tenelia

In June 2012, Mitsubishi Tanabe Pharma received manufacturing and marketing approval for type 2 diabetes mellitus treatment, Tenelia. Created by Mitsubishi Tanabe Pharma, Tenelia is the first DPP-4 inhibitor to originate in Japan. It improves blood sugar levels after every meal and when the stomach is empty, with a once-daily oral administration. Tenalia has the characteristic of being eliminated from the body via two routes—through the kidneys and the liver.

#### ●TA-7284

The phase 3 trials of TA-7284 are ongoing for type 2 diabetes mellitus treatment in Japan. Outside Japan, the product's licensee, Janssen Pharmaceuticals, Inc., has submitted new drug applications in the U.S. and Europe with type 2 diabetes mellitus as the indication. TA-7284 has a novel mechanism of action not mediated by insulin. While it has a strong hypoglycemic effect, it has a low risk of causing hypoglycemia. A weight-loss effect can also be expected, something not seen with other oral diabetes drugs.

In March 2012, Mitsubishi Tanabe Pharma entered into an agreement with Daiichi Sankyo Co., Ltd. regarding a strategic sales alliance for Tenelia and TA-7284. The two companies will conduct joint sales activities for these drugs under a onebrand, two-channel framework. Moreover, the companies will implement new types of information provision, including mutual visits to their client medical institutions, thereby providing new treatment options for type 2 diabetes mellitus.

#### **Strengthening Capabilities to Create New Drugs Providing Pharmaceuticals That Are Valuable to Patients**

#### Imusera

In November 2011, Mitsubishi Tanabe Pharma launched the multiple sclerosis (MS) treatment, Imusera. Originally created by the Company, the drug was Japan's first oncedaily oral treatment for MS. Until then, only injectable drugs had been available for the treatment of MS. Outside Japan, the drug's licensee, Novartis, has obtained approvals for this drug under the name Gilenya in more than 60 countries, including the U.S., Australia, and Canada, as of June 2012. More than 38,000 patients have been treated with the products since its launch in 2010.

#### Telavic

In November 2011, the Company launched chronic hepatitis C treatment, Telavic, which is an oral antiviral agent developed by Vertex Pharmaceuticals. It is a firstin-class drug that suppresses the proliferation of the hepatitis C virus by inhibiting the action of the enzyme involved in the replication of the virus. In a clinical trial conducted in Japan, a new triple-drug combination including Telavic showed improved effectiveness and shortened the required treatment period compared to the standard double-drug regimen. For example, the three combined drugs elicited positive results in patients that either did not respond to or had had a recurrence after taking the conventional therapy.

#### Lexapro

In August 2011, the Company launched antidepressant, Lexapro under a co-marketing agreement with Mochida Pharmaceutical Co., Ltd. Lexapro is a selective serotonin reuptake inhibitor (SSRI) created by Danish company H. Lundbeck A/S. In 2002, it was launched in the U.S. and Europe, where it has gained the biggest share of the SSRI market. Mitsubishi Tanabe Pharma hopes that Lexapro will help improve the quality of life of patients with depression as a new therapeutic option in Japan.

#### **Contributing to Disease Prevention** through the Supply of Vaccines

Mitsubishi Tanabe Pharma is striving to increase the rate of vaccinations through the marketing of vaccines developed and manufactured by the Research Institute for Microbial Diseases, Osaka University (BIKEN).

The Company operates a health support website, Wakuchin.net, which provides accurate information in Japan about vaccinations. Mitsubishi Tanabe Pharma also offers free educational tools and other materials to support municipalities and educational institutions engaged in vaccination education throughout Japan.

#### Enhancing the Development of Vaccines and Promotion of Vaccinations in Japan

In December 2011, Mitsubishi Tanabe Pharma concluded a licensing agreement with Nuron Biotech (U.S.) for HibTITER®, a vaccine for Haemophilus influenzae type B (Hib), thereby acquiring exclusive development and marketing rights in Japan. Hib causes diseases such as bacteremia and meningitis. In particular, pediatric meningitis can have serious aftereffects or even be fatal. Accordingly, prevention through vaccination is considered highly important. HibTITER® has been used in more than 50 countries and regions worldwide since the late 1980s. The Company will move forward with development so that it can guickly provide a safe and effective vaccine in Japan.

In February 2012, Mitsubishi Tanabe Pharma concluded a research collaboration agreement with Medicago Inc. (Canada) to create vaccines that use Medicago's technologies for manufacturing virus-like particles (VLPs). VLPs, which have an artificially created viral envelope, are expected to induce effective immune responses and offer superior safety. Under this agreement, the companies have begun research on a rotavirus VLP vaccine as the first project. In Japan, infection with rotavirus causes gastroenteritis in an estimated 800,000 infants each year, of which about 80,000 develop into serious illness. The Company will push collaborative research with Medicago forward with the aim of creating new VLP vaccines, including one for rotavirus.

## **Creating Pharmaceuticals That Are Valuable to Patients**

#### Development Pipeline (as of July 29, 2011)

	Development code/ Generic name	Indications	Development Site	Development Stage		tage				
	Simponi	Rheumatoid arthritis	Japan					Approved July 2011		
	Imusera	Multiple sclerosis	Japan					Approved Sept. 2011		
	Telavic	Chronic hepatitis C Japan						Approved Sept. 2011		
	Livalo	Hypercholesterolemia, Familial hypercholesterolemia	Indonesia					Approved Nov. 2011		
			Japan					Approved June 2012		
	MP-513	Type 2 diabetes mellitus	EU							
	3.3		U.S.							
		Type 2 diabetes mellitus, additional combination	Japan							
	BK-4SP	Vaccines	Japan					Approved July. 2012		
z	MCI-196	Hyperphosphatemia	EU				MAA filed Aug. 2011			
ew (	TA-7284	Type 2 diabetes mellitus	Japan							
<b>New Compounds</b>	MP-214	Schizophrenia	Japan	Phase Phase Phase		Phase Phase		Phase		
oun	MP-146	Chronic kidney disease	U.S., EU	_	2	ũ				
ds	MP-435	Rheumatoid arthritis	Japan							
	MT-4666	Alzheimer's disease	Japan							
	MT-3995	Hypertension	Japan							
	IVI 1-3993	Hypertension	EU							
	MT-1303	Multiple sclerosis	Japan							
	1011-1303	Multiple scierosis	EU							
	GB-1057	Stabilizing agent	U.S.							
	TA-8995	Dyslipidemia	EU							
	MP-124	Acute ischemic stroke	U.S., Canada							
	MP-157	Hypertension	EU							
	MT-7716	Alcohol use disorder	U.S.							

					_		
	Development code/ Generic name	Indications	Development Site		D	evelopment S	tage
		Crohn's disease (dose changes)	Japan				Approved Aug. 2011
	Remicade	Subtype of Behcet's disease	Japan				
	Kernicade	Pediatric Crohn's disease	Japan				
		Kawasaki disease	Japan				
		Pediatric Ulcerative Colitis	Japan				
	Venoglobulin	Systemic myasthenia gravis	Japan				Approved Sept. 2011
_	IH	Immunoglobulin G2 deficiency	Japan			Application Dec. 1997	
d		Systemic scleroderma	Japan				
Additional Indications	Novastan	Prevention of clotting during hemodialysis and percutaneous coronary intervention using HIT	Japan				Approved May 2011
Ind	Maintate	Chronic heart failure	Japan				Approved May 2011
ica		Chronic atrial fibrillation	Japan				
tion	Azanin	Refractory rheumatic disease	Japan				Approved May 2011
S	Anti D (Rho) human normal immunoglobulin	Suppression of immunological sensitization due to the D (Rho) factor around the 28th week of pregnancy	Japan				Approved May 2011
	Modiodal	Obstructive sleep apnea	Japan				Approved Nov. 2011
	Radicut	Amyotrophic lateral sclerosis	Japan				
	Talion	Pediatric allergic rhinitis	Japan				
	Telavic	Genotype 2 chronic hepatitis C	Japan				
	Cholebine	Type 2 diabetes mellitus	Japan				
	Cholebine	Hyperphosphatemia	Japan				
			Korea				Approved Aug. 2011
	TA-1790	Erectile dysfunction	U.S.				Approved Apr. 2012
			EU			filed Mar. 2012	
Lic		Type 2 diabetes mellitus	U.S.			filed May 2012	
Licensing-out	TA-7284	Type 2 diabetes meliitus	EU			filed June 2012	
<u></u>		Obesity	U.S., EU				
ò	MP-513	Type 2 diabetes mellitus	Korea				
Ħ	T-0047	Multiple sclerosis	EU				
	MKC-242	Insomnia	U.S.				
	Y-39983	Glaucoma	Japan				
	MT-210	Schizophrenia	EU				
	sTU-199	Gastroesophageal reflux disease	EU	_	$\vdash$		
	TT-138	Pollakiuria, urinary incontinence	U.S.	-	-		
	TA-7906	Atopic dermatitis	Japan		$\perp$		

#### **Voice** Meeting Unmet Medical Needs and Putting Smiles on the Faces of Patients

Mitsubishi Tanabe aspires to produce drugs that meet unmet medical needs, where satisfaction with current treatments is low. Research and development of pharmaceuticals is becoming more and more difficult, making this more challenging than ever. Creating effective pharmaceuticals requires balancing the main effects (benefits) and side effects (risks), and detailed examinations of this balance during the research process requires an enormous amount of time and labor.

We endeavor to obtain highly reliable data and build up a sound strategy based on that data in order to develop drugs that are not only highly effective but also as safe as possible, allowing patients to use them without worry. The development of drugs requires a great deal of time, sometimes as much as 10 years for the compounds to reach the market. We are proud that we will be able to put smiles on the faces of patients 10 years from now. We tackle pharmaceutical development based on the spirit that we will overcome today's limitations tomorrow.



Naoya Masutomi Molecular Toxicology Group Safety Research Laboratories, Department II

## **Manufacturing and Supply Chain**

## **Pharmaceutical Manufacturing Process**

Mitsubishi Tanabe Pharma continuously strives to improve its quality in order to manufacture and supply premium products, and as an assurance to its customers that it is a company to trust and depend upon. The CMC Division works together with the Group's production plants, from the very beginning of development through the entire process of getting new drugs to market. It also collaborates in the development of production technologies designed to enhance the quality, guarantee a stable supply, and reduce the manufacturing costs.

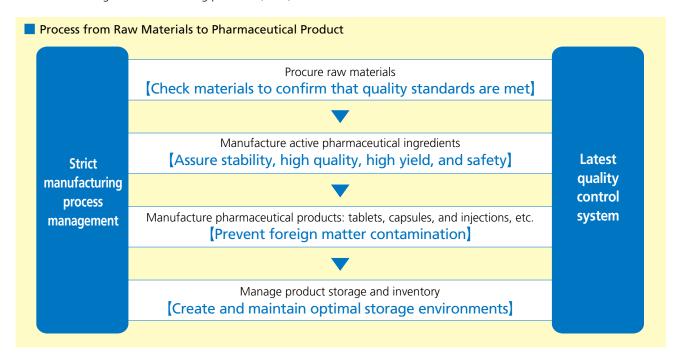
The Mitsubishi Tanabe Pharma Group's global manufacturing system is made up of 12 production plants in Japan and 5 outside the country, as well as subcontracted manufacturers, that deliver the products to people worldwide.

Through this system, raw materials procured from around the world undergo acceptance testing before the production of pharmaceuticals begins. Applying original technologies and expertise it developed over many years, the Group manufactures active pharmaceutical ingredients and pharmaceutical products while conducting a battery of tests and inspections in accordance with good manufacturing practices (GMP).

#### **Measures to Prevent Medical Malpractice**

One example of a measure designed to prevent medical malpractice is the Company's relabeling of its Anplag tablets (5-HT<sub>2</sub> blocker). The name of the product is now clearly displayed in Japanese on each tablet. This has been done to help prevent dispensing errors at medical facilities and other incidents of medical malpractice, as well as to improve efficiency at pharmacies and ensure that individual patients take the correct medication.

In an effort to guard against mistakes involving its products, Mitsubishi Tanabe Pharma has been modifying the brand names of its pharmaceuticals to make them easier to understand. Thus the brand names shown on the packaging for two medications marketed in Japan— Ceredist (oral spinocerebellar degeneration treatment) and Maintate (selective  $\beta_1$  antagonist)—have been improved. There is now a clearer indication of tablet unit dose of active pharmaceutical ingredients.



## **Managing the Supply Chain**

Mitsubishi Tanabe Pharma operates by a defined set of Purchasing Principles. Its basic purchasing policy calls for fair, equitable and transparent transactions with suppliers and CSR-oriented purchasing activities that comply with relevant laws and regulations, are environmentally friendly, and respect human rights. The Company selects suppliers on a global and open basis with the aim of ensuring the quality of procured materials and their stable supply. Its own strict supplier selection standards are designed to ensure fairness and impartiality when evaluating and selecting suppliers.

The Company is also focused on reinforcing its supply chain by incorporating CSR purchasing and business continuity management (BCM).

- (1) CSR purchasing—case in point Mitsubishi Tanabe Pharma's basic purchasing policy is CSR-oriented. It uses a questionnaire to gather information concerning its suppliers' business structure, products and CSR measures.
- (2) BCM practices—case in point Taking on board the lessons learned from the Great East Japan Earthquake in 2011, the Company has taken a particularly close look at product categories designated "emergency-use pharmaceuticals," which are critical to sustaining patients' lives, and those that would greatly impact medical institutions and patients if supplies were interrupted. Mitsubishi Tanabe Pharma is taking steps to further reinforce its supply chain so as to establish a stable supply of these products even in the face of a large-scale disaster.

## **Compliance in Purchasing Operations**

Mitsubishi Tanabe Pharma has developed a Compliance Code of Conduct for Purchasing Operations that all employees engaged in purchasing-related activities must follow. In doing so, it is boosting compliance in purchasing operations throughout the Group.

Main Pillars of Compliance Code of Conduct for Purchasing **Operations** 

- 1. Awareness, responsibility
- 2. Fairness, impartiality, integrity
- 3. Legal compliance
- 4. Moderation
- 5. Transparency, openness

## **Manufacturing System in Asia**

The Mitsubishi Tanabe Pharma Group has established subsidiaries in China, South Korea, Taiwan, and Indonesia to manufacture and sell products tailored to each country's market and quality standards.

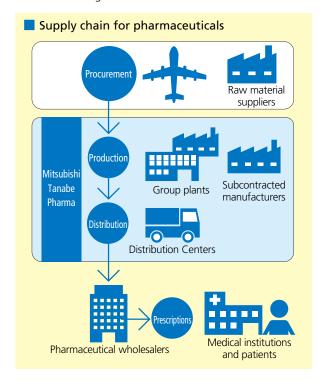
In China, a country currently experiencing remarkable growth, Tianjin Tanabe Seiyaku Co., Ltd. manufactures oral agents, and Mitsubishi Pharma (Guangzhou) Co., Ltd. manufactures intravenous (IV) solutions. Mitsubishi Tanabe Pharma Korea Co., Ltd. and Taiwan Tanabe Seiyaku Co., Ltd. handle products for their respective markets, as well as products sold in Japan. Finally, P.T. Tanabe Indonesia serves as a manufacturing base for Indonesia and other Southeast Asian countries.

The Group is also actively complying with the increasingly strict GMP standards in countries throughout Asia. As a result of these efforts, in October 2011, Tianjin Tanabe Seiyaku Co., Ltd. became the first pharmaceutical company in Tianjin City to be certified under China's new GMP standards. The Mitsubishi Tanabe Pharma Group is committed to consistently and continuously improving the quality of its pharmaceuticals and ensuring their stable supply.



## **Pharmaceutical Supply Chain**

The Mitsubishi Tanabe Pharma Group recognizes that a pharmaceutical company's duty is to get pharmaceuticals to patients when they are needed. To fulfill this duty, it has in place a supply system designed to stably deliver pharmaceuticals to patients even during times of disaster and other emergencies.



## **Managing Distribution to Ensure Stable Supplies**

The ultimate goal of the Company's distribution system is the stable supply of pharmaceuticals even in a state of emergency such as due to a massive natural disaster. The Mitsubishi Tanabe Pharma Group has developed a dualbase distribution system with Distribution Centers in both eastern and western Japan. This ensures that if either Distribution Center becomes inoperable at any time, the remaining center will be able to provide backup for a stable supply of pharmaceuticals.

Each Distribution Center employs an inventory control system that carefully monitors product inventory and operations down to individual lots. Under this system, the

Company is able to quickly and accurately fill purchase orders, while safeguarding a stable supply of products.

## **Quality Control in the Distribution**

Mitsubishi Tanabe Pharma Group Distribution Centers take a rigorous approach to quality control in the distribution process. This attention to detail helps ensure that pharmaceuticals are as high in quality when they reach patients as they are when manufactured under the strict GMP of the Company's production plants.

The Group works to maintain both the operational and physical aspects of distribution quality. While complying with the building and facility requirements for a wholesaler under the Pharmaceutical Affairs Law of Japan, Mitsubishi Tanabe Pharma's distribution policies and procedure manuals are designed to ensure that pharmaceuticals are appropriately managed. It is particularly vigilant about regulating the temperature at which its products are stored, and equips its warehouses with both 5°C storage units and room temperature storage units.

In addition to various measures such as periodic temperature validation and thermometer calibration, the Company has designed a system that maintains product storage at a constant temperature, 24 hours a day, seven days a week. The system also has emergency response measures in place, including private power generators that can be used when electricity supplies are interrupted, as well as an emergency information process that kicks in when abnormal conditions are detected.

Products are shipped from the Distribution Centers by contracted transport companies that are in compliance with pre-determined qualifications. With an understanding of the importance of the pharmaceuticals that they are carrying, these companies strictly supervise the transport of this cargo, utilizing facilities and vehicles specifically designed for loading and unloading pharmaceuticals.

Mitsubishi Tanabe Pharma designed its entire transportation system with the focus on supplying highquality pharmaceuticals. The Company also works to minimize any loss of quality during the distribution process by carrying out periodic inspections of its subcontractors, as well as using a comprehensive distribution method with precise temperature control validation and special insulated boxes for packing the products.

## A New System for Surveying **Pharmaceuticals Usage**

Mitsubishi Tanabe Pharma and its Group company, Benesis Corporation, have jointly developed a new system for issuing medicine usage survey forms in cooperation with Mitsubishi Electric Corporation. Based on this new system, a project team has been set up, together with the National Hospital Organization Kyoto Medical Center, to help medical practitioners and facilities with the time-consuming surveying task. The system automates the collection of data, accelerating the process and making it more accurate. By accessing digitized medical records, it automatically extracts necessary medical information for the survey and utilizes the RFID tag traceability system to compile post-administration drug manufacturing numbers and other data related to patients' prescription histories. By combining these functions, the Company will automate nearly every aspect of drug usage surveys.

Mitsubishi Tanabe Pharma is committed to helping provide safe medical care that patients can rely on and intends to continue participating in verification testing that utilizes information technology.



RFID tag traceability system reads drug information

the world. To obtain permits for these exports, the pharmaceuticals must be inspected to determine their compliance with the laws and customs regulations of Japan and the importing countries.

Therefore, it is the Company's responsibility that the products being exported meet all pharmaceuticalrelated regulations effective in destination countries and regulations concerning the international transport of hazardous materials. Since the nuclear plant accident in Fukushima, certain countries have imposed regulations requiring that pharmaceuticals imported from Japan be tested for radioactivity, and Mitsubishi Tanabe Pharma is doing its utmost to certify that its products meet these regulations.

## **Export Security Control**

Export security control is a system that prevents exported products and technologies from being illegally used for military or other detrimental purposes. Mitsubishi Tanabe Pharma has instituted a voluntary control system based on all laws and regulations related to export security, as well as its own export control regulations. In addition to inspecting products and technologies to determine their compliance, auditing client companies, preserving all related documents, training employees, and conducting on-site audits, the Company also periodically exchanges information related to export control with other Mitsubishi Chemical Holdings Group companies in order to continuously improve these safeguards.

## **Export of Pharmaceuticals**

In 2011, Mitsubishi Tanabe Pharma exported pharmaceuticals to approximately 50 countries around

#### Voice Tianjin Tanabe Seiyaku—For the stable supply of reliable, high-quality drugs

GMP standards are becoming increasingly strict in countries around the world. China also raised its GMP standards in March of last year, requiring the same level of soft and hard aspects of manufacturing as that of international standards and practices.

At Tianjin Tanabe Seiyaku, we readily took on the challenge of meeting these new standards. We conducted more than 3,000 hours of employee training over a one-year period, underwent practice inspections based on the new GMP standards, exchanged information with the relevant agencies, and carried out the necessary renovations at production plants. As a result of these concerted efforts, in October 2011, of the 143 pharmaceutical companies in Tianjin City, we were the first to be certified under the new GMP standards.

We at Tianjin Tanabe Seiyaku will continue to work on a number of different initiatives to raise our GMP level even higher. These include staff rotations, as well as a quality patrol unit on our production lines. At the same time, we are also focused on fostering communication among departments through company recreation activities. Our entire team is committed to working together to deliver a stable supply of reliable, high-quality pharmaceutical products.



Staff from Tianjin Tanabe Seiyaku's Manufacturing Division

## **Providing Comprehensive Information**

#### An MR's Responsibility: Collecting Data and **Providing Information to Medical Institutions**

The Mitsubishi Tanabe Pharma Group recognizes that providing physicians, pharmacists, and other medical professionals with a full array of information on its pharmaceutical products, including their efficacy and safety, is absolutely essential to its responsibility for providing patients with pharmaceuticals that effectively improve their health.

In Japan, the Group's 2,300 general and specialized medical representatives (MRs) work each day to supply medical institutions throughout the country with scientific information concerning the benefits of Mitsubishi Tanabe Pharma's products, as well as their possible side effects, in order to ensure that the products are used appropriately. The Group's reps are also responsible for collecting data on the efficacy and safety of the drugs at the usage stage information that could not be gleaned during R&D—and providing medical institutions with data-based evaluations. Specialized MRs are responsible for products that require a high level of knowledge about specific illnesses and drug treatments. General MRs, on the other hand, focus on facilitating effective communication by coordinating meetings between the specialized MRs and medical professionals.

Mitsubishi Tanabe Pharma supports its MRs' activities with an exclusive website for medical professionals called Medical View Point, which provides a constant source of useful information on drug products and

diseases. In response to requests from medical professionals, the website offers a subscription-based e-mail magazine featuring information on various medical practices.

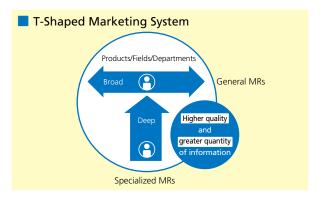


Medical View Point—an exclusive website for medical professionals

## **Stronger Coordination between General and Specialized MRs**

Mitsubishi Tanabe Pharma recognizes the need to reform its methods of communicating with the medical community so that a wide range of information on its new products gets to those who need it. Toward this end, it has instituted a

T-shaped marketing system (as illustrated below), under which general MRs who cover a broad range of hospital departments and medical fields are backed by targeted support from specialized MRs with extensive knowledge in specific fields. With its general and specialized MRs coordinating more effectively, the Company will be better able to meet the diverse needs of its customers.



## **Providing Comprehensive Information through Seminars**

In March 2012, Mitsubishi Tanabe Pharma co-sponsored the Nikkei Health Seminar 21 forum held by newspaper publisher Nikkei Inc. In coordination with the National Health Promotion Movement in the 21st Century (Healthy Japan 21) promoted by the Ministry of Health, Labour and Welfare of Japan, the purpose of this educational seminar was to help prevent lifestyle diseases and other illnesses. The seminar was attended by some 440 members of the general public, and Mitsubishi Tanabe Pharma organized the keynote speech and a panel discussion on multiple sclerosis to raise the as-yet low level of public awareness about this disease.

Mitsubishi Tanabe Pharma understands that promoting understanding of illnesses among the general public and raising interest in general health issues is key to early detection and prevention. It is committed to sponsoring

seminars as one of many ways in which it can provide comprehensive information on the diseases and illnesses that its products have been developed to treat.

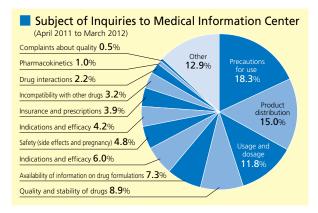


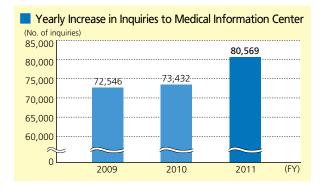
Nikkei Health Seminar 21

## **Providing Comprehensive Information** through the Medical Information Center

Mitsubishi Tanabe Pharma has established its own Medical Information Center to respond directly to inquiries from patients and consumers, as well as physicians, pharmacists, wholesalers, and others in the medical profession. A highly unique resource in the private sector, the center provides patients and consumers with clear explanations that are reliable, accurate, and prompt, while at the same time making certain not to dispense the type of medical advice that should only come from a physician.

The center plays a vital role in ensuring that the Company's products are trusted by giving phone callers accurate information on such issues of safety and quality as drug side effects. Receiving approximately 80,000 calls a year, the Medical Information Center staff relay the content of these inquiries to the relevant Mitsubishi Tanabe Pharma department as feedback to be addressed. By sharing objective facts and data taken from drug approval documents and scientific evidence, the center helps ensure that the Company's products are used appropriately.





## **Protecting Customer Privacy**

Mitsubishi Tanabe Pharma is committed to protecting its customers' personal information. In keeping with its strong sense of responsibility regarding this subject, it has made its Policy on Protecting Personal Information available to the public. Toward this end, the Company uses only fair and reasonable methods to collect customers' personal information and utilizes this information only to the extent necessary to achieve the purpose for which it was intended. In addition to these measures, it has taken the following initiatives with regard to the handling of personal information.

- (1) Established defined regulations regarding the protection of personal information
- (2) Instituted a structure for the protection of personal information, headed by a chief privacy officer (CPO) and staffed by privacy protection division managers and privacy protection personnel
- (3) Educated and trained employees; supervised and audited subcontractors
- (4) Implemented robust data encryption and all security measures on company computers

## Calls to Medical Information Center Improve Products: A Case Study

Staff at the Medical Information Center began getting calls from patients with complaints about Gastrom, a Mitsubishi Tanabe Pharma drug for treating gastritis and gastric ulcers that is dispensed at clinics in granular form. Patients were finding it difficult to pour the medication into their mouth, and requests were made that something be done about it. This patient feedback was relayed to the Company's quality control and manufacturing divisions. The MRs were hearing similar complaints at the medical facilities they visited, and the Company took action to remedy the situation.

Mitsubishi Tanabe Pharma's quality control and manufacturing divisions conducted a battery of tests. In the end, the original Gastrom strip packages (transparent, flat envelopes) were replaced with stick packages (cylindrical packets) to make it easier for patients to take the drug orally.



#### **Supporting Proper Self-Medication** for Skin Problems

Mitsubishi Tanabe Pharma believes it is important to help people suffering from dermatological problems to obtain accurate information and find a treatment as guickly as possible. Toward this end, it has been conducting a variety of educational programs in Japan since fiscal 2009 designed to get people "thinking about how to treat one's own skin problems."

These initiatives include TV commercials, magazine ads, and website content that explain the causes, symptoms, and treatment of skin problems.

The primary purpose of the TV commercials is to

educate viewers on when to see a doctor and when to self-medicate. These ads also stress that, in either case, early diagnosis of dermatitis, rashes, and other skin problems is important.



Mitsubishi Tanabe Pharma's website on dermatological issues

## **Providing Community Pharmacists** with a Network of Support

As part of its efforts to provide pharmacists who stock OTC drugs with the comprehensive knowledge that they need, the Company formed the Community Pharmacist Support Network in October 2011. Through this service, a pharmacist who becomes a member of the network receives information via an email magazine and access to an exclusive website for pharmacists.

The network's email magazine features a variety of timely content, including facts that pharmacists need regarding sales of OTC drugs and sample conversations

between pharmacists and customers. The exclusive website offers free online courses on OTC drugs, as well as email magazine archives, to give members constant access to the data that they need.



The Community Pharmacist Support Network website

#### **Providing Information on Generic Drugs**

Mitsubishi Tanabe Pharma Group applies the same strict quality control system and extensive distribution network that it has developed for its traditional brand-name drug businesses to generic drugs, as well. Under the slogan "Reliable generics," the Company maintains a stable supply of high-quality generic drugs across Japan through Tanabe Seiyaku Hanbai Co., Ltd., a Mitsubishi Tanabe Pharma Group company.

Tanabe Seiyaku Hanbai employs MRs with extensive experience and knowledge in generic drugs. Coupled with the Mitsubishi Tanabe Pharma Group's business assets, patients can expect to receive comprehensive information regarding the Company's generic drugs and the assurance

that the drugs can be relied upon. The Tanabe Seiyaku Hanbai website for medical professionals also provides the latest, most accurate data on the company's products.



Tanabe Seiyaku Hanbai's generic medicines

#### Medical News App for iPhone/iPad Launched

In June 2011, the Company launched its Mitsubishi Tanabe Pharma iPhone/iPad app for medical professionals. The app delivers Reuters Health Medical News articles to its subscribers.

Reuters Health Medical News is a news service for medical professionals provided by the U.S. company Thomson Reuters. With news stories from international conferences, articles from more than 100 medical

journals, and press releases from pharmaceutical companies, this service distributes the latest important medical news, organized according to specific disease or illness. The Company's app gives subscribers free access to articles in 11 categories, including rheumatism, cerebral circulation, and diabetes/ metabolic diseases.



Reuters Health Medical News in Mitsubishi Tanabe Pharma app

#### **Providing Information through** Websites

Mitsubishi Tanabe Pharma has set up websites in Japanese to provide clear explanations on subjects such as vaccines, as well as a number of different conditions and their symptoms, diagnosis, and treatment: rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriasis, cerebral infarction, sleep disorders, hemorrhoids, and liver failure.

In fiscal 2011, the Company added new health support websites about multiple sclerosis, Behcet's disease, and spinocerebellar degeneration and multiple system atrophy (MSA).

Imu Navi is a site focusing on multiple sclerosis. It was created to promote a better understanding of the disease among patients, their families, and medical professionals, as well as to help ensure that patients receive the proper treatment that allows them to live more comfortable lives.

Behcet's Disease Navi is a site designed to give patients with refractory uveoretinitis caused by Behcet's disease a clear understanding of the condition and an explanation of appropriate treatment.

SCD MSA Net is for patients with spinocerebellar degeneration or MSA. This website gives patients advice on how they can prolong their independent lives and also offers much-needed support to the family members who care for these patients on a day-to-day basis.



Behcet's Disease Navi

#### **Providing Information around** the World

To ensure that its drugs are used properly around the world, Mitsubishi Tanabe Pharma provides comprehensive information about its pharmaceutical products outside of Japan through its overseas subsidiaries.

In the United States, Mitsubishi Tanabe Pharma America, based in Warren, New Jersey, makes all the necessary preparations in the American market. In Europe, Mitsubishi Pharma Deutschland in Dusseldorf handles the marketing and sales of pharmaceutical products in its territory. MRs involved in sales need to have a wealth of knowledge, experience, and skills to communicate effectively with physicians and pharmacists. Each company provides the MRs in these countries with periodic training to improve their ability to provide comprehensive information.

In Asia, the Company provides a wide array of useful information to medical professionals through the Mitsubishi Tanabe Pharma Group companies operating in China, South Korea, Taiwan, and Indonesia. By exchanging views with opinion leaders, carrying out scientific research, and creating and distributing educational materials throughout academia, these subsidiaries support medical professionals.

The Mitsubishi Tanabe Pharma Group is providing comprehensive data on its pharmaceutical products with the overarching goal of contributing to people's health worldwide.

#### Fostering Relationships of Trust between Physicians and Patients Voice

In a conversation between a hepatologist and a patient with Hepatitis C, the doctor explains, "The Peginterferon-Ribavirin-Telaprevir combination therapy is extremely effective, but you do understand that there are definite side effects?" The patient answers, "Yes, I do, and that's the treatment I would like to go with."

This patient wants to eradicate the Hepatitis C virus, and based on the implicit trust he has in his doctor, he decides to go ahead with the more grueling antiviral drug combination. By explaining the pros and cons of the therapy, the doctor sets the stage for an effective treatment.

The conventional prescription for Hepatitis C worked extremely slowly and was not entirely adequate. Adding Telaprevir to the standard treatment, for a triple antiviral combination, substantially shortens the period of treatment required and increases its effectiveness in most cases. The downside is that the addition of Telaprevir causes more severe side effects than conventional treatment, and this means that the therapy must be administered under the strict supervision of a hepatologist or dermatologist.

As Mitsubishi Tanabe Pharma MRs, we work under the strict requirement that we document every single case. We do our best every day to foster close ties between physicians and their patients by providing these medical professionals with the knowledge they need regarding proper drug usage.

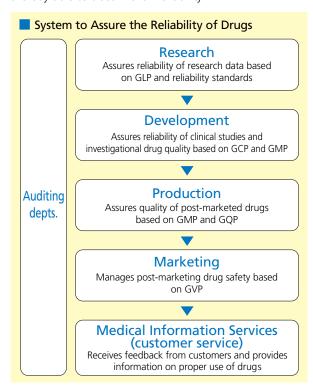


Takeshi Kobayashi Jonan Sales Office No. 2 Sales and Marketing Division, Tokyo Branch

## Assuring the Reliability of Drugs

## **Assuring the Reliability of Drugs**

Both in Japan and overseas, pharmaceutical reliability of drugs rests on three important factors: efficacy, quality, and safety. Pharmacovigilance and quality assurance for drugs means ensuring that the Company's drugs remain effective, of high quality, and safe throughout their entire lifecycles. In order to achieve this, each of Mitsubishi Tanabe Pharma's divisions in charge of the processes from research and development through post-marketing drug safety surveillance are mandated to uphold and comply with "good practice" guidelines and regulations (GLP, GCP, GMP, GVP, GPSP). The supervisory units, namely clinical and reseach QA and product QA sections, provide objective appraisals of the Company's compliance with these regulations and offer suggestions and instructions on the improvements, as appropriate. With those who abide by the good practices guidelines, and those who audit compliance with these guidelines fulfilling their respective roles, Mitsubishi Tanabe Pharma is able to ensure the efficacy, quality, and safety of its drugs, and healthcare professionals and patients alike are thereby able to trust in their reliability.



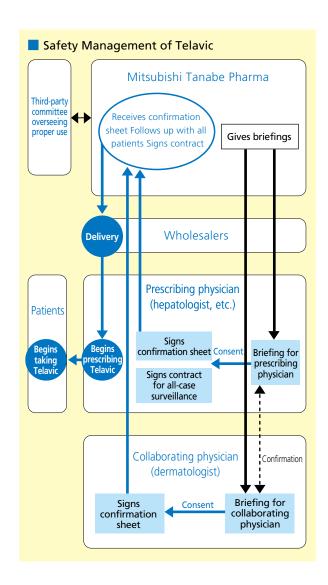
## **Safety Measures for New Drugs**

In the case of most new drugs, the process from clinical trial to marketing approval will not yield sufficient safety data. To address this issue. Mitsubishi Tanabe Pharma is required to gather further safety information during the post-marketing stage, in order to put safety measures

Mitsubishi Tanabe Pharma has launched a number of new drugs on the market since fiscal 2011. Two of them offer patients substantial benefits, but also come with high risks. Imusera is a drug having an entirely new pharmacological action, and Telavic is a drug with high possibility of serious adverse reactions. The Company recognizes the need to minimize such risks for patients by taking important safety measures in the postmarketing stage.

The safety measures developed for Imusera and Telavic are fundamentally the same. Patients taking Imusera are expected to experience arrhythmia after the first dose is administered and/or develop visual impairment during use. With Telavic, there is a high possibility of skin problems and/or blood disorders. The Company therefore requires that these two drugs be administered at medical institutions with the capacity to appropriately treat these adverse reactions. Additionally, prescribing physicians are asked to take an online education course on Imusera. The Company has set up a Committee for the Proper Use of Telavic, made up of medical experts who serve as a third party to advise and consult on drug safety. Through such means, proper distribution management of these drugs is implemented.

Although safety measures for drugs that Mitsubishi Tanabe Pharma provides vary according to the specific product, an increasing number of its safety measures in recent years involve third-party organizations and patients, in addition to the traditional involvement of corporations, governments, and healthcare professionals. The Company follows up on every patient's case to be certain that it does not miss important reports from any patient taking these drugs or any adverse reactions that occurred. In addition, it helps ensure that patients are able to detect as early as possible the adverse reactions that may be present in their own individual cases by providing patient notebooks and explanatory materials on the drugs that they will be taking.



## **Quality Assurance for Pharmaceuticals**

Mitsubishi Tanabe Pharma's highest priority is providing reliable drugs for patients. Its Quality Assurance Affairs Division undertakes a variety of activities to ensure that all products are of the highest quality. The Company rigorously supervises, audits, and directs its factories in Japan and overseas and handles any quality defects that may arise. It maintains product quality in accordance with ministerial ordinances on GMP for regulating drug manufacturing and on GQP for regulating the quality of drugs, as well as with the Mitsubishi Tanabe Pharma Group Quality Assurance Standards. In fiscal 2011,

the Company instituded a Quality Policy at the QA Management Department and all Group factories, as part of an effort to create a more robust drug supply system.

Mitsubishi Tanabe Pharma continues these efforts even after its products reach the market, by gathering feedback from those working directly with patients. The Company calls on nurses and pharmacists to hear about the actual use of drugs at medical institutions and talks with doctors, nurses, and pharmacists to find out how the Company's products are being used and under what conditions.

The Company will continue to make every effort to ensure that patients are able to trust in the reliability of the high-quality drugs that it produces.

#### **Education and Training in Pharmaceutical Safety**

As a measure to prevent recurrence of problem similar to the incident in Japan involving HIV-tainted blood products, the Company initiated a drug safety-education program in fiscal 2008 for all Mitsubishi Tanabe Pharma directors and executive officers, as well as the presidents, management teams, and all employees at Group companies engaged in the pharmaceutical business. The program aims to promote a greater awareness of safety issues related to drugs.

The drug safety education program for employees in fiscal 2011 focused on the litigation in Japan involving drug-induced Hepatitis C. The program featured a summary of the Hepatitis C incident, the process from litigation to settlement, and the proposals put forth by the Advisory Committee named "Drug Administration for preventingrecurrence of drug-induced suffering", a third-party committee formed post-settlement by Japan's Ministry of Health, Labour and Welfare.

The Company also conducted upper management seminars for executives at Mitsubishi Tanabe Pharma and

presidents of Group companies, in which an outside expert was invited to give lectures on the topic of Compliance as Risk Management in fiscal 2011.



Participants at an educational seminar on pharmaceuticals and safety

## Corporate Governance

#### **Basic Stance on Corporate Governance**

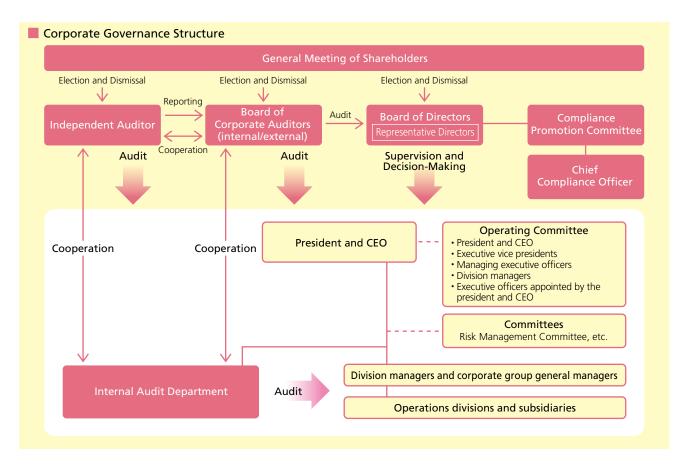
Mitsubishi Tanabe Pharma contributes to society through a corporate philosophy of creating pharmaceuticals that help people around the world lead healthier lives and through a corporate vision of being a global, research-driven pharmaceutical company that is trusted by local communities.

Mitsubishi Tanabe Pharma operates under a system of corporate governance designed to ensure that the Company fulfills its responsibilities to shareholders and all other stakeholders, and that great importance is placed on maximizing corporate value. This system promotes effective, speedy decision-making related to business management, transparency and objectivity through systematic oversight and supervision that incorporates robust auditing and outside directors.

## **Management System**

Mitsubishi Tanabe Pharma has adopted a Corporate Officer System to clearly distinguish business executive management functions and policy-making from the supervision of business operations. The Operating Committee is comprised of the President and CEO, Managing Executive Officers, and Executive Officers appointed by the President and CEO, and generally meets at least twice a month to discuss and deliberate all important issues related to business operations. This system ensures that effective decisions are made quickly.

The Board of Directors is charged with policy-making and the supervision of business operations. To ensure transparency and objectivity in the management of Mitsubishi Tanabe Pharma, this eight-member body includes two outside directors. In addition to regular monthly Board of Directors meetings, the Board calls interim meetings as needed to deliberate and report on items regarding important business administration matters.



## **Auditing System**

Mitsubishi Tanabe Pharma's auditing system centers on its Board of Corporate Auditors, comprised of four members, two of whom are outside auditors. The members of this Board audit the execution of corporate activities in a number of different ways. They attend important meetings, including those of the Board of Directors and the Operating Committee; interview directors, executive officers, and individual division managers regarding business operations; review documents related to major decisions; and investigate the operations of the Company's principal business sites and subsidiaries. The corporate auditors also exchange views closely with independent auditors. They have access to the independent auditors' auditing plans and policies, receive explanations concerning measures to ensure the proper execution of independent auditors' duties, and confirm the semiannual independent auditors' auditing results.

Auditors receive audit information on a monthly basis from the in-house, autonomous Audit Department concerning plans, progress and results of their internal auditing. The auditors also receive reports on the results of the semiannual evaluation of the internal control system concerning financial reporting.

Mitsubishi Tanabe Pharma has established a Corporate Audit Office with three full-time members who operate independently from business operations to provide support to these internal and external corporate auditors in the execution of their auditing duties.

Ernst & Young ShinNihon LLC has been appointed as Mitsubishi Tanabe Pharma's independent auditor. Every effort is made to provide them with accurate managerial information in an environment in which proper auditing can be conducted.

## **Accountability to Stakeholders**

At Mitsubishi Tanabe Pharma, we recognize the importance of public disclosure to provide an accurate basis by which stakeholders—including patients, medical professionals, shareholders, investors, and society at large—are able to evaluate corporate performance. Mitsubishi Tanabe Pharma therefore publicly discloses

important information concerning all of its corporate activities encompassing managerial policies, operational goals, and financial performance in a fair, prompt, and appropriate manner. Mitsubishi Tanabe Pharma complies with all applicable laws and ordinances, including Japan's Financial Instruments and Exchange Law, and the information disclosure regulations of stock exchanges on which this Company is listed. Compliance with these laws and ordinances is mandated by in-house information disclosure regulations to ensure appropriate content and timing of information disclosure to our stakeholders. Mitsubishi Tanabe Pharma takes feedback from all stakeholders seriously and strives to share information in an effort to deepen mutual understanding.

At the periodic institutional investor meetings, Mitsubishi Tanabe Pharma presents information on financial performance, the development of new products, important managerial policies, and business expansion. Briefings are also held as necessary to discuss research and development, as well as other importnat business issues. The Mitsubishi Tanabe Pharma website provides video and audio recordings of these meetings along with details of Q&A sessions for individual and overseas investors. The annual report for shareholders and investors provides information on corporate performance for each fiscal year.



Financial performance briefing



Briefing on Medium-Term Management Plan



Annual Report 2012

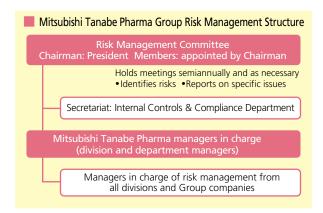
## Risk Management

#### **Management of Risks Associated** with Business Activities

The Mitsubishi Tanabe Pharma Group has established risk management rules to manage appropriately the risks associated with its business activities. Based on these rules, each of the divisions at Group companies works to accurately identify the existence, type, and importance of the risks associated with its activities and to take the necessary steps to manage these risks. The Group has implemented a system for reducing risks that affect the organization as a whole. This system operates under the supervision of the Risk Management Committee, which is chaired by the president and CEO and meets semiannually as well as when deemed necessary.

In fiscal 2011, Group divisions and companies focused on identifying potential risks that affect their respective units. The Group has reviewed those deemed serious (risks for which potential damage is estimated at one billion yen or more), identified the divisions primarily and peripherally responsible, and established the roles of those divisions and the responsibility for reporting on risks to the management team. Risks affecting management strategy come under the general control of the Corporate Planning Department.

Serious risks that potentially affect the organization as a whole are monitored closely by tracking progress on measures taken by the divisions primarily and peripherally responsible for mitigating these risks. Individual divisions and Group companies take responsibility for informing their employees of identified risks and raising awareness in order to foster an environment in which individuals are able to identify problems and propose measures to trigger Group-wide action.



Classifications for Risk Management Activities (Measures for Reducing Standard Risks) Identified Risks Associated with Business Activities Risk Control Adapted to Classification (1) Management strategy risks (managed by Corporate Planning Department) (2) Other risks (managed by Internal Controls & Compliance Department) Organizational or Divisional Response (1) Response coordinated by divisions primarily and peripherally involved (2) Independent divisional or company measures to reduce risk Risk Control Classified by Gravity and Priority (1) Serious risks (potential damage estimated at one billion yen or more) (2) General risks (potential damage estimated at less than one billion yen)

## **Guidelines for Large-Scale Disasters**

As an organization that manufactures and supplies pharmaceuticals, the mission of the Mitsubishi Tanabe Pharma Group is to maintain sufficient inventory of emergency-use pharmaceuticals. These are pharmaceuticals for which there are no substitutes and are therefore crucial to sustaining the lives of patients, making an uninterrupted and stable supply of pharmaceutical products to the extent possible a matter of critical importance. The Group's Guidelines for Large-Scale Disasters outlines concrete measures for preparedness and provides a framework for ensuring a steady supply of pharmaceuticals in the face of massive earthquakes and tsunamis in Japan.

#### Overview of Guidelines for Large-Scale Disasters

Basic Emergency Response Policy

- 1. Measures to prevent and mitigate disaster
- 2. Initial response when large-scale disaster strikes
- 3. Resumption of business and Business Continuity
- 4. Support for victims and recovery activities

#### **Crisis Management** When Risks Occur

There are times when the best efforts to reduce risks by developing and implementing a risk management system are not enough—an unexpected disaster or accident occurs or a potential risk materializes and develops into a crisis. In these cases, the Mitsubishi Tanabe Pharma Group divisions primarily responsible take the measures required to minimize the impact on and damage to society, and depending on the severity of the situation, the Group may set up an emergency response headquarters to handle the crisis.

Mitsubishi Tanabe Pharma Group has established the following crisis management procedures.

- (1) The division bearing responsibility should report immediately to the Internal Controls & Compliance Department and to the division primarily responsible for handling that specific situation.
- (2) The division responsible for risk handling should take measures in coordination with peripheral divisions and report the situation to the relevant authorities, the Company's suppliers, and any other entities involved.

(3) The division primarily responsible should devise preventative measures and trigger the involvement of peer groups to ensure a coordinated Mitsubishi Tanabe Pharma Group effort to reduce risks.

If a crisis threatens to have an extensive impact on the public or requires a Group-wide response, Mitsubishi Tanabe Pharma will set up an emergency response headquarters. The Great East Japan Earthquake in 2011 was one such situation. The headquarters, set up immediately following the earthquake, responded with measures in two steps: an initial emergency phase focused on ensuring a steady supply of pharmaceuticals and providing relief to earthquake victims, and a secondary stage focused on responding to aftershocks, electricity shortages, and radiation.

#### Major Assumed Risks

- 1. Risks that cause a profound loss of trust in the Company as a pharmaceutical manufacturer
  - Failure to gather data and provide safety-related information in a timely and appropriate manner
  - \* Failure to maintain a stable supply and sufficient quality of products
- 2. Risks that cause loss of life or bodily harm to executives and employees

#### Column Responding to the Great East Japan Earthquake

Although Mitsubishi Tanabe Pharma Group offices were damaged in the Great East Japan Earthquake that struck on March 11, 2011, the Group was able to maintain a stable supply of pharmaceuticals with cooperation from wholesalers and in collaboration with production, distribution, and other divisions at Group companies.

#### Mitsubishi Tanabe Pharma Factory Ltd, Kashima Plant

The Kashima Plant in Ibaraki Prefecture experienced intermittent loss of power, loss of water, and aftershocks. In spite of those problems, the Group was able to ascertain the extent of the damage the day after the earthquake, and was able to restore operations. Although there was no irrevocable damage to the plant or its facilities, restoration work required repairs to fallen walls and damaged pipes and ducts, as well as the

procurement of replacement machinery parts for repairs. Without knowing for certain when water service would be restored, maintaining water supplies to the factory was a particularly serious problem. The Kashima Plant was back up and running on April 11, 2011, because Mitsubishi Tanabe Pharma was able to carry out repairs with extensive support not only from Group companies but from others as well.

#### Mitsubishi Tanabe Pharma Factory Ltd, Ashikaga Plant

The Ashikaga Plant in Tochigi Prefecture sustained damage from the intense seismic tremors, including displaced pallets that



Manhole cover displaced by liquefaction of the ground near the Kashima Plant



Raw materials strewn across the warehouse floor after the earthquake

caused the loss of raw materials in its multistoried warehouse. Although clearing and repairing the damage was a difficult job, with the invaluable help of employees from Company offices, the warehouse was back in operation by April 11, 2011.

#### MP-Logistics Corporation, East Japan Distribution Center

The East Japan Distribution Center in Kashiwa City, Chiba Prefecture, sustained damage to the cranes, conveyor belts, and other equipment in its automated multistoried warehouse, forcing the temporary suspension of its distribution functions. Under MP-Logistics' distribution backup system, the West Japan Distribution Center took over these functions while the East Japan Distribution Center was offline. In order to handle the load, the West Japan Distribution Center went into 24-hour-a-day operation mode, with ten East Japan Distribution Center employees on loan to provide additional help. Employees from other divisions also

provided initial distribution support until the backup system was fully in place, ensuring that there was no disruption in the shipment of pharmaceuticals. Thanks to these efforts and accelerated restoration work, the East Japan Distribution Center was once again fully operational by April 11, 2011.



Automated warehouse immediately after the earthquake

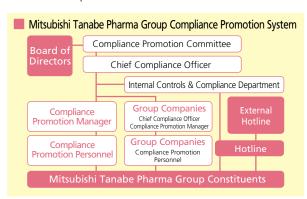
## Compliance

#### **Compliance Promotion System**

The Mitsubishi Tanabe Pharma Group has in place a Group-wide compliance promotion system overseen by its Compliance Promotion Committee, which is chaired by the Chief Compliance Officer.

Under this system, the Group conducts compliance training, raises awareness of its hotlines and consultation services, and carries out other compliance-related activities, in line with its Compliance Code of Conduct, which sets forth specific behavioral guidelines in accordance with its Corporate Behavior Charter.

Throughout the Group, the department heads are designated Compliance Promotion Managers, and the most qualified employees are compliance promotion personnel tasked to take responsibility for the activities in each workplace. The compliance promotion managers and personnel meet semiannually to discuss compliancerelated issues in the workplace, promote the exchange of compliance-related information, and conduct training programs to enhance the capacity of individual workplaces to handle compliance issues related to each location.



#### Compliance Code of Conduct

- 1. We conduct our business with high ethical standards and in a professional manner as a global healthcare company.
- 2. We respect our employees, encourage open and honest communication, and promote safe and healthy working conditions.
- 3. We comply with all legal requirements and regulations that apply to our businesses and corporate activities.
- 4. We actively work to protect the global environment and strive to realize the harmonious co-existence of the Company and society.
- 5. We strive to trade and transact business in a fair manner at all times.
- 6. We appropriately manage company information and data, and work to ensure that such information and data are disclosed in a timely and reasonable manner.
- 7. We appropriately manage and efficiently use company assets.

## **Compliance Training**

The Mitsubishi Tanabe Pharma Group holds a number of different training programs throughout the year in order to foster a strong sense of ethics and raise awareness of compliance requirements among employees at Group companies engaged in the pharmaceuticals business.

Group-wide compliance training in fiscal 2011 was designed not only to provide information on and increase understanding of this subject, but also to instill a sense of the importance of greater awareness. For these training programs, the Group shifted away from a conventional lecture format to encourage conversations and discussions that would cultivate a greater awareness of compliance issues among all employees, including those at Mitsubishi Tanabe Pharma affiliates. The discussion format was also utilized at divisional training sessions, with topics that related specifically to the respective divisions.

#### List of Training Sessions Held in Fiscal 2011

	•		
	Type of training	Times held	Number of participants
	Company-wide sessions	218	7,627
Compliance training	Divisional sessions	303	7,236
training	Top seminars	1	39
New management training		2	67
Management training		14	749
New employee training		1	74

## **Hotlines**

The Mitsubishi Tanabe Pharma Group's internal and external hotlines allow employees and managers to seek consultations and make reports regarding violations of laws, ordinances, or social conventions. At the end of each six-month period of the fiscal year, the number of calls handled by these hotlines is posted on the Group's intranet, and the recent trends and issues indicated by the consultations and warranting special mention are reported during training sessions.

To improve accessibility to the hotlines, the Group has provided toll-free numbers and extended hotline operations beyond business hours. The Mitsubishi Tanabe Pharma Group has also set up a system for direct calls from suppliers regarding concerns related to the Group.

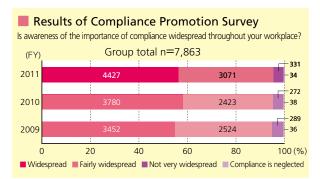
#### Number of Hotline Cases in Fiscal 2011

Regulations	Labor management	Preliminary consultations	Other	Total
26	16	5	6	53

#### **Monitoring Compliance Promotion Conditions**

The Mitsubishi Tanabe Pharma Group monitors how compliance issues have been promoted by conducting a yearly Compliance Promotion Survey of all Group employees in order to increase awareness of compliance issues throughout the entire Group. In fiscal 2011, the Group provided employees with information regarding quality control problem, following this with a compliance questionnaire that included a survey on the Medway Issue and the quality control problem. This combined online survey drew 7,941 responses, a response rate of 93.4 percent.

In answer to the question, "Is awareness of the importance of compliance widespread throughout your workplace?" a combined total of 95 percent responded that awareness was "widespread" or "fairly widespread."



## **Corporate Behavior Charter Day**

Taking into account the seriousness of the Medway Issue and the quality control problem, and recognizing the need to prevent any recurrence of such situations, the Mitsubishi Tanabe Pharma Group has established an annual Corporate Behavior Charter Day. This day provides an opportunity for all employees to review the Group's Charter and reflect on their individual conduct. In addition, Bipha, a Mitsubishi Tanabe Pharma Group company in Japan, has also introduced a designated Compliance Day on April 13 each year.

For the 2012 Corporate Behavior Charter Day, Mitsubishi Tanabe Pharma invited outside experts to speak at its Osaka Headquarters and Tokyo Head Office on April 13 and at the Kashima Office on April 19. To mark Compliance Day, Bipha presented the results of an in-house awareness

survey focused on the workplace environment and had employees sign Compliance Cards.

Compliance meetings were held in April, during which time every employee studied the Compliance Guidebook, reconfirmed the Code of Conduct, and affixed their signature to their personal copies of the Guidebook.

## **Compliance at Overseas Group Companies**

The Mitsubishi Tanabe Pharma Group consults regularly with the relevant divisions of its Group companies concerning their respective action programs. These programs outline concrete approaches and program timelines designed to enhance risk management and compliance systems at overseas subsidiaries.

Based on reviews and analysis of calls made to overseas subsidiary hotlines, the Group works to strengthen risk management in line with the particular circumstances at each subsidiary and in accordance with that country's laws, regulations, and cultural mores.

In preparing for compliance with overseas anticorruption laws that were strengthened recently, the Group is focused on gathering all relevant information. This includes, for example, the Foreign Corrupt Practices Act (FCPA) in the U.S., the UK Bribery Act 2010, and bribery and corruption measures in China.

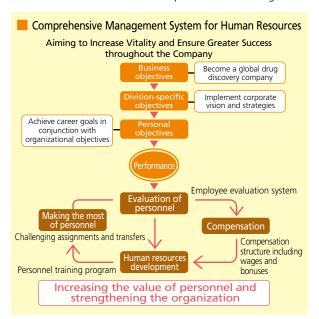
## **Restoring Public Trust**

Mitsubishi Tanabe Pharma recognizes the gravity of the fact that additional quality control problem that further damaged the public's trust in the Company were identified in January 2011, just when the Company was working to implement its business improvement plan related to the Medway Issue. In response to this incident, the Company devised a new improvement plan to address overall quality control issues based on a reevaluation of the effectiveness of the orginal plan, and submitted the revised plan to the Ministry of Health, Labour and Welfare in August 2011. Since that time, the entire Mitsubishi Tanabe Pharma Group has been working to prevent a recurrence of such incidents and restore the public's trust in its operations. As part of this effort, the Group has set up a committee made up of experts from outside the Group to objectively assess conditions related to the Medway Issue and the quality control problem.

## **Training Human Resources and Promoting Work-Life Balance**

#### **Fundamental Approach to Human Resources**

Requiring employees to follow high standards of ethics, fairness, and integrity, Mitsubishi Tanabe Pharma focuses its human resources training on four standards for conduct: Pride and a Sense of Mission, Challenge and Innovation, Trust and Teamwork, and Harmonious Co-Existence with Society. In an effort to build a flexible and dynamic organization, the Company established its Comprehensive Management System for Human Resources to create a system that encourages employees to pursue personal growth, while at the same time channeling their energies toward strengthening the Company. In its Medium-Term Management Plan (2011 to 2015), Mitsubishi Tanabe Pharma is focused on positioning itself as a company that continuously produces new value. Toward this end, the Company is taking steps to enhance its human resources and organizational systems to facilitate global development that will accelerate its businesses and corporate restructuring.



#### Number of Employees

	March 31, 2009	March 31, 2010	March 31, 2011	March 31, 2012
Consolidated	10,030	9,266	9,198	9,187
Unconsolidated	5,715	5,186	4,957	4,826
Males	4,563	4,152	3,968	3,869
Females	1,152	1,034	989	957

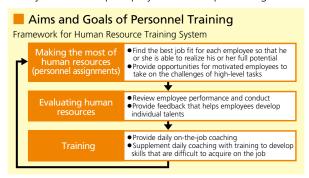


#### **Management System for Personnel Training**

Mitsubishi Tanabe Pharma regards its human resources as its most important asset and the wellspring of its value as a company. In order to ensure the best from and for its employees, Mitsubishi Tanabe Pharma has introduced a management system and framework for personnel training that promotes medium- to long-term career planning and fosters the development of highly motivated employees who will contribute even more to the vitality and performance of the Company.

The Company offers the following programs to support employees in realizing their full potential and individual talents.

- (1) A rotation system based on a respect for personal growth and motivation and designed to find the best job fit for each employee so that he or she is able to realize his or her full potential
- (2) On-the-job training and other support programs designed to help employees fulfill their personal goals and successfully contribute to the Company through proper goal management
- (3) Training programs tailored to specific subjects and objectives to help employees achieve personal growth



#### **Improving Personnel Training by Enhancing Training Seminars**

As it strives to become a global drug discovery company, Mitsubishi Tanabe Pharma offers employees systematic medium- to long-term career planning. In fiscal 2011, the Company introduced next-generation leadership training programs to provide systematic career planning for employees destined for upper management positions, as well as global staff training programs designed to pave the way for the Company's future global development.

The Company established the Human Resources Development Department in 2011 to integrate its recruitment and training activities, and the subsequent restructuring in April 2012 has allowed this department to function with greater flexibility and resources. In fiscal 2012, this department has been actively focused on measures to improve its tiered and career-track training programs, as well as to provide support for career management and individual skills development.

Training Program									
Level	Targeted staff	Car tr	eer tr	ack g	Career management support	Inc de	lividu evelo	ıal ski pmen	lls t
Managers and highly skilled staff	Directors General managers Newly appointed GMs Managers Newly appointed managers Manager assessment Promoted employees Employees eligible for new K1 training	Next-generation leadership training programs	Global leadership training programs	Education leave	Self-improvement training f developing valuable skills	Optional training programs	Correspondence courses	English and Chinese conversation courses	In-house TOEIC classes
Regular employees	Employees eligible for new E-level training Third-year employees New employees	adership ams	training	Ve	aining for ole skills	ograms	ourses	Chinese courses	lasses

## **Surveying Employee Attitudes**

In October 2011, the Mitsubishi Tanabe Pharma Group introduced employee attitude surveys. The surveys provide a comprehensive understanding of employee attitudes toward their jobs and a clear picture of the Company's workplace environments. The findings are incorporated into the Group's management policies.

At Mitsubishi Chemical Holdings, these surveys are conducted as part of its own employee satisfaction surveys. Responses to questions concerning employee satisfaction are included in calculations of the MOS index used in the APTSIS15, which is Mitsubishi Chemical Holdings' medium-term action plan.

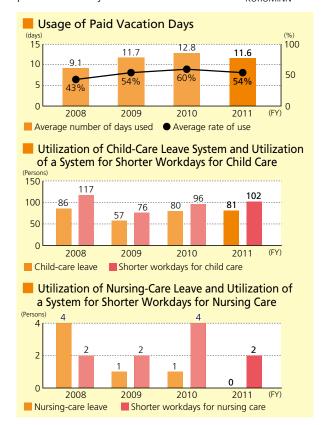
## **Promoting Work-Life Balance**

Mitsubishi Tanabe Pharma strives to create an environment in which every employee can comfortably balance work with his or her personal life and family commitments. The Company recognizes the importance of employees gaining satisfaction and pride from their work while fully experiencing meaningful life events, such as the birth of a child or caring for children and family members. This approach contributes to general business owner action plans formulated in compliance with the Next Generation Nurturing Support Measures Promotion Law. Since 2007, the Company has been certified for three consecutive periods as a "general business owner conforming to standards," earning it the next generation accreditation

mark "KURUMINN". In working to achieve the objectives laid out in its fourth Business Owner Action Plan, the Company has instituted a regularly scheduled "No-Overtime Work Day" and encourages employees to use their annually allotted paid vacation days.



Next generation accreditation mark "KURUMINN"



## **Ensuring a Safe and Fair Working Environment**

#### **Occupational Health and Safety Initiatives**

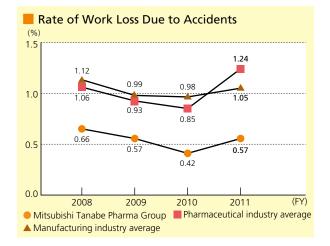
In accordance with the belief that safety is fundamental to its very existence, Mitsubishi Tanabe Pharma Group takes safety measures designed to eliminate workplace accidents or disasters. In order to promote ongoing efforts to assist employees in managing their health and ensuring their safety at work, the Company operates an occupational health and safety management system based on the Plan-Do-Check-Act (PDCA) cycle to minimize safety risks in the workplace.

Under the occupational health and safety management system, Mitsubishi Tanabe Pharma Group is working to raise safety awareness among all employees. Recognizing that increasing employees' awareness is vital to any effort to prevent workplace disasters and accidents, especially risks associated with unsafe practices, the Group's annual safety training covers not only hazard prediction and the prevention of human error, but provides employees with experience-

based activities, as well. The overarching aim of this training is to improve employees' ability to recognize unseen hazards in the workplace.



Hazard prediction training helps prevent accidents by training employees to recognize unseen hazards in the workplace and in work procedures.



#### **Safety Management of Chemical Substances**

Mitsubishi Tanabe Pharma Environmental Safety Assessment Guidelines were developed to help prevent accidents and disasters before they occur. These guidelines call for potential risks to be evaluated through safety assessments (SA) whenever changes are made to processes, raw materials, equipment, or personnel. In fiscal 2011, as part of its work to improve the safety management of chemical substances, the Company revised portions of its Environmental Safety Assessment Guidelines in accordance with a thorough review of the laws and regulations related to the substances in use at the time of its safety assessment. The guideline revisions were carried out to mitigate the risks posed by changes in the chemical substances used in operations.

## **Addressing Mental Health Issues**

Mitsubishi Tanabe Pharma actively works with employees on managing stress for better mental health. In fiscal 2010, the Company introduced a self-diagnosis program to help employees identify and relieve stress before it takes a toll on their mental and emotional state. Mitsubishi Tanabe Pharma offers general mental health counseling as part of its health insurance package. Following the Great East Japan Earthquake in fiscal 2011, the Company added a counseling office operated by the Japan Industrial Counselors Association and expanded the specialized counseling available to employees. The Company has also released a Guidebook for Managing Mental Health as part of its efforts to bolster its Group-wide measures for maintaining mental health.

## **Implementing Project NVC**

In December 2011, the Mitsubishi Tanabe Pharma Group implemented Project NVC, a project that focuses on new value creation to build a more dynamic and robust organization. Project NVC targets a variety of different initiatives, including cross-divisional exchanges of opinion and the reevaluation of work structures and rules, with the goal of ensuring continuous growth for the Mitsubishi Tanabe Pharma Group going forward. The Group is committed to creating a corporate culture, in both individual workplaces and the organizational structure, that encourages each employee to play an active and vital role.

## Valuing Diversity in the Workplace

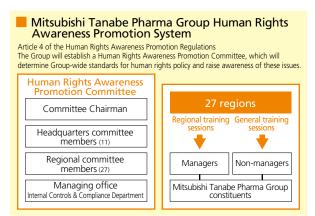
In response to Japan's shrinking workforce, caused by a combination of a falling birthrate, aging population, and increasingly diverse and individualistic values, Mitsubishi Tanabe Pharma has introduced working conditions that accommodate differing work styles. Adapting to the diversity in employees' lifestyles, the Company offers flextime, a discretionary work system for planning or specialist roles, and system of deemed working hours outside workplace or work fewer hours. The Company assists female employees in acquiring the expertise needed for promotion to managerial positions and assuming other leadership responsibilities. Mitsubishi Tanabe Pharma encourages older employees who wish to work to continue utilizing their wealth of experience and skills, and toward this end, introduced a reemployment system in 2009 for retired employees The reemployment system is open to employees over the age of 60 who fulfill certain requirements.



#### **Initiatives to Raise Human Rights Awareness**

The Mitsubishi Tanabe Pharma Group respects the ten principles of the United Nations Global Compact, which address human rights, labor, the environment, and anticorruption, and upholds these principles in its business activities as a responsible corporate citizen in line with its Corporate Behavior Charter. The Company's Human Rights Awareness Promotion Committee, chaired by the president, plays a key role in both in-house employee training and other Group-wide human rights training programs, which include collaborating with outside groups and employee participation in outside lectures.

In anticipation of Human Rights Week in December every year, the committee holds a contest in which employees are encouraged to consider human rights issues and increase their general awareness by composing human rights slogans. In fiscal 2011, a total of 208 entries were submitted by employees throughout the Group.



#### Addressing Harassment

Under its Compliance Code of Conduct, the Mitsubishi Tanabe Pharma Group is committed to "respecting our employees, encouraging open and honest communication, and promoting safe and healthy working conditions." As part of its commitment to raising awareness and eliminating harassment in the workplace, the issue of harassment is addressed in both Group-wide compliance training and management training. The Group has also established multiple channels for reporting harassment, including internal and external hotlines dedicated to harassment issues.

#### Labor Union Relations

In April 2009, the labor unions from the former Tanabe Seiyaku Co., Ltd. and the former Mitsubishi Pharma Corporation merged to form the Mitsubishi Tanabe Pharma Labor Union. This union reached a labor agreement with the newly merged Mitsubishi Tanabe Pharma Corporation guaranteeing the working conditions and rights of union members. The Company and the union regularly hold labor and management meetings in which the two parties exchange an array of information and opinions on workplace conditions. The members of the Labor and Management Committee also contribute their views on specific issues to promote a better working environment.

## **Participating in the Community**

#### **MSC Volunteer Salon**

Mitsubishi Tanabe Pharma sponsors the MSC Volunteer Salon, an event held every other month featuring seminars and small concerts. An acronym for "makers, sellers, and consumers" as members of society, the MSC Volunteer Salon provides opportunities for people interested in volunteer activities to interact with active volunteers. In fiscal 2011, the salon focused on issues concerning food and the global environment and attracted more than 600 participants in all.

The MSC Volunteer Salon collects donations of used stamps and telephone cards. The salon administrative

office collects the donated items and presents them to welfare groups and other organizations in Japan to be used to support the activities of these organizations.



Food culture historian Hisao Nagayama

#### **Summer Festival in** Yoshitomi Town

In August 2011, the Mitsubishi Tanabe Pharma office in Yoshitomi Town (Fukuoka Prefecture) sponsored the Yoshitomi Summer Festival, an event that takes place every year. The day was filled with stage performances by classical Japanese drummers, comedians, Tahitian dancers, and others, and the audience exceeded 2,000 people, including local residents, employees, and their family members. Festival goers were treated to a fireworks display that was the event's grand finale.



Children dance on stage at the Yoshitomi Summer Festival

#### Column **MSC Volunteer Salon Activities**

#### Message from an MSC Volunteer Salon

Founded in 1967 as the MSC Health Salon, the first MSC Volunteer Salon was held the following year at Ginza Gas Hall in Tokyo, with the former Tanabe Seiyaku as its main sponsor. At the time, the word "volunteer" had not yet become a part of everyday Japanese vocabulary, and its meaning only gradually became clear as the salon host explained it at each meeting.

Several Tanabe Seiyaku employees took on the salon's administrative duties, while the members divided up into volunteer groups to focus on specific activities: folding diapers at a daycare center, visiting child welfare facilities and nursing homes, collecting used stamps, or editing the newsletter. As part of the group that worked on the newsletter, I summarized lectures given at the salon meetings and wrote articles on local events and circumstances.

Before long, membership in our salon grew as Japanese people came to better understand the meaning of the word "volunteer." I believe that as volunteers, the spirit with which we undertook these activities shifted from doing for others to being grateful for being able to do for others. My newsletter continued to come out until 1997, with 258 issues in all.

After taking some time off to recharge our batteries,

we began holding bimonthly meetings at Jujiya Hall in the Ginza area of Tokyo in April 1997. Today, the Corporate Communications Department at Mitsubishi Tanabe Pharma has taken over the administration of the salon, plans lectures, and has introduced mini concerts by the Grace Society, an association that promotes arts and social welfare through volunteer activities that incorporate music. Another difference in our salon today is greater participation from men.

It surprises me to realize that I have been involved with the MSC Volunteer Salon for more than 40 years now. I hope that I can continue serving the community in useful ways, and always from a spirit of gratitude.

Finally, I would like to take this opportunity to offer my heartfelt appreciation to Mitsubishi Tanabe Pharma for their extensive help with our salon activities.

Mayumi Miyajima MSC Volunteer Salon member



## **Supporting Employee Volunteerism** in Earthquake-Stricken Areas

Between July 2011 and March 2012, the Mitsubishi Chemical Holdings Group provided support for volunteer activities conducted by Group employees in areas hit by the Great East Japan Earthquake.

A total of 200 employees from the Mitsubishi Chemical Holdings Group took part over the course of the volunteer program. Of these, 40 were employees of the Mitsubishi Tanabe Pharma Group. Conducted in collaboration with the non-profit organization, Peace Winds Japan, employee volunteers took part in removing rubble and surveying disaster victims living in temporary housing in the Kesennuma, Rikuzen Takada, Ofunato, and Kamaishi areas.

#### **Donating Drugs to a Children's Park**

As part of its social contribution activities, Mitsubishi Tanabe Pharma has been donating over-the-counter (OTC) drugs to Kodomo-no-kuni (Children's Land) since 1971. This children's park in Yokohama City is operated by the Kodomo-no-kuni Association, a social welfare service organization.

On the day the donation was made, Park Director Katsuhide Yasuzawa expressed his appreciation, saying, "This year marks the 40th year of assistance from

Mitsubishi Tanabe Pharma, and we are extremely grateful. The donated drugs help keep the children well, so they can have a great time playing in the park."



Donating OTC drugs

## Field Trips to Tanabe Seiyaku **Yoshiki Factory**

As part of its contributions to the local community, Tanabe Seiyaku Yoshiki Factory Co., Ltd. hosted 100 third graders from the local elementary school on a tour of its facilities in December 2011. The tour featured an animated film to help the children understand the processes involved in manufacturing medicine in a sanitary environment and the special uniforms worn in laboratories. Touring the factory itself, the children were surprised and impressed by the speed and accuracy of the packaging machines and the size of the multilevel warehouse. In the days after the field trip, there was much talk in the community about

how excitedly the children were chatting about their impressions, and this provided another opportunity for parents and others to see the factory as a solid member of the community.



Children listen to a presentation at the factory

#### Column | **Great East Japan Earthquake Volunteer Activities**

#### Message from Great East Japan Earthquake Recovery Volunteer Employee

After the Great East Japan Earthquake had struck, I began thinking that, if I had the opportunity, I would want to do something to help in the stricken area. I heard that my company, Mitsubishi Chemical Holdings, was looking for volunteers to help with activities in the area, and thanks to the support of my boss and other members of our project, I arranged to join seven employees for two days of work on August 16 and 17, 2011.

On our first day there, we visited temporary housing set up in the Ryori area in Ofunato City and close to Ofunato Junior High School in Iwate Prefecture. We surveyed residents on the situation regarding their use of local certificates for daily necessities. The certificates were being distributed by Peace Winds Japan to disaster victims, to help revitalize the local economy.

The second day, we participated in cleanup activities at Ninohama Beach in Kesennuma. Among other adverse conditions, the roads here would flood during high tide, so little progress had been made to clean up Ninohama. The area was piled high with garbage and rubble washed in by the tsunami, and we spent the entire day working to sort the waste.

One person can only do so



Volunteers sorting waste (Numata, second from left)

#### Atsushi Numata

Department I, Drug Discovery Research Facility I, Research Division

much, but when different groups of volunteers pull together, a great deal can be accomplished. I hope to see the area that was hit so hard by the earthquake and tsunami recover as soon as possible, and I plan to find a number of different ways to contribute in the future.

#### **Supporting Research through Foundations**

Mitsubishi Tanabe Pharma provides financial assistance to the Mitsubishi Pharma Research Foundation and the Japan Foundation for Applied Enzymology as a means to fund research in a broad range of fields including medicine, pharmaceuticals, agriculture, and the physical sciences. By providing support for the activities of both foundations, the Company works to promote research and provide information that benefits medical treatment and public health.

In fiscal 2011, the Company added research grants to support areas affected by the Great East Japan Earthquake for the purpose of promoting advanced research in medicine and pharmacology in this region.

#### Grants to the Mitsubishi Pharma Research Foundation in Fiscal 2011

	Total	119 projects	141 million yen	
stricken areas	Cardiovascular medicine	2 projects	3 million yen	
research that supports disaster-	Hematology	2 projects	3 million yen	
Grants for	Pharmacotherapy	3 projects	8 million yen	
Special projects		1 project	10 million yen	
medicine research	Financial aid for education abroad	2 projects	4 million yen	
cardiovascular medicine research	New research areas	10 projects	10 million yen	
Grants for	Basic research	23 projects	23 million yen	
research	Financial aid for education abroad	1 project	2 million yen	
hematology research	New research areas	11 projects	11 million yen	
Grants for	Basic research	27 projects	27 million yen	
research	Financial aid for education abroad	3 projects	6 million yen	
pharmacotherapy	New research areas	10 projects	10 million yen	
Grants for	Basic research	24 projects	24 million yen	

#### Grants to the Japan Foundation for Applied Enzymology in Fiscal 2011

Grants for enzyme	Applied research on enzymes and enzyme research related to life science	30 projects	22.5 million yen
research	The Japanese Society of Applied Glycoscience	1 project	300,000 yen
Grants for	Research groups focused on determining causes and conditions of adult-onset diseases	42 projects	14.95 million yen
specific groups	Vascular Biology Innovation Conference	17 projects	10.5 million yen
and activities	Research groups focused on determining causes and conditions of systemic inflammation	7 projects	7 million yen
Total		97 projects	55.25 million yen

#### **Seminars for Patients and Their Families**

In collaboration with the Japan Spinocerebellar Degeneration & Multiple System Atrophy Society, Mitsubishi Tanabe Pharma co-sponsored the Seminar for SCD & MSA Patients and Their Families in March 2011.

The seminar included lectures by three specialists on these conditions and a panel discussion with a Q&A session. Actress Kazuko Kato joined the panel discussion as a special guest to speak about the invaluable experience she gained in her film role as a mother suffering from spinocerebellar degeneration.

The seminar was held in Tokyo and open to the public. To accommodate all those unable to attend in person, however, videos of the proceedings were streamed online as well. With 74 persons attending in the audience and 212 via the web stream, a grand total of 286 individuals participated.

Mitsubishi Tanabe Pharma will continue working on a variety of different activities in order to better provide information to patients and their families.



Seminar for SCD & MSA Patients and Their Families



## ODIC Supporting Patients' Associations

As a means of fostering patient-centered healthcare, Mitsubishi Tanabe Pharma provides support for patients' associations in a variety of ways, including sharing useful information and providing assistance for volunteer activities. Invaluable feedback from two of these patients' associations follows below.

### It's important to get to know each patient individually.

Founded more than 35 years ago, Asebikai is a support organization for patients suffering from extremely rare and incurable diseases such as neurofibromatosis (types 1 and 2) and epidermolysis bullosa. These patients would gather to discuss what they were going through and the difficulties of having so few specialists with whom to consult. With no one to get advice from, they were often left to face the situation alone. Recognizing the need, we created a nationwide network of patients, as well as their families and doctors, to provide as much support as possible.

Throughout the years, we have worked in various ways to put pressure on government officials and politicians about this issue. This experience has made me keenly aware of just how difficult it is for individuals with special needs, particularly those with rare and incurable diseases, to fit within the various government systems in place.

It is true that with the Internet, patients do have access now to a great deal of information, but our association still plays an essential role in getting to know patients as individuals and putting together accurate information tailored to their specific conditions. In fact, that role is even more important in this day and age. I would invite everyone who works at a pharmaceutical company to do more to take into account the perspectives of individual patients as they work to develop drugs to treat rare, incurable diseases.

Having an incurable disease herself, Emiko Sato has been involved with the administration of a number of patients' associations. In 1977, she formed Asebikai, an organization that provides support to patients with rare and incurable diseases with a counseling hotline, lectures, and recuperation facilities. Mitsubishi Tanabe Pharma will continue to provide support as a corporate contributor to the association.

#### **Emiko Sato**

Director, Asebikai (National Association of Persons with Rare and Incurable Diseases) Chairman of the Board, Social Welfare Corporation Fukusei Asebikai



### Hoping for the development of more new drugs and the provision of more information in the future

Inflammatory bowel disease (IBD) is a generic term for ulcerative colitis, Crohn's disease, and other conditions that indicate intractable chronic enterocolitis in the large and small intestines. The specific conditions and quality of life associated with IBD varies substantially among individuals, and patients therefore need support tailored to their own specific situation. Another difficulty that we face is forging connections among patients, who tend to become socially isolated.

What IBD patients want most is the development of drugs that are useful in treating this condition. Mitsubishi Tanabe Pharma has launched Remicade, the first effective therapeutic drug for IBD, and we hope to see more new drugs come to market in the future. We also hope that the Japanese government will expedite approval of new drugs that are developed overseas, and at the same time, provide detailed information more quickly regarding drug safety and treatment options.

We greatly appreciate the support that Mitsubishi Tanabe Pharma already provides to our association. If we were to ask for anything more, it would be for additional help in providing information to patients across the country and in the administration of our organization.

#### Profile

Having diagnosed himself with IBD, Yoshihiro Nunotani now serves as chairman of Osaka IBD, a patient-run non-profit organization for individuals with ulcerative colitis and Crohn's disease. He serves concurrently as the officer in charge of public relations of the IBD Network, an organization that links patients' associations nationwide.

### Yoshihiro Nunotani

Chairman, Osaka IBD Public Relations Officer, IBD Network



## **Environmental Management**

### **Environmental Safety** Management

In order to help protect the global environment and create a sustainable society, Mitsubishi Tanabe Pharma must be cognizant of how every aspect of its business operations impacts the environment. Accordingly, the Mitsubishi Tanabe Pharma Group works proactively and aggressively to ensure that its operations are environmentally friendly. Furthermore, the Group discloses information related to the environment and promotes dialogue with the public in its initiatives aimed at contributing to the environment and society.

Additionally, as a member of the Mitsubishi Chemical Holdings Group, the Mitsubishi Tanabe Pharma Group is pursuing the creation of a KAITEKI (comfortable) society and is reducing its global environmental impact, through measures such as the reduction of greenhouse gases, in an effort to attain a KAITEKI world.

### Mitsubishi Tanabe Pharma **Environmental Safety Philosophy**

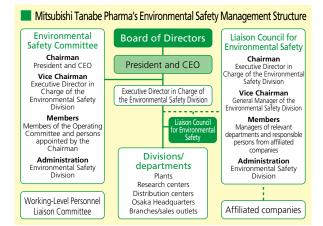
As it strives to be a trusted international pharmaceutical company, Mitsubishi Tanabe Pharma is committed to environmental preservation and human safety.

#### Basic Policy on Environmental Safety

- 1. Evaluate the environmental impact of corporate activities in Japan and overseas, and continuously strive to reduce environmental impact
- 2. Give precedence to safety considerations for all employees and prevent occupational accidents
- 3. Establish clear objectives regarding environmental safety activities, and uphold and improve effective systems to achieve
- 4. Comply with laws and regulations relating to environmental safety, and act in compliance with internally or externally established management standards that are more stringent than those stipulated in laws and regulations.
- 5. Conduct systematic education and training to raise the environmental safety awareness of every employee.
- 6. Be active in disclosing information relating to environmental safety and engage in more public dialogue about the environment.
- 7. Participate in local community-based environmental or disaster preparedness programs and actively cooperate with the organizers of such programs, while devising preventative measures for accidents, disasters, and other possible incidents, so as to minimize their impact.
- 8. Have affiliated companies take action in line with the present Basic Policy and support their actions.

### **Management Structure**

Mitsubishi Tanabe Pharma has instituted an environmental and occupational safety management system, overseen by the president and CEO. Within the framework of this system, the Environmental Safety Committee has been established as the consultative body, with members comprising representatives from the Operating Committee. The Liaison Council for Environmental Safety plans and carries out activities in response to issues relating to the environmental safety of the Mitsubishi Tanabe Pharma Group and promotes the management of environmental issues both in and outside Japan.



### **Scope of Environmental Information Collection and Disclosure**

Mitsubishi Tanabe Pharma Group collects and discloses information in its CSR reports regarding the manufacturing, research, and distribution facilities of Mitsubishi Tanabe Pharma, its consolidated subsidiaries, and equity-method-applicable subsidiaries in Japan, as well as the manufacturing sites of its overseas consolidated subsidiaries. The 2011 CSR report introduced environmental information pertaining to its research facilities located outside Japan.

#### Companies Subject to Environmental Information Disclosure

In Japan: Mitsubishi Tanabe Pharmaceutical Corporation; Mitsubishi Tanabe Pharma Factory, Ltd.; Benesis Corporation; Bipha Corporation; Tanabe Seiyaku Yoshiki Factory Co., Ltd.; MP-Logistics Corporation; Tanabe R&D Service Co., Ltd.; Choseido Pharmaceutical Co., Ltd.; Hoshienu Pharmaceutical Co., Ltd. Outside Japan: Taiwan Tanabe Seiyaku Co., Ltd.; Tai Tien Pharmaceuticals Co., Ltd.: Mitsubishi Tanabe Pharma Korea Co., Ltd.: Mitsubishi Pharma (Guangzhou) Co., Ltd.; P.T. Tanabe Indonesia; Tanabe Research Laboratories U.S.A., Inc.

### **Environmental Compliance**

The Mitsubishi Tanabe Pharma Group is committed to proactively protecting the global environment. The Group complies with environmental laws, regulations, and ordinances as well as all related revisions, properly manages soil and polychlorinated biphenyls (PCBs), and thoroughly fulfills the responsibilities of a wastedischarging enterprise for handling waste correctly and ensuring proper treatment by contractors. Going forward, in order to retain society's trust, the Group will continue strengthening its environmental compliance by routinely checking, through environmental audits, to ensure that the PDCA cycle is being implemented appropriately and smoothly.

### **Environmental Safety Risk** Management

The Mitsubishi Tanabe Pharma Group upholds and enhances its corporate value by maintaining a system for properly following through on risk management rules established for all risks associated with business operations. Furthermore, the Group has established detailed operational regulations regarding environmental risk and maintains constant awareness of the dangers of harmful chemical leaks. It has also established procedures for quickly and precisely handling emergencies, which are routinely practiced in employee training.

### ISO 14001 and Eco Action 21 **Certifications**

Mitsubishi Tanabe Pharma Group's principal production sites have acquired either ISO 14001 certification, Eco Action 21 Certification, or other certifications established by relevant local municipalities. In the Asian region, production bases Mitsubishi Tanabe Pharma Korea, Mitsubishi Pharma (Guangzhou), Tanabe Indonesia, and Tianjin Tanabe Seiyaku have acquired ISO 14001 certification. In other areas, research institutes and offices manage environmental and safety issues in ways that are appropriate to their locations and business activities, with the view to improving their environmental performance.

### **Environmental Safety Audits**

Mitsubishi Tanabe Pharma Corporation conducts environmental safety audits at every relevant site, department, and facility both internally as well as for Group companies in and outside Japan.

In fiscal 2011, the Company continued to concentrate on audits for legal compliance while strengthening PDCAbased improvement efforts by verifying environmental activity plans and their progress.

From the current fiscal year, the Company began an effort to deepen mutual understanding by having environmental

affairs personnel from different departments in the Group companies in Japan participate in audits. From now on, the Group will implement mutual audits on a larger scale to invigorate environmental activities.



An environmental safety audit in progress

### **Soil Contamination Control**

The Mitsubishi Tanabe Pharma Group proactively monitors soil and water contamination at production, research, and other facilities and takes appropriate measures to prevent pollution dispersion. Measures to prevent dispersion have been taken on unused land in the city of Nikko in Tochigi Prefecture and by the Yoshitomi Office in Fukuoka Prefecture.

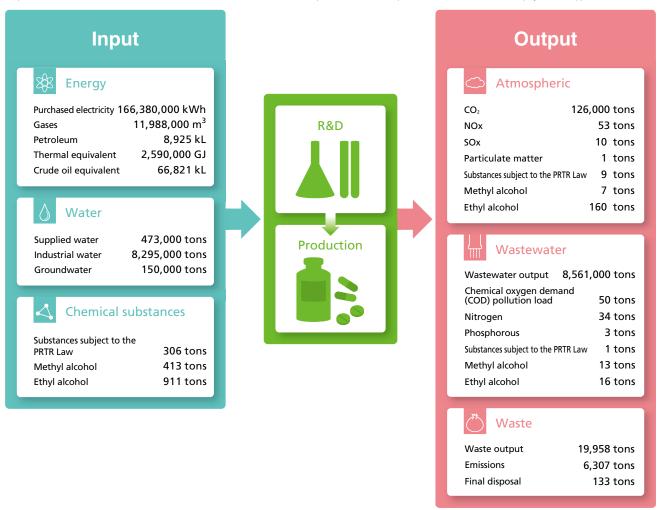
At the former site of API Corporation's Kusu Plant (Yokkaichi City, Mie Prefecture), which closed in 2009, the Company completed a cleanup operation of contaminated soil and is now proceeding with an operation to carry out anaerobic bioremediation of groundwater. Efforts will be made to continue proper measures, including monitoring the effects of contamination on areas outside the plant, under the guidance of government agencies.

There were no new soil pollution sites identified in fiscal 2011. In the future, at events involving Company-owned land such as consolidating, decommissioning, or reconstructing facilities, the Company will conduct appropriate investigations, make reports, and submit required paperwork in accordance with the Soil Pollution Control Act. The Group will release inspection results and take full and immediate responsibility for incidents involving contamination.

## **Overview of Environmental Impact**

### Input and Output in R&D and Production in Japan

Scope: Production, research, and distribution facilities of Mitsubishi Tanabe Pharma Corporation and the Group's consolidated subsidiaries and equity-method-applicable subsidiaries



### **Environmental Performance of Production and Research Sites Outside Japan**

	Electricity	11.48 million kWh
Energy consumption	Gases	581,000 m <sup>3</sup>
Petroleum		255 kL
Water consumption		224,000 tons
CO <sub>2</sub> emissions		9,200 tons
Waste output		404 tons

- ◆ Scope: Taiwan Tanabe Seiyaku Co., Ltd.; Tianjin Tanabe Seiyaku Co., Ltd.; Mitsubishi Pharma (Guangzhou) Co., Ltd.; P.T. Tanabe Indonesia; Mitsubishi Tanabe Pharma Korea, Co., Ltd.; and Tanabe Research Laboratories U.S.A., Inc.
- ◆ Period: January 1 to December 31, 2011
- ◆ CO₂ were calculated with reference to the *Greenhouse Emission Calculation* and Reporting Manual (Ver. 3.2) and the List of Calculation Methods and Emission Coefficients for Calculation, Reporting and Publication, published by Japan's Ministry of the Environment and Ministry of Economy, Trade and Industry. The electricity output coefficient was set at 0.000559 t-CO<sub>2</sub>/kWh.

### **Medium-Term Environmental Action Plan**

### Objectives and Fiscal 2011 Results of the Medium-Term Environmental Action Plan (2011 to 2015)

Area	Objectives	Fiscal 2011 results
Energy conservation and global warming mitigation	• Reduce CO <sub>2</sub> emissions for FY2015 by at least 30% compared to the FY2005 level	Reduced CO <sub>2</sub> emissions by 34.7% compared to the FY2005 level     Increased number of hybrid vehicles used by sales personnel to 929 from 700 in FY2010     Performed energy conservation analysis at Bipha Corporation
Reduction of waste, reuse and recycling of resources	Promote zero emissions and continually reduce waste and emissions output and final waste disposal  Fulfill the responsibility of a waste-discharging enterprise for handling waste correctly and ensuring proper treatment by contractors	Achieved a final waste disposal rate of 0.67% (0.84 % in FY2010)     Promoted recycling and effective use of resources     Performed on-site inspections of waste collection and transportation companies and intermediate and final disposal sites
Chemical substance emissions reductions	Properly manage chemical substances and continually reduce their discharge into the environment	Maintained emissions of PRTR substances to air and water at the same level as the previous year
Enhancement of environmental management	Improve environment-related risk management at company facilities     Maintain zero environmental accidents	Introduced environment-related legal compliance management methods     Conducted environmental safety audits at 20 Group worksites in and outside Japan     Conducted online environmental and safety training courses     Had zero environmental accidents or trouble

## **Environmental Accounting**

Mitsubishi Tanabe Pharma works to promote effective and efficient environmental management by ascertaining and analyzing the costs and effects of environmental conservation and the impact these activities have on economic performance. Environmental conservation costs for fiscal 2011 were ¥78 million in investments and ¥1.227 billion in running costs. The economic benefit of environmental conservation measures was ¥27 million.

#### Environmental Conservation Costs (millions of yen)

ItemInvestedExpendedPollution prevention57475Global environmental protection1861Recycling and reuse of resources3405Upstream and downstream activities033Administrative activities0245Research and development00Community activities00	(minoris or year)		
Global environmental protection 18 61  Recycling and reuse of resources 3 405  Upstream and downstream activities 0 33  Administrative activities 0 245  Research and development 0 0	ltem	Invested	Expended
Recycling and reuse of resources 3 405 Upstream and downstream activities 0 33 Administrative activities 0 245 Research and development 0 0	Pollution prevention	57	475
Upstream and downstream activities 0 33  Administrative activities 0 245  Research and development 0 0	Global environmental protection	18	61
Administrative activities 0 245  Research and development 0 0	Recycling and reuse of resources	3	405
Research and development 0 0	Upstream and downstream activities	0	33
•	Administrative activities	0	245
Community activities 0 0	Research and development	0	0
	Community activities	0	0
Environmental damage compensation 0 8	Environmental damage compensation	0	8
<b>Total</b> 78 1,227	Total	78	1,227

#### Environmental Conservation Effects

Reduction of	environmental impact	Quantity reduced
Global environmental protection	Greenhouse gas emissions	350 tons-CO₂

### Economic Effects Resulting from Environmental Conservation Measures (millions of yen)

Material economic effects	Amount saved	
Sales of valuable materials	14	
Electric consumption reduced through energy-saving measures	13	
Total	27	

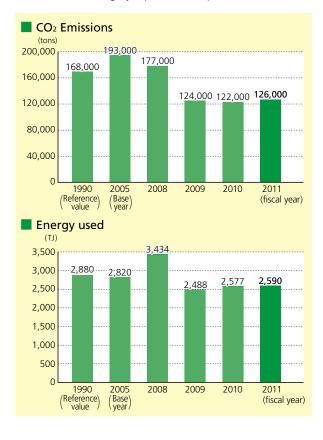
Notes regarding calculations for fiscal 2011 data: 1. Data were calculated in line with the *Environmental Accounting Guidelines* (2005 edition) published by the Ministry of the Environment of Japan. 2. Period: April 1, 2011, to March 31, 2012. 3. Scope: All worksites in Japan. 4. Calculation methods: (1) Simple method for amount invested (25%, 50%, 75%, 100%); (2) Depreciation is calculated based on the legally defined service life of applicable items; and (3) The full amounts for non-amortization costs are posted only if 100% environment related. 5. Calculation and evaluation methods for effects resulting from environmental conservation measures: (1) Only material effects based on conclusive grounds for each environmental measure are tallied and assessed; and (2) Effects observed within the fiscal year are tallied by converting them to a period of 12 months, and evaluated by comparing them to the year before the measures were implemented (or the previous fiscal year).

## **Energy Conservation and** Global Warming Mitigation

### **Energy Conservation and Global Warming Prevention**

The Mitsubishi Tanabe Pharma Group has made the conservation of energy and the curbing of global warming two of its top-priority environmental objectives. In its efforts to reduce greenhouse gas emissions, the Group implements energy conservation initiatives in consideration of the size and location of its various worksites, including plants, research facilities, distribution centers, and offices.

Under its Medium-Term Environmental Action Plan, the Group set the target of reducing CO2 emissions for fiscal 2015 by at least 30 percent compared to its fiscal 2005 level. The Group's CO<sub>2</sub> emissions in fiscal 2011 totaled 126,000 tons, a 34.7-percent reduction compared to the fiscal 2005 level. In fiscal 2011, the effects of the Great East Japan Earthquake saw worksites, particularly in the Kanto region, strengthening energy-saving measures. A change in the emission factor, used to determine CO<sub>2</sub> emissions related to the purchase of electric power, resulted in CO<sub>2</sub> emissions increasing by 3 percent compared to fiscal 2010.



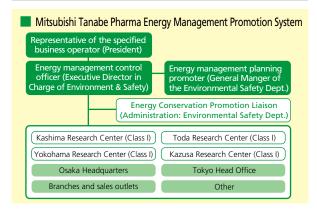
### **Observing the Amended Act on** the Rational Use of Energy

Four companies in the Mitsubishi Tanabe Pharma Group— Mitsubishi Tanabe Pharma, Mitsubishi Tanabe Pharma Factory Ltd., Benesis Corporation, and Bipha Corporation—have been designated as Specified Business Operators under the Act on the Rational Use of Energy. As a result, these companies will be expected to reduce their energy consumption and report the results of their efforts. The Company is enhancing the Group's energy management by holding energy conservation promotion liaison committee meetings twice a year to monitor any changes in energy consumption and CO2 emissions and to discuss energy-saving measures for worksites.

The Kashima, Toda, Yokohama, and Kazusa research sites were designated as Class I Designated Energy Management Factories. Combined energy usage at the four sites in fiscal 2011 totaled approximately 21,200 kL, a 7-percent reduction from the previous fiscal year, while CO2 emissions totaled approximately 34,500 tons, down 6 percent year-on-year. This accounts for 87 percent of the Company's energy consumption and 88 percent of its CO<sub>2</sub> emissions.

#### Energy Consumed by Mitsubishi Tanabe Pharma from Fiscal 2010 to 2011

Citan	Crude oil equivalent (kL)		CO <sub>2</sub> emissions (tons-CO <sub>2</sub> )	
Sites	FY 2010	FY 2011	FY 2010	FY 2011
Kashima Research Center	7,050	6,980	10,610	10,830
Toda Research Center	5,760	5,070	10,050	8,770
Yokohama Research Center	3,680	3,530	6,240	5,840
Kazusa Research Center	3,050	2,850	5,500	5,050
Osaka Headquarters	740	660	840	790
Tokyo Head Office	670	580	1,000	850
Braches and sales outlets	1,070	1,010	1,750	1,670
Other	700	560	900	740
Total	22,720	21,240	36,890	34,540



### **Initiatives at Worksites and Offices**

 Saving Electricity and Energy in the Summer In the aftermath of the Great East Japan Earthquake, efforts were made at the Company's worksites across the country to save electricity during the summer of fiscal 2011. They also disclosed internally their energy-saving target figures to increase awareness among employees.

The Toda, Yokohama, and Kazusa offices stopped using or transferred to other sites energy-intensive equipment such as air-conditioners and heat source equipment and made use of in-house power generators. Their efforts paid off: the Toda Office, for example, achieved a 20-percent reduction in energy consumption from July to September 2011, compared to a year earlier.

In the Tokyo Head Office area (at both the former Nihonbashi Building and the current Sanbancho Building), the Company reduced summertime energy consumption by an average of 27 percent from the previous year. It accomplished this by adjusting the running times for building-wide and individual air-conditioners, increasing air-conditioning efficiency with electric fans, and implementing thorough electricity-saving measures for lighting and office automation (OA) equipment.

#### Installation of Solar Power Generators

Choseido Pharmaceuticals Co., Ltd., located in Tokushima City, Tokushima Prefecture, installed solar power generators

on the roof of its Kawauchi Factory (in the same city) to make use of the location's moderate climate and long hours of sunlight.

The factory's plan for combined upgrading with solar power generation and LED lighting fixtures was registered under the Tokushima Prefecture Program to Support Earth-Friendly Companies and NPOs, and the equipment was installed in March 2011. The solar power generators became fully operational the following



Rooftop solar power generation panels Kawauchi Factory installed 48 solar panels with an output of approximately 12,000 kWh per year, producing a maximum of 10.08 kW, and resulting in the reduction of 4 tons of CO<sub>2</sub> emissions per year.



Solar power generation monitor The monitor displays the current output and CO2 emissions reduction effect, helping to raise employee awareness of energy conservation.

month and the generated power is being used to run new wastewater treatment equipment.

### **Initiatives with Company Vehicles**

In fiscal 2011, Mitsubishi Tanabe Pharma reduced its fleet of vehicles by 17 to 1,966 vehicles. It also expanded the proportion of environmentally friendly vehicles such as electric and hybrid vehicles to approximately 50 percent. Going forward it will strive to reduce CO<sub>2</sub> emissions by aggressively increasing its number of environmentally friendly vehicles and continuing to promote economical driving practices.

#### Company Vehicles

	FY 2009	FY 2010	FY 2011
No. of company vehicles	1,661	1,983	1,966
Electric vehicles	50	50	49
Hybrid vehicles	76	700	929

### CO<sub>2</sub> Emissions Verified in **Accordance with ISO 14064-3**

ISO 14064 is the international standard relating to the quantification, reporting, and verification of greenhouse gas emissions. It is composed of three parts (14064-1 to 14064-3). Section 14064-3 specifies rules relating to the validation and verification of the quantification of greenhouse gas emissions.

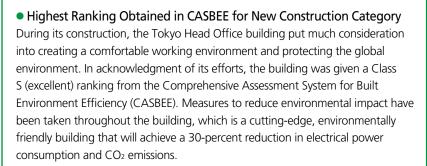
Mitsubishi Tanabe Pharma had an outside certification body verify that the CO<sub>2</sub> emissions from its worksites in Japan are in accordance with ISO 14064-3 before disclosing them in this report. The Company had the verification conducted with the purpose of obtaining a limited assurance for the greenhouse gas



emissions it quantified. Greenhouse gas emissions verification report

# ODIC Environmental Considerations at the New Tokyo Head Office Building

In May 2012, offices in the Nihonbashi Building (Nihonbashi Honcho, Chuo-ku) and the Sanbancho Building (Sanbancho, Chiyoda-ku) were consolidated into a single area, in Nihonbashi Koamicho. In the nine-story new Tokyo Head Office building, Mitsubishi Tanabe Pharma and the building owner are working together to realize the Company's numerous proposals for incorporating environmentally friendly features into the office spaces.



 Solar Power Generation System Fifteen solar panels with a maximum output of 3.15 kW have been installed on the roof of the building. The generated power is being used to partially power lighting in common-use areas.



Rooftop solar panels

#### LED Lighting

High-efficiency, long-lived LED lighting has been installed in offices as well as common-use areas. Other measures have also been taken to reduce electrical power consumption, such as installing human-detection sensors for lighting in common-use toilets and office kitchenettes and automatic dimming systems that detect the brightness of outside light and control the lighting in offices accordingly.



A rooftop garden has been created to reduce the heat load on the working environment through water retention and insulation effects and to provide a green, open space for office workers to enjoy. The garden will hopefully also contribute toward easing the heat island effect.



Rooftop Garden

 Electrical Vehicle Charging System The Tokyo Head Office has electric vehicles available for use by sales representatives and other employees. Inside the multilevel parking lot, 200-volt chargers have been installed. The single-

level parking lot also has a rapid charger.



Rapid charger in use



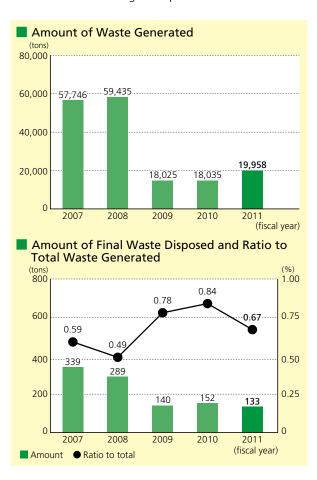
New Tokyo Head Office building

### **Waste Reduction**

### **Waste Reduction Initiatives**

In pursuit of its zero emissions goal, the Mitsubishi Tanabe Pharma Group is continually trying to reduce both the amount of waste generated and the final amount of waste disposed. Plants and research centers thoroughly separate wastes discharged from work sites and attempt to make improvements so that wastes can be recycled as resources or sold for reuse.

The Company's research centers all put into practice environmentally friendly initiatives such as thorough separation and collection of clean plastic. The plastic is used for "refuse paper and plastic fuel" (RPF), which is high-calorie solid fuel, thereby reducing the final amount of waste disposed. When the Company commissions the treatment of industrial waste, it will pay regular visits to the treatment contractors and use its own check sheet to confirm the status of legal compliance and treatment.



### **Initiatives of a Work Site that Achieved Zero Emissions**

As part of its efforts to reduce its environmental impact, the Mitsubishi Tanabe Pharmaceutical Factory's Kashima Plant in Kamisu City, Ibaraki Prefecture, has been reinforcing compliance with rules for separating different types of waste material and promoting, as much as possible, the reuse and recyling of waste. Aware of its responsibilities as a discharger of waste, the plant continually verifies and promotes proper management by disposal contractors.

When the Kashima Plant began zero emissions initiatives in fiscal 2005, it had no record of recycling, and its amount of final waste disposal was 43.3 tons, with a ratio to total waste generated of 9.4 percent. Thereafter, it established a recycling process, including identifying recycling companies, reviewing treatment contractors and revising the contracts the plant had made with them, and turning waste plastic into RPF. At the same time, it established a plant-wide program for thorough waste separation and management. In this way, the plant achieved zero emissions (zero final waste disposal) in fiscal 2011.

### **Treatment and Proper Management of PCB Waste**

With regard to polychlorinated biphenyl (PCB) waste, Mitsubishi Tanabe Pharma has completed the treatment of 89 out of 112 capacitors and transformers with high PCB concentrations. The Company will continue working on the small number of sites remaining.

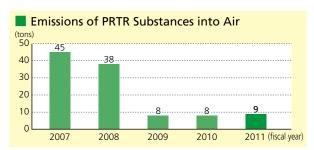
The Company has also registered its PCB-containing fluorescent light ballasts with the Japan Environmental Safety Corporation (JESCO) and is having them treated. While awaiting the disposal, the Company is ensuring the proper storage of the ballasts, keeping them under locked control and implementing measures to prevent PCB leakage into the soil and so forth. In addition, each time a transformer or capacitor with possible trace contamination of PCB is used, the insulating oil is analyzed, and other steps are taken to ensure appropriate handling.

## **Proper Management of Chemical Substances**

### **Proper Management of Chemical Substances**

One of the Company's objectives in its Medium-Term Environmental Action Plan is managing chemical substances in a suitable manner and continuously reducing emissions into the environment. To this end, the Company is striving to ascertain and control its emissions into the environment of pollutant release and transfer register (PRTR) substances (Class I Designated Chemical Substances) specified in the Law Concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management (PRTR Law) as well as non-PRTR volatile organic compounds (VOCs) such as ethyl alcohol and methanol.

In fiscal 2011, the amount of Class I Designated Chemical Substances handled by the Group as a whole was 305.8 tons, up 14 percent from fiscal 2010, while the amount released to the air was 8.7 tons, a 4-percent increase over the previous year. The Group will continue making efforts to reduce overall emissions.



Class I Designated Chemical Substances Handled by a Worksite in a Quantity of One or More Tons Per Year

Acetonitrile	Xylene
Chloroform	Dichloromethane
N,N-dimethylformamide	Triethylamine
1,2,4-trimethylbenzene	Toluene
N-(4-hydroxyphenyl) acetamide	Pyridine
Hexane	

### **Management of Air and Water Systems**

The Company complies with all standards stipulated by the Air Pollution Control Law and Water Pollution Control Law as well as local government ordinances and agreements with related organizations. In addition, there are protocols in place to deal with incidents in which harmful substances leak from outdoor tanks or piping, or problems that arise concerning exhaust gas or wastewater drainage, so as to minimize the impact on the environment outside the facility where the accident occurred.

Mitsubishi Tanabe Pharma Factory's Onoda Plant (Sanyo Onoda City, Yamaguchi Prefecture) has established separate Emergency Response Protocols to be followed (1) during accidental leakage of chemical substances and (2) when there is abnormal water quality due to an unknown accidental leakage of chemical substances. The intention of these protocols is to avoid environmental pollution and damage to the health of employees and community residents associated with the leakage of chemical substances and to minimize human and physical damage by taking precise measures guickly. Further, the plant maintains a list of disposal methods, protective equipment, and treatment agents to use during a leakage for each toxicant, deleterious substance and dangerous material handled at the plant in order to carry out disposal work precisely and swiftly during an accidental leak. Meanwhile, it has also strengthened its risk management by identifying areas with a high risk of leakage and installing manual gates at each location. It has also set up total organic carbon (TOC) meters and pH meters in order to discover abnormalities early and respond quickly.

Additionally, following the partial amendment of the Water Pollution Control Law (June 2012), the Company has ensured thorough legal compliance by conducting investigations at relevant worksites that are legally authorized to use or store hazardous substances.



Manual gate installed on facility grounds

### **Environment-Related Incidents**

The Group strengthened its measures to prevent a recurrence of past incidents and near-miss events that could have led to environmental accidents and implemented emergency training drills.

In fiscal 2011, the Group experienced no environmentrelated problems. Nevertheless, it will continue making thorough efforts to improve environmental management throughout the Group to prevent accidents by implementing quick and precise responses to potential incidents.

## **Promotion of Environmental Communications**

### **Environmental and Social Contribution Activities**

As a model corporate citizen, Mitsubishi Tanabe Pharma values interaction with the local community and engages in environmental and social activities with employees and their families, including cleanups around worksites and activities in nearby forests.

#### Greening of Office Surroundings and Nature Preservation Activities

In October 2011, before the Osaka Marathon, the Headquarters and Kashima Office participated in the Osaka Marathon Cleanup, a citywide cleaning held by the city government, in cooperation with residents and businesses.



Osaka Marathon Cleanup campaign

Bipha Corporation, located in Chitose City, Hokkaido, held cleanups around its plant and also participated in various activities such as planting flowers around the New Chitose Airport and cleaning up around Lake Shikotsu on Natural Parks Clean-Up Day.



Planting flowers along a national road near New Chitose Airport



Natural Parks Clean-Up Day

### • Ikoma Mountain Range "Folding Screen" of Flowers Project

In November 2011, 36 Mistubishi Tanabe Pharma Group employees and their families participated in the Ikoma Mountain Range "Folding Screen" of Flowers Project held by the Osaka Prefectural Government. Together with 200 prefectural residents, the volunteers enjoyed a hike

through woodlands near settlements up to Mt. Kannabi (Hirakata City) on the border between Osaka and Kyoto. There, they cooperated in forest regeneration, planting cherry trees and rhododendrons in areas damaged by oak wilt.





Ikoma Mountain Range "Folding Screen" of

## **Environmental Education**

The Company's Corporate Behavior Charter, which is the priority code of conduct for all employees states: "We will work to achieve harmonious coexistence with society by acting with consideration for local communities and the environment." Accordingly, the Company provides environmental education with the aim of increasing awareness of environmental conservation.

In fiscal 2011, the Company continued to provide environmental education for new hires, e-learning programs for medical representatives, and workshops for employees in charge of environmental matters.

The Company also made efforts to increase environmental awareness by disseminating environmental information in a clear and timely manner both inside and outside the Company, including using its intranet to post changes in the amount of CO<sub>2</sub> generated and energy consumed at each worksite in the Group.

## Independent Verification Report

### Independent Verification Report

To: Mitsubishi Tanabe Pharma Corporation



Bureau Veritas Japan Co. Ltd. System Certification Services Headquarters

#### Objective of verification

Bureau Veritas Japan Co., Ltd. has evaluated the environmental performance data for the Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe Pharma) CSR Report 2012, (the Report), covering the Fiscal Year 2011. The Report is issued under the responsibility of Mitsubishi Tanabe Pharma. Bureau Veritas' responsibility is to provide independent verification of environmental performance data, based on objective evidence.

#### Scope of work

Bureau Veritas verified the environmental performance data and related information for the reporting period April 2011 to March 2012.

Bureau Veritas visited the following sites to conduct its verification work:

Mitsubishi Tanabe Pharma Corporation Head Office: Mitsubishi Tanabe Pharma Factory Ltd. Yoshitomi Site Tanabe Seiyaku Yoshiki Factory Co., Ltd.

Hoshienu Seiyaku Co., Ltd.

Administration

Manufacture of pharmaceuticals Manufacture of pharmaceuticals Manufacture of pharmaceuticals

#### Verification Methodology

Bureau Veritas has conducted the following verification based on agreement with Mitsubishi Tanabe Pharma;

#### **Head Office**

- The reliability and adequacy of data collection and aggregation systems and related processes
- The effectiveness of internal verification processes
- The accuracy of the environmental data and of related information collected for the

#### Research and manufacturing sites

- The appropriateness of boundaries for data collection
- The effectiveness of data measurement, collection and aggregation methods
- The effectiveness of internal verification process
- The accuracy of final aggregated data from visited sites

The verification was conducted using Bureau Veritas' standard procedures and guidelines for external verification of non-financial reporting, based on current best practice. Bureau Veritas refers to the International Standard on Assurance Engagements (ISAE) 3000 (2003) in providing a limited assurance for the scope of work stated herein.

#### Verification findings

#### Key findings:

- 1. No significant errors were detected in the reported environmental performance data and related information contained within the Report.
- All errors in reported data identified during the verification process have been duly corrected.
- Mitsubishi Tanabe Pharma's internal systems for the data monitoring, collection and aggregation are considered to be reliable and appropriately implemented at the Head Office and each of the visited sites.

Bureau Veritas has implemented a code of ethics across its business which is intended to ensure that all our staff maintain high standards in their day to day business activities. We are particularly vigilant in the prevention of conflicts of interest. Bureau Veritas activities for Mitsubishi Tanabe Pharma Corporation are for social reporting verification only and we believe our verification assignment did not raise any conflicts of interest.

## Third-Party Opinion •

### Comments on the Mitsubishi Tanabe Pharma CSR Report 2012

### Overall Approach

The Mitsubishi Tanabe Pharma CSR Report 2012 addresses activities in relation to creating pharmaceuticals, management, employee relations, social contribution activities, and relationship with the global environment—all subjects that can quickly become dry and technical. This is avoided, however, with each topic laid out in a careful and comprehensible manner. The report is outstanding in terms of its comprehensiveness and readability. Of the thousandplus reports issued by Japanese companies, Mitsubishi Tanabe Pharma certainly deserves an honorable mention for its excellent presentation of the conditions that the Company currently faces.

### Notable Initiatives

The Company's efforts in certain areas are particularly impressive: research and development of pharmaceuticals to fulfill unmet medical needs; the launch of four new drugs in Japan in fiscal 2011; the identification of risks posed by potential natural disasters and the preparation of contingency plans; and the ability to quickly restore operations after the earthquake, ensuring a continuous and stable supply of pharmaceuticals. I would like to take this opportunity to convey my respect for Mitsubishi Tanabe Pharma's hard work in this regard.

The creation of prescription and over-the-counter drugs is a service that only pharmaceutical companies are able to perform and is in and of itself a form of social contribution. This report presents clearly and carefully information on the Company's social contribution activities that an annual report cannot cover in their entirety: the moral considerations involved in drug discovery research; human rights and bioethical considerations in clinical trials; helping to prevent disease by supplying vaccines; measures enforced to prevent medical malpractice; safeguarding a stable supply of pharmaceuticals; export safety and security controls; the Company's Medical Information Center, health support websites, and other forums for providing a broad range of information; the implementation of safety measures for new drugs and training programs on the safety of pharmaceuticals; and support provided for patients associations and research grants.

### Looking to the Future

Although the section on environmental activities outlines the Company's Medium-Term Voluntary Action Plan for Environmental Safety, it is incumbent upon Mitsubishi Tanabe Pharma to present a clearer vision for the Company in the future. In addition, the final section of this CSR report references Management of Sustainability (MOS), one of Mitsubishi Chemical Holdings Group's basic approaches to social responsibility.

However, it remains unclear how this relates to Mitsubishi Tanabe Pharma's initiatives to promote and achieve its KPI indices related to sustainability, health, and comfort.

Finally, we will see less emphasis, I believe, on CSR reports published in printed form as other ways of communicating CSR information become increasingly important in the future. There are pharmaceutical companies around the world that employ unique and powerful methods to convey their CSR messages. I would hope that Mitsubishi Tanabe Pharma would set itself apart from the crowd by using a range of communication methods to convey specific, effective activities with a strong impact on the community and cultivate a true appreciation for the Company's CSR activities.

#### CSR for a Global Research-Driven Pharmaceutical Company

In his message at the beginning of the report, the president of Mitsubishi Tanabe Pharma, Michihiro Tsuchiya states, "At Mitsubishi Tanabe Pharma, helping improve the quality of life of people suffering from disease through our business activities [researching and developing pharmaceuticals and ensuring stable supplies] is the essence of our social mission." This is a mission that would presumably be respected in communities throughout the world, regardless of culture or custom, and CSR could be defined as the process of determining how this can be done how to earn the appreciation of the community, how to proceed with specific business activities, and how to manage the risks associated with these activities. Moving from an outstanding CSR to a CSR that is assertive, flexible, and at times safeguarded is an issue that every Japanese company must address to achieve corporate and social sustainability.

Finally, Mitsubishi Tanabe Pharma is a company with a long tradition of contributing to society throughout its history. This, I believe, fosters a type of wisdom that is uniquely adapted for true corporate social responsibility. CSR that lives through tradition should be considered a source of universal wisdom, and linking this sensibility to business innovation via proactive CSR may just lead the way to an entirely new form of corporate strength.

Prof. Saka received her Doctorate in Commercial Science from the Graduate School of Business Administration at Kwansei Gakuin University. She is a member of the Science Council of Japan and the Environment Council of the Osaka Prefectural Government, and a director of the Japan Corporate Social Accounting and Reporting Association. She is also the author of Environmental Accounting Theory (Tokyo Economic Information Publishing).



Chika Saka, PhD. Professor at the School of Business Administration, Kwansei Gakuin University

## Explanation of Terms ····

### Appropriate use of pharmaceuticals

Prescribing and preparing pharmaceuticals in their optimum form in regards to ingredient selection, formulation, appropriate administration and dosage, based on a precise diagnosis. Also, encouraging patients to understand the prescribed drug, evaluating the efficacy and negative side effects, and reflecting the results in subsequent prescriptions. Appropriate use refers to this entire cycle.

#### Clinical trials

Tests in which pharmaceuticals that have not yet been approved are administered to patients and healthy subjects in order to determine their efficacy and side-effects.

### Development pipeline

The entire process from the initial development stage to the marketing of drugs at a pharmaceutical company.

#### Electronic chart

A system by which medical charts written by doctors are electronically recorded and stored on computers at medical institutions.

#### Generic drugs

Drugs that are launched after the initial new drug patent runs out. They have the same effective ingredients in the same amounts as the new drug and have the same clinical efficacy.

#### Good Clinical Practice (GCP)

Standards on how clinical trials for drugs should be conducted.

### Good Laboratory Practice (GLP)

Standards related to safety on how non-clinical trials for drugs should be conducted.

#### **Good Manufacturing Practice** (GMP)

Production and quality standards for control of pharmaceutical and quasidrug products.

### **Good Post-marketing Study** Practice (GPSP)

Standards for conducting postmarketing surveys and tests for pharmaceuticals.

#### Good Quality Practice (GQP)

Standards for controlling the quality of pharmaceuticals, quasi-drug products, cosmetics and medical equipment.

### Good Vigilance Practice (GVP)

Standards for safety vigilance after production and marketing.

#### Good x Practice (GxP)

A general term meaning good practice standards where the "x" is variable and could be replaced by "C" (GCP) for good clinical practice, "L" (GLP) for good laboratory practice, or "M" (GMP) for good manufacturing practice, etc. The standards are set by the government or other public agencies to guarantee product safety and reliability during manufacturing, maintenance, storage, and distribution. Most often used for products in the pharmaceutical industry.

#### **ICH GCP**

International Good Clinical Practice guidelines for pharmaceuticals related to tests and clinical trials, agreed to at the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

#### Informed consent

A process in which the doctor provides the patient with adequate information on the medical care and obtains agreement from said patient.

#### Medical Representative (MR)

A pharmaceutical company's employee in charge of sales and providing medical information. An MR visits medical institutions, sells pharmaceuticals and exchanges information regarding the quality, efficacy, safety, etc. of pharmaceuticals so as to ensure their proper use.

#### Over-the-counter (OTC) drug

Drugs that can be purchased at pharmacies and drug stores without a prescription from a doctor. OTC drugs can be purchased at many stores like ordinary goods over the counter.

### Quality of Life (QOL)

Criteria used to evaluate medical treatment to consider, in addition to simply judging the cure of the disease, whether a person is living his or her daily life with a sense of fulfillment and contentment, without a decline in the patient's quality of life after treatment.

#### Self-medication

Medication of oneself without the supervision of trained health professionals in order to mitigate health problems. This is done at one's own risk using products, information, and knowledge related to health and medical care available in one's own surroundings. This includes the use of over-the-counter (OTC) drugs to prevent or alleviate mild symptoms.

#### Unmet medical needs

Medical needs that are yet to be fulfilled. The lack of effective therapies urgently requires the development of pharmaceuticals since little or no progress is being made.

The Mitsubishi Chemical Holdings Group's basic approach to social responsibilities

Drawing on the three decision criteria of Sustainability, Health, and Comfort, the MCHC Group aims to contribute to the attainment of KAITEKI.

In view of the MCHC Group's philosophy "Good Chemistry for Tomorrow — Creating better relationships among people, society, and our planet," we believe that we have a responsibility to put KAITEKI into practice, by disseminating the idea of KAITEKI value widely across society, through our corporate activities based on the three decision criteria of Sustainability, Health, and Comfort.

To achieve that, we will commit to maintaining and reinforcing basic corporate activities in areas that are essential to enhancing KAITEKI value, including corporate governance, safety, the environment, labor and human rights, aiming to contribute to the sustainable development of society.

### Organization of the Mitsubshi Chemical Holdings Group

