# CSR Report 2011





Mitsubishi Tanabe Pharma Corporation CSR Report 2011

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 in fiscal 2010 to stakeholders, including patients, medical professionals, shareholders, investors, local communities, and employees.

Editors aimed to present specific initiatives in sections covering research and development, reliability assurance, the production system, and provision of information, in relation to the Company's philosophy of contributing to the healthier lives of people around the world through the creation of pharmaceuticals.

Explanations of technical terms were also included at the end of the report.

# About the Mitsubishi Tanabe Pharma Corporation CSR Report 2011

- This report covers the period from April 1, 2010 to March 31, 2011, along with certain activities and policies undertaken after this period.
- This report covers Mitsubishi Tanabe Pharma Corporation and its Group companies both within and outside Japan. Some information is 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: October 2011
- •Issuance of next report: August 2012
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# Message from the President

We are continuously re-evaluating our social mission as a pharmaceutical company, and accordingly, implementing new management reforms while striving to make further contributions to healthcare.

# Providing a Stable Supply of Pharmaceuticals in a Time of Disaster

Japan's northeastern Tohoku region was devastated by the Great East Japan Earthquake and subsequent tsunamis that occurred on March 11, 2011. We hope for a rapid recovery of all the region and of the people affected by this disaster.

As a result of the disaster, the Mitsubishi Tanabe Pharma Group was forced to temporarily suspended operations at its Ashikaga Plant in Tochigi Prefecture, Kashima Plant in Ibaraki Prefecture, and East Japan Distribution Center in Chiba Prefecture. Through strenuous efforts, each of these sites resumed operations on April 11, 2011.

Everyone who experienced the disaster was shocked at the unimaginable scope of devastation left in its aftermath. All of us at Mitsubishi Tanabe Pharma immediately considered what kind of assistance the Group could offer, and driven on by a sense of responsibility to society as a pharmaceutical company, we put our plans into action. When reports surfaced that transportation routes to the disaster-affected areas were damaged, making it impossible to supply medical supplies, we recognized anew that our social mission as a pharmaceutical company is not only to research, develop, and manufacture pharmaceuticals, but also to do everything possible to ensure that pharmaceuticals can reach patients under any and all circumstances.

Therefore, we were more determined than ever to fulfill our responsibility of making sure that the pharmaceutical products we offer end up in the hands of the people who need them.

# Pursuing New Pharmaceuticals That Benefit Patients

At Mitsubishi Tanabe Pharma, our mission is to be recognized as a pharmaceutical company that contributes to society through its business activities in and of themselves. These activities are centered on providing an array of pharmaceutical products, including orphan drugs and vaccines, that play a vital role in society and directly benefit the lives of patients. For example, Remicade, a monoclonal antibody against human tumor necrosis factor (TNF  $\alpha$  ), has become an indispensable drug for medical facilities. Initially used to treat rheumatoid arthritis, Remicade's indications have been increased to include a variety of incurable diseases.

With a total commitment to responding to unmet medical needs, Mitsubishi Tanabe Pharma carries out research and development on pharmaceuticals designed to treat patients with incurable diseases, while working to discover new drugs that can improve their quality of life. I believe that pursuing these kinds of drugs through research and development is the right approach for a pharmaceutical company today.

The Mitsubishi Tanabe Pharma Group's pharmaceuticals are widely used not only in Japan but also across Europe, the United States, and Asia. This fact gives substance to our corporate philosophy: "We contribute to the healthier lives of people around the world through the creation of pharmaceuticals."

# Implementing an Improvement Plan to Prevent Recurrence of Quality Control Problems

In response to problems with Medway Injection that occurred in 2010, the Company drew up a business improvement plan designed to prevent a similar recurrence. In January 2011, however, while the plan was underway, it was discovered that the Ashikaga Factory, operated by Mitsubishi Tanabe Pharma Factory Ltd., had failed to adequately perform quality tests to determine if products were suitable for shipping. Consequently, in July 2011 Mitsubishi Tanabe Pharma received a business improvement order from Japan's Ministry of Health, Labour and Welfare, and the Ashikaga Factory received a 10-day suspension of its pharmaceutical manufacturing operations from the government of Tochigi Prefecture. As president of Mitsubishi Tanabe Pharma Corporation, I wish to express my sincerest regret for the problems that this incident caused, and offer my deepest apologies to the patients, medical professionals, and members of the public who were affected.

While the Company had formulated a business improvement plan in response to the Medway Injection incident, and the Group had been implementing measures aimed at preventing any recurrence of such problems and restore the public's trust, the fact that a similar problem occurred during this time demonstrated that these measures were insufficient.

Therefore, we reviewed the preventative measures that had been based on our original improvement plan, and submitted a revised plan to the Ministry of Health, Labour and Welfare in August 2011. Recognizing that this revised plan is of critical importance, the entire Group is determined to undertake reforms to the management system to ensure the plan's success, with the overall objective to regain the trust of the public.

# Pursuing Inspiring New Drugs as an Innovative Company

Since its establishment in October 2007, Mitsubishi Tanabe Pharma has been tackling the priority issues laid out in its Medium-Term Management Plan 08-10, with

the goal to grow as an international pharmaceutical company as quickly as possible. By pursuing the plan's key development projects, we have improved the Company's R&D pipeline for releasing new pharmaceuticals to the market. Furthermore, we are aggressively leveraging our global strategic alliances to strengthen the Group's operations in Europe, the United States, and Asia, and accelerate business growth worldwide.

Moving forward, we intend to promote greater unity across the Group and work toward creating a new corporate culture in which employees can more freely pursue their goals in an open atmosphere. Upper management is dedicated to continuously initiating reforms to the Company's way of doing things, regardless of how long it takes to create this new and dynamic corporate culture.

Through these reforms, we aim to enhance the capabilities of worksites involved in research, development, manufacturing, and sales. In this way, we will pursue our goal of becoming an innovative company that makes inspiring new drugs, while continuing to give first priority to making contributions to healthcare. As we carry out these endeavors, we ask all stakeholders of the Mitsubishi Tanabe Pharma Group for their continued support and understanding.

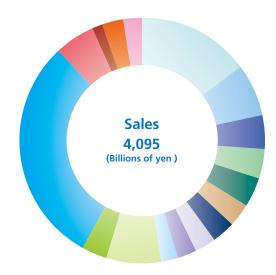


President and Representative Director Michihiro Tsuchiya

Michi Tauchiyo

# **Business Overview**

# Sales in Fiscal 2010



	ions of yen)
Domestic Sales of Ethical Drugs	361.6
Remicade	60.4
Radicut	28.7
■Ceredist	18.0
■Anplag	16.4
■Urso	15.3
■Talion	13.4
■Maintate	12.3
Depas	11.4
■Tanatril	9.6
Herbesser	9.6
■ Vaccines	29.6
■ Generics	14.0
Other pharmaceuticals	122.9
Overseas Sales of Ethical Drugs	21.3
OTC	5.4
Pharmaceuticals under license from other companie	
Fine chemicals and related products	9.3
= i irie crierricais ariu felateu products	9.5

# Corporate Data

Company Name Mitsubishi Tanabe Pharma Corporation Representative President and Representative Director

Michihiro Tsuchiya

50 billion yen Paid-in Capital

Number of Employees (consolidated)

9,198 (as of March 31, 2011)

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

Japan

Date of Merger October 1, 2007

BusinessActivities Manufacture and Sales of Pharmaceuticals

# Network

Headquarters Osaka Headquarters, Tokyo Head Office Sales Network Hokkaido Branch, Tohoku Branch, Kita-Kanto Branch, Koushinetsu Branch, Tokyo Branch, Chiba Branch, Saitama Branch, Yokohama Branch, Tokai Branch, Kyoto Branch, Osaka Branch, Kobe Branch, Chugoku Branch, Shikoku Branch, Kyushu Branch

Research Centers Toda Office, Kazusa Office, Yokohama Office,

Kashima Office

Network: Shanghai Office Overseas

# ■ Consolidated Net Sales



# ■Operating Income and R&D Expenses



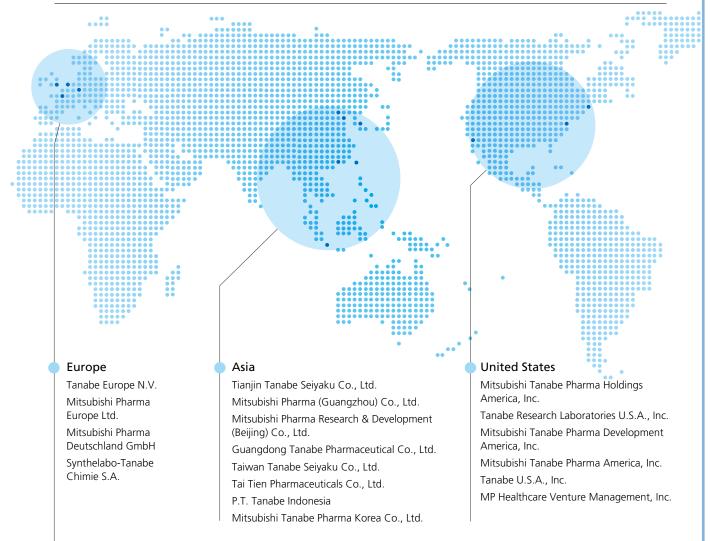
# **Group Companies in Japan**

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**



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



#### Rheumatoid arthritis

A cytokine (substance present within the body) known as TNF lphais involved in rheumatoid arthritic inflammation. A biological drug, Remicade, is used in the treatment of this ailment and its therapeutic effects have drawn considerable attention.





Methotrexate tablets "Tanabe'

#### Cerebral circulation

These products are mainly used in treatment during the acute phase of a cerebral infarction (stroke). Currently, the types of drugs used in Japan during the acute phase of cerebral infarction include thrombolytic drugs, cerebroprotective drugs, and selective thrombin inhibitors.







Radicut

# Hypertension and heart disease

Antihypertensive drugs are used in the treatment of high blood pressure. Divided into several categories depending on their efficacy and side effects, these products are prescribed to treat specific symptoms.







Maintate

#### Peripheral circulation

Arteriosclerosis and diabetes cause poor peripheral circulation, which may lead to pain, coldness, and ulceration on the hands and feet. These products improve circulation and the above symptoms by expanding peripheral blood vessels and thinning the blood to reduce the likelihood of blood clots.





Allergies

Tanatril

Allergic rhinitis and bronchial asthma are caused by hypersensitivity of the immune system, which triggers allergic reactions. These products suppress disease-specific allergic reactions and improve symptoms.







Disorders of the digestive system

These products are used to treat gastritis and gastric ulcers by suppressing the secretion of stomach acid and protecting the gastric mucosa. Urso is used in the treatment of liver disease, reducing damage to liver cells by replacing bile acid and improving liver function.









Omeprazon

#### Central nervous system

The central nervous system comprises the brain and spinal cord, and controls sensation, movement, thinking, emotions, reactions, breathing, and all other physical activities. These products are used to treat diseases of the central nervous system, such as insomnia, depression, spinocerebellar degeneration, and narcolepsy.









# Infectious diseases

The immune systems of elderly people or post-operative patients are weakened, leaving them liable to serious bacterial and viral infections. The following antibacterial and antiviral agents are used in these cases.









Pazucross

Valixa

Denosine

#### **Vaccines**

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, which helps protect the body from infection by the pathogen.







Varicella Vaccine Live Attenuated "Biken"

#### Plasma fractionation products

Plasma fractionation products are pharmaceuticals that are derived from the human blood component known as plasma and are manufactured by breaking down and refining useful proteins. Because they are made from human blood, a variety of safety measures are in place to ensure product safety.







Neuart

Donated blood albumin

#### **IV** solutions

These products are used for intravenous infusions, which are used to provide lost fluids supplementally, electrolytes, and nutrients in cases when patients cannot take food by mouth or are dehydrated due to diarrhea or vomiting.







Amigrand

# Generic drugs

Generic drugs can be launched after the patent expiration of the respective drug. Building on its superior track record as a manufacturer of new drugs, Mitsubishi Tanabe Pharma markets safe generic drugs under the slogan, "Reliable Generics."







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 personal health and treat simple physical ailments.



Over-the-counter drugs



Aspara drinks Flucort F skin ointment Nan Pao herbal medicine



# Responding to **Unmet Medical Needs**

Many people around the world suffer from diseases that still cannot be effectively treated.

Therefore, research and development of drugs for the medical needs yet to be met is in great demand.

In response, the Mitsubishi Tanabe Pharma Group aims to leverage its capabilities in research and development to create innovative new drugs that can meet unmet needs and contribute to the health of people worldwide.

# Increasing the Indications of Remicade

Remicade 100mg (generic name: Infliximab), anti-TNF  $\alpha$ monoclonal antibody was put on the market in Japan in May 2002 as a treatment for Crohn's disease. Since then it received approval for the treatment of rheumatoid arthritis in July 2003, Behcet's disease with refractory uveoretinitis in January 2007, psoriasis in January 2010, ankylosing spondylitis in April 2010, and ulcerative colitis in June 2010. The drug is currently used by over 70,000 people in Japan.

# The Treatment of Ulcerative Colitis

Ulcerative colitis is a chronic disease of the colon in which inflammations repeatedly appear on the mucosa of the colon, become ulcerated, and cause chronic diarrhea or soft stools, bloody feces, abdominal pain, and other symptoms. Because the cause is unknown and there is essentially no known treatment, Japan's Ministry of Health, Labour and Welfare has designated it an intractable disease under its Incurable Disease Treatment Research Program. Many patients with ulcerative colitis have a markedly poor quality of life because they face limitations in their daily life and feel anxious about the possible need for surgery.

The basic treatment of the disease is pharmaceutical, and aims to reduce the inflamed intestinal mucosa and control the symptoms. Remicade suppresses the action of TNF  $\alpha$ , which is directly related to intestinal inflammation, while also destroying the cells that produce TNF  $\alpha$  . For ulcerative colitis patients who have used conventional drugs with no clear results, treatment using Remicade

can alleviate symptoms and reduce the number of cases of hospitalization and surgery.

# **Treating Ankylosing Spondylitis**

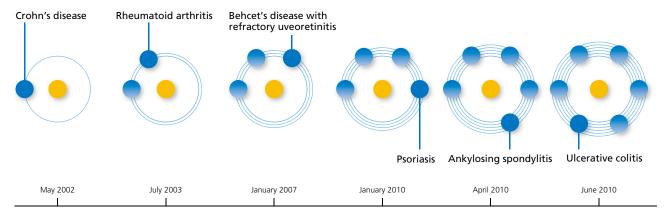
Ankylosing spondylitis is a chronic disease that inflames and causes pain in the joints in the spine and limbs until eventually the joints fuse. As the disease progresses, patients find it impossible to move their affected joints, which often degenerate to the extent that patients take a forward-bent posture. The disease is less common in Japan than in Europe and the United States.

The cause of ankylosing spondylitis is unknown and there is no basic treatment. Nevertheless, it has recently been discovered that an excess of TNF  $\alpha$  in the spine and joints is one cause of the pain and inflammation seen in this disease. Because Remicade interferes with the action of TNF  $\alpha$ , there are indications that it will have a strong effect against the pain and inflammation caused by ankylosing spondylitis.



Remicade 100 mg for use in infusions

#### History of Indications Approved for Remicade



# **Application for Approval of the Multiple Sclerosis Drug FTY720**

In December 2010 Mitsubishi Tanabe Pharma submitted an application for marketing approval for the multiple sclerosis drug FTY720, which is being co-developed in Japan with Novartis Pharma.

Designated as an intractable disease by Japan's Ministry of Health, Labour and Welfare, multiple sclerosis presents outbreaks of neurological symptoms interspersed with periods of remission. Symptoms vary depending on the specific areas affected, but in general, patients experience visual impairments, numbness, motor paralysis, and difficulty walking. When the disease progresses to the chronic stage, use of the limbs is lost and a wheelchair becomes necessary.

FTY720 is a multiple sclerosis drug with a new mechanism of action. While all previous drugs for treating the disease were injected, FTY720 is Japan's first orally administered treatment agent, with a once-perday dosage. It has been designated as an orphan drug in Japan as it is effective for treatment but costly because of rare demand. FTY720 is raising expectations that it will be an important option for treating multiple sclerosis since it reduces the frequency of relapses, lessens the severity of symptoms, and slows the progress of physical disabilities.

The Company has licensed the drug to Novartis Pharma, which has received approval in more than 35 countries including the United States, Canada, and Germany.

# **Application for Approval of the Chronic Hepatitis C Drug MP-424**

Mitsubishi Tanabe Pharma submitted an application for marketing approval in Japan for the chronic hepatitis C drug MP-424 in January 2011.

In Japan, between 1.5 to 2 million people are estimated to be infected by the hepatitis C virus, which causes 70 to 80% of liver cancer cases. If left untreated. the virus can cause cirrhosis of the liver and liver cancer within 20 to 30 years. Standard methods for treating hepatitis C in Japan are not regarded as sufficiently effective, so a more effective treatment is required.

Based on results of clinical trials in Japan, when MP-424 is used in conjunction with a standard therapy, the therapeutic effect is improved and the length of time for necessary treatment is reduced. The drug has

proved effective against recrudescence and is recognized as beneficial for patients whose prior treatments were unsuccessful. Consequently, expectations are high that MP-424 will become a new treatment for chronic hepatitis C.

# **Additional Indications for Venoglobulin IH for the Treatment of Polymyositis and Dermatomyositis**

In October 2010 the liquid injectable immunoglobulin preparation Venoglobulin IH received approval for the treatment of polymyositis and dermatomyositis in cases when treatment using steroids has been ineffective.

Polymyositis and dermatomyositis fall under the classification of connective tissue diseases, the causes of which are unknown. Polymyositis and dermatomyositis cause muscle pain and weakness as a result of inflammation and degeneration of the muscles and are often accompanied by complications that include joint, lung, heart, and digestive disorders.

First-line treatment is steroids; however, some patients do not respond. Clinical trials of Venoglobulin IH conducted in Japan comparing symptoms before and after the drug was administered indicated that, for patients for whom steroids were ineffective, indices of basic everyday movements and muscle tests on the major muscles improved significantly. It has also been established that the drug is as safe and effective as therapies that are currently approved.



Venoglobulin IH 5% I.V. 1 g/20 mL

# **Strategic Alliances for Developing New** Drugs

Guided by its philosophy, "We contribute to the healthier lives of people around the world through the creation of pharmaceuticals," Mitsubishi Tanabe Pharma actively pursues strategic alliances with the aim to continuously develop new drugs.

In December 2010, Mitsubishi Tanabe Pharma commenced joint research with the U.S. firm Anaphore, Inc., in which it is applying an Atrimer technology developed by that company. Atrimer is a functional protein created with a next-generation biologics technology, through which the three-dimensional form of the protein can be modified to bind with specific target substances. The goal of this joint research, which also includes the Company's subsidiary, Tanabe Research Laboratories U.S.A., Inc., is to develop a treatment for autoimmune diseases such as rheumatoid arthritis, ulcerative colitis, and psoriasis.

In March 2011, Mitsubishi Tanabe Pharma launched a project with Kyoto University to carry out basic and clinical research on innovative treatments for chronic kidney disease. Chronic kidney disease results a progressive loss in renal function and can cause kidney failure if left untreated, making dialysis and kidney transplantation necessary. An estimated 13 million people suffer from the disease in Japan. Through this joint research project, the Company will spend five years beginning from April 2011 pursuing and developing target drugs for chronic kidney disease with the goal of creating an innovative new therapy.

# **Research System**

The Research Division works to promote cooperation between the corporate division, the CMC Division, and the Research Division. It helps research projects achieve intended results by promoting free and open exchanges between researchers to create synergies between various fields of expertise. Furthermore, the Research Division actively pursues collaboration with other corporations and research institutes to strengthen its drug discovery research, while promoting internal reforms to ensure the high ethical standards and spirit of collaboration needed to obtain highly reliable data.

#### Development of the Drug Discovery Research System



## **Consideration of Bioethics**

Animal testing is essential to new drug research for anticipating and determining the efficacy and safety of pharmaceuticals. Likewise, human tissue and cells donated by patients are increasingly important for new drug research. When planning research using animals, Mitsubishi Tanabe Pharma requires that the research proposals go through its Animal Experiment Committee, which follows international standards for animal testing, and conducts the research with high regard for the animals' welfare. Meanwhile, research using human samples is subject to strict examination by the Company's Ethics Review Committee, which considers ethical issues such as informed consent, protection of personal information, and the scientific validity of research proposals. Both committees, which include members from outside the Company to ensure objective, impartial, and transparent decisions, work to raise awareness of bioethical issues and maintain standards.

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

Mitsubishi Tanabe Pharma is pursuing global projects aimed at creating pharmaceuticals that are valuable to patients and can benefit the health of people

around the world. In order to offer patients the pharmaceuticals they need as quickly as possible, the Company not only develops its own new drugs, but also actively utilizes strategic alliances to strengthen and improve its R&D pipeline.

# Development Pipeline (as of July 29, 2011)

	Development code	Indications	Development					Origin	Developing Company			
	(Generic name)	marcations	Site	Phase 1	Phase 2	Phase 3	NDA filed	Approval	Origin	Developing Company		
	CNTO148	Rheumatoid arthritis	Japan					2011.7	Janssen Biotech Inc. (U.S.)	Co-development with Janssen Pharma		
	FTY720	Multiple sclerosis	Japan				2010.12		In-house	Co-development with Novartis Pharma		
	MP-424	Chronic hepatitis C	Japan				2011.1		Vertex Pharmaceuticals (U.S.)	In-house		
	Livalo	Hypercholesterolemia	Taiwan					2011.1	Kowa (Japan)	Tai Tien Pharmaceuticals		
	Livalo	Familial hypercholesterolemia	Indonesia				2010.6		Kowa (Japan)	P.T. Tanabe Indonesia		
			Japan									
	MP-513	Type 2 diabetes mellitus	EU						In-house	In-house		
			U.S.									
Compounds	BK-4SP	Vaccines	Japan						BIKEN (Research Foundation for Microbial Diseases of Osaka University)	BIKEN (Research Foundation for Microbial Diseases of Osaka University; Co-development with the Research Foundation for Microbial Diseases of Osaka University		
ŏ	MCI-196	Hyperphosphatemia	U.S., EU						In-house	In-house		
Ē	MP-146	Chronic kidney disease	U.S., EU						Kureha	In-house		
ပိ	MP-214	Schizophrenia	Japan						Gedeon-Richter (Hungary)	In-house		
New	TA-7284	Type 2 diabetes mellitus	Japan						In-house	In-house		
ž	MP-435	Rheumatoid arthritis	Japan						In-house	In-house		
	MT-2832	Secondary hyperparathyroidism	U.S., Canada						Cytochroma (Canada)	In-house		
+	MCI-186	Acute ischemic stroke	EU						In-house	In-house		
	MT-4666	Alzheimer's disease							EnVivo Pharmaceuticals (U.S.)	In-house		
	GB-1057		Japan U.S.						In-house	In-nouse In-house		
	TA-8995	Stabilizing agent	U.S.									
	MP-124	Dyslipidemia Acute ischemic stroke	U.S., Canada			-			In-house In-house	In-house In-house		
	MP-136	Dyslipidemia	EU						In-house	In-house		
	MT-3995	Hypertension	EU						In-house	In-house		
	MP-157	Hypertension	EU						In-house	In-house		
	MT-1303	Multiple sclerosis	EU						In-house	In-house		
	Remicade	Ankylosing spondylitis	Japan					2010.4				
		Ulcerative colitis	Japan					2010.6	Janssen Biotech (U.S.)	In-house		
_		Crohn's disease: dose escalation	Japan				2010.12					
		Polymyositis, dermatomyositis	Japan					2010.10				
		Agammaglobulinemia (additional dosage)	Japan					2010.5				
	Venoglobulin IH	IgG2 deficiency	Japan				1997.12		In-house	In-house		
SU		Myasthenia gravis	Japan				2010.12		iii iidase			
a a		Systemic scleroderma	Japan									
ndica	Pazucross	Septicemia, pneumococcus Severe, intractable cases (additional dosage)	Japan					2010.7	Toyama Chemical Co., Ltd.	Co-develoment with Toyama Chemical Co., Ltd.		
Additional Indications	Novastan	Prevention of clotting during hemodialysis and percutaneous coronary intervention using HIT	Japan					2011.5	In-house	Co-development with Daiichi Sankyo Co., Ltd.		
등	Maintate	Chronic heart failure	Japan					2011.5	Merck KGaA (Germany)			
Ao	Azanin	Refractory rheumatic disease	Japan					2011.5	GlaxoSmithKline (UK)			
	Anti D (Rho) human normal immunoglobulin	Suppression of immunological sensitization due to the D (Rho) factor around the 28th week of pregnancy	Japan					2011.5	In-house	In-house (open applications)		
	Modiodal	Obstructive sleep apnea	Japan				2010.5		Cephalon (U.S.)	Co-development with Alfresa Pharma		
	Radicut	Amyotrophic lateral sclerosis	Japan						In-house	In-house		
	Cholebine	Type 2 diabetes mellitus	Japan						In-house	In-house		
	Cholebille	Hyperphosphatemia	Japan						ii -i iouse	ii r-i louse		
	Development code		Development		Dev	elopment S	itane					
	(Generic name)	Indications	Site	Phase 1	Phase 2		NDA filed	Approval				
	FTY720	Multiple sclerosis	U.S., EU					2010.9	Novartis P	harma (Switzerland)		
			Korea				2011.1	20.0.5		rma (South Korea)		
	TA-1790	Erectile dysfunction	U.S.				2011.6		,	/ivus (U.S.)		
Ħ	TA-7284	Diabetes mellitus	U.S., EU						Johnson & Johnson Pharmas	eutical Research & Development (U.S.)		
ō.	IA-7204	Obesity	U.S., EU						JOHNSON & JOHNSON FRANKLA	eutical Research & Development (0.3.)		
		Multiple sclerosis	EU						Glaxo	SmithKline (UK)		
ng-	T-0047					-			Med	diciNova (U.S.)		
-guist	T-0047 MKC-242	Insomnia	U.S.			1	1			BrainCells (U.S.)		
ensing-			U.S.						Bra	inCells (U.S.)		
Licensing-out	MKC-242	Insomnia								inCells (U.S.) irmaceutical (Japan)		
Licensing-	MKC-242 MKC-231	Insomnia Depression and Anxiety	U.S.						Senju Pha			
Licensing-	MKC-242 MKC-231 Y-39983	Insomnia Depression and Anxiety Glaucoma	U.S. Japan						Senju Pha Cyr	irmaceutical (Japan)		
Licensing-	MKC-242 MKC-231 Y-39983 MT-210	Insomnia Depression and Anxiety Glaucoma Schizophrenia Gastroesophageal reflux disease	U.S. Japan EU						Senju Pha Cyr Edusa Ph	rmaceutical (Japan) enaic (France) armaceuticals (U.S.)		
Licensing-	MKC-242 MKC-231 Y-39983 MT-210 MKC-733	Insomnia Depression and Anxiety Glaucoma Schizophrenia	U.S. Japan EU U.S.						Senju Ph Cyr Edusa Ph Negma L	rmaceutical (Japan) enaic (France)		

# Highlight Developing Vaccines and Promoting Vaccinations in Japan

Vaccines are pharmaceuticals and yet completely unique in that they are given to healthy people to maintain health and reduce susceptibility to diseases, whereas most pharmaceuticals are administered in order to treat patients' diseases.

Recognizing that vaccination is the most effective weapon against infectious diseases, Mitsubishi Tanabe Pharma is now mainly handling pediatric vaccines, specifically a freeze-dried live attenuated measles and rubella combined vaccine and a freeze-dried Japanese encephalitis vaccine. These vaccines are especially important in Japan, which despite having one of the world's most advanced healthcare systems, has no drugs specifically for the treatment of measles and Japanese encephalitis, as well as other infectious viruses.

The Company operates the health support website, Wakuchin.net, to provide accurate information about vaccinations with an emphasis on their importance for preventing illness in advance. The website provides free educational tools and other materials to support people engaged in vaccination educational activities in municipalities and at educational institutions throughout Japan.

People are constantly surrounded by infectious diseases, among which only a small percentage can be prevented by vaccinations. In this light, Mitsubishi Tanabe Pharma is working tirelessly each day to develop and promote more effective vaccines that can reduce people's risk of infection.

# The Wakuchin.net Initiative

# http://www.wakuchin.net/

Educational materials provided through Wakuchin.net are used by people engaged in vaccination-related educational activities at nursery schools, kindergartens, and junior and senior high schools around Japan. These materials are offered free of charge to those who place orders, and they are also available for download in PDF format.



The Wakuchin, net home page

#### Examples of the Site's Educational Materials



Content related to schools



Content related to public health facilities

# Pharmacovigilance and Quality Assurance

Recognizing that information related to the efficacy, quality and safety of pharmaceuticals must ensure appropriate usage, Mitsubishi Tanabe Pharma has established an integrated reliability assurance system that covers every stage of operations from R&D through to services at the post-marketing stage. Through this system, the Company is working to ensure that patients use its products appropriately.

# **Pharmacovigilance and Quality Assurance System of Drugs**

Mitsubishi Tanabe Pharma employs its integrated reliability assurance system to assess the information related to safety from the clinical trial stage through to post-marketing, while also fully investigating potential risks uncovered at the R&D stage and working to minimize such risks after products are sold.

The Company employs a quality management system based on the ICH Q10 Pharmaceutical Quality System, starting from the time an investigational new drug enters the manufacturing phase through the entire product lifecycle. Mitsubishi Tanabe Pharma is also committed to strict pharmaceutical auditing in accordance with regulations, making efforts to ensure the reliability of data by employing the GxPs (Good x Practices) while conducting a wide range of inspections spanning from the initial phase of research to medical information services at the post-marketing stage.

# **Global Reliability Assurance System**

Mitsubishi Tanabe Pharma recognizes that sharing information worldwide about pharmaceutical quality and safety is essential for ensuring the safey of patients. Accordingly, the Company is continuously improving its global reliability assurance system to maintain compliance with laws and standards in Japan and countries around the world. Through cooperation between Group companies and partner companies in Europe, the United States, and Asia, the Company takes steps to set up and improve frameworks for supervising the quality of products sold internationally, maintain the quality and safety of clinical trial drugs and pharmaceutical products, and implement quality control for both bulk substances and finished pharmaceuticals. The global reliability assurance system also ensures the reliability of research data collected both in Japan and in other countries.

Pharmacovigilance and Reliability Assurance System of Drugs

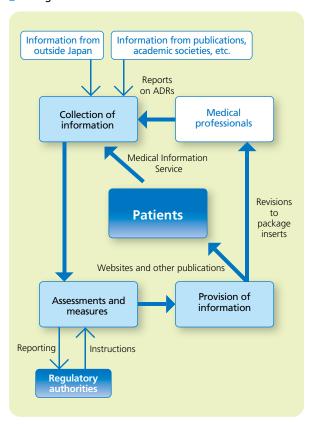


# **Handling Reports on Adverse Drug Reactions** and Infections

In Japan, Mitsubishi Tanabe Pharma compiles reports on Adverse Drug Reactions (ADR) and infections experienced by patients who use its products, collected from medical institutions by medical representatives (MRs), as well as information provided by patients and their families via its Medical Information Service. Outside Japan, the reports are based on information obtained by Group companies or partner companies.

The Company submits these reports to Japan's Minister of Health, Labour and Welfare (MHLW) pursuant to relevant laws and regulations. Mitsubishi Tanabe Pharma revises and amends information accompanying its products according to correspondence with regulatory authorities and implements various measures when necessary to ensure safety. It announces these safety measures to medical institutions by way of its MRs and website. The Company uses this information to promote the safe usage of its pharmaceuticals and help prevent recurrences of ADRs or infections.

#### ■ Management of Information on Side Effects and Infections

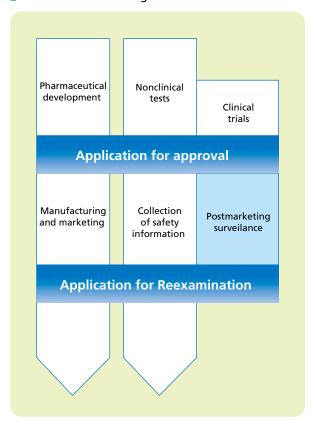


# **Post-Marketing Surveilance**

Mitsubishi Tanabe Pharma releases its pharmaceutical products to the market after subjecting them to stringent clinical trials and gaining approval for manufacturing and marketing from the MHLW. The Company recognizes, however, that the safety profiles of drugs may be incomplete since clinical trials employ patients of limited ages and conditions, cover a relatively small number of cases, and exclude patients suffering from severe liver or kidney diseases, as well as children and pregnant women.

Recognizing this fact, the Company carries out post-marketing surveilance on its newly marketed pharmaceuticals, by which it collects thousands of items of data to identify rare side effects and issues related to safety and efficacy among elderly patients and patients suffering from a variety of complications or concurrent diseases. Based on these findings, Mitsubishi Tanabe Pharma develops safer and more effective ways to use its pharmaceuticals.

#### Role of Post-Marketing Surveilance



# **Quality Assurance for Pharmaceuticals**

Placing the highest priority on the safety of patients so that they are able to recover from illness, Mitsubishi Tanabe Pharma's Quality Assurance Division undertakes various activities to ensure the quality of the Company's pharmaceuticals. These include supervising manufacturing operations and handling any product defects that arise at all Group factories, in accordance with "Good Quality Practice (GQP)" and the "Mitsubishi Tanabe Pharma Group's Quality Policy."

The Company is also working with its subcontracted manufacturers and raw material suppliers to help improve their level of quality assurance. Having experienced the Medway Issue and other quality control problems, Mitsubishi Tanabe Pharma has put in place stringent measures aimed at preventing a recurrence of such problems in the future. The Company will continue to implement ongoing improvements with these business partners so that patients can put their trust in its pharmaceuticals.

# **Education in Pharmaceutical Safety**

In fiscal 2008, Mitsubishi Tanabe Pharma initiated a training program for all directors and employees of Group companies engaged in the pharmaceutical business to promote a greater awareness of safety issues related to pharmaceuticals.

This training focused on safety measures in fiscal 2010, featuring lessons on health hazards posed by pharmaceuticals, the need to ensure reliable information and data routinely handled by employees, and the

benefits of cooperation for solving problems. A total of 96 training sessions have been held with 8,280 employees participating.

Mitsubishi Tanabe Pharma also conducts upper management seminars for directors, auditors, and executive officers, in which it invites experts from outside the Company to give lectures. In fiscal 2010, lectures focused on the social responsibilities of pharmaceutical companies in light of health hazards posed by pharmaceuticals in the past.



Pharmaceuticals and safety education programs



A seminar for upper management

# The Pharmacovigilance & Quality Assurance Division Works to Keep the Company's Pharmaceuticals Safe and Effective

Mitsubishi Tanabe Pharma understands that completely eliminating ADRs is impossible, and people with serious illnesses may have no choice but to use drugs regardless of potential ADRs. With this in mind, the Company takes into consideration both the benefits and risks of using its products when carrying out marketing activities.

Following this policy, the Pharmacovigilance & Quality

Assurance Division collects and evaluates data from Japan and other countries about the safety and efficacy of pharmaceuticals so that the patients use the Company's drugs appropriately. Employing statistical analysis and other methods to analyze the data, the Division can quickly recognize potential risks and create precise prevention measures to ensure the highest standards of safety and efficacy for the Company's pharmaceuticals.



# Maintaining a Stable Supply of High-Quality Pharmaceuticals

To ensure that patients can rely on its pharmaceuticals, Mitsubishi Tanabe Pharma has implemented stringent manufacturing, quality, and hygiene controls at every stage of operations from manufacturing to test verification and distribution. The Mitsubishi Tanabe Pharma Group strictly follows these controls as it produces pharmaceuticals through its global manufacturing system, thereby maintaining a stable supply of high-quality pharmaceuticals for customers around the world.

# **Pharmaceutical Manufacturing Process**

While Mitsubishi Tanabe Pharma produces and supplies premium products, it continuously strives to improve their quality in an effort to ensure that customers can trust and depend on them. Toward this end, the Company's Chemistry, Manufacturing and Control Division and the Group's production plants work together from the development stage of new drugs onward to develop production technologies aimed at enhancing quality, guaranteeing a stable supply, and reducing costs.

The Mitsubishi Tanabe Pharma Group's global manufacturing system comprises 12 production plants in Japan and five outside the country, as well as subcontracted manufacturers. Through this system, raw materials procured from around the world undergo acceptance testing before the production of pharmaceuticals begins. Applying its original technologies and expertise developed over many years, the Group manufactures bulk and finished products while conducting a battery of tests and inspections in accordance with good manufacturing practices (GMP) and strict quality controls standards.

# **Measures to Prevent Medical Malpractice**

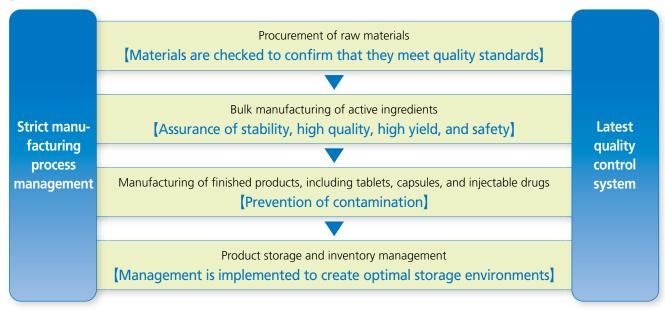
As one example of a measure designed to prevent medical malpractice, the Company changed the labeling of its Anplag tablets, which are used to treat chronic arterial occlusion, to more clearly display the product name. This measure may contribute to preventing incidents of medical malpractice, such as dispensing errors at medical facilities, as well as improve efficiency at pharmacies and help ensure that individual patients choose the correct medication.

In an effort to guard against mistakes involving its products, Mitsubishi Tanabe Pharma has been changing the brand names of its pharmaceuticals to more suitable and understandable names, with over 200 product names changed as of March 31, 2010. The Company has also been improving the shape of tablets and the concentrations of active ingredients when appropriate.



The new brand name "Anplag" is clearly displayed on the tablet

#### Process from Raw Materials to Finished Product



#### **Procurement Controls**

Mitsubishi Tanabe Pharma's basic purchasing policy calls for open, fair, and transparent transactions.

Mitsubishi Tanabe Pharma selects suppliers on a global and open basis with the aim to ensure the quality of procured materials and their stable supply. The Company applies its own strict supplier selection standards to ensure fairness and impartiality when evaluating and deciding on suppliers.

# **Ensuring Compliance in Purchasing Operations**

The Mitsubishi Tanabe Pharma Group has established the following Compliance Code of Conduct for Purchasing Operations for all employees engaged in purchasingrelated activities.

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 for each country's market and quality standards. In China, a country with strong growth prospects, Tianjin Tanabe Seiyaku Co., Ltd., based in Tianjin City, manufactures oral agents, and Mitsubishi Pharma (Guangzhou) Co., Ltd., operating out of Guangzhou City, manufactures IV solutions.

Mitsubishi Pharma Korea Co., Ltd., and Taiwan Tanabe Seiyaku Co., Ltd., handle products for their respective markets as well as products sold in Japan, and accordingly, work to maintain and continuously improve product quality in line with Japanese standards. Finally, P.T. Tanabe Indonesia serves as a manufacturing base not only for Indonesia but also the entire Southeast Asian region.



Tianjin Tanabe Seiyaku manufactures Herbesser.

# Working to Ensure Reliable Pharmaceuticals at Tianjin Tanabe Seiyaku

As a member of the Mitsubishi Tanabe Pharma Group, Tianjin Tanabe Seiyaku manufactures and supplies Herbesser, Tanatril, Cerekinon, and other original Group products to patients in China. As GMP standards become increasingly strict around the world, new GMP standards became effective in China in March 2010, requiring the same level of standards for the qualitative and tangible aspects of manufacturing as practiced in Europe and the United States. In response, Tianjin Tanabe Seiyaku upgraded its factory, revised its manuals related to GMP standards, and implemented company-wide training to ensure that it complies with the country's new standards.

Along with these measures, Tianjin Tanabe Seiyaku carries out surveys to monitor and promote compliance, in an effort to fulfill its social responsibilities as a pharmaceutical company. The company's overarching goal is to help improve the health of people in China and around the world as a trusted company by providing

a stable supply of high-quality pharmaceuticals. Toward this end, employees continually strive to fulfill the aims embodied in the company's slogan, "Create, Anticipate, Challenge."

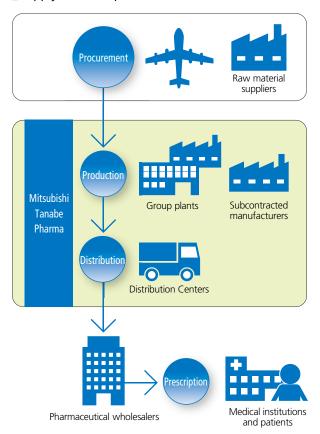


Staff from Tianjin Tanabe Seiyaku's manufacturing division

# **Supply Chain** Management

Recognizing that a pharmaceutical company's duty is to ensure that pharmaceuticals reach patients when needed, Mitsubishi Tanabe Pharma Group has established a supply system designed to stably deliver pharmaceuticals to patients even during disasters and other times of emergency.

## Supply chain for pharmaceuticals



# **Maintaining Stock to Ensure Stable Supplies**

Mitsubishi Tanabe Pharma fully understands its social responsibilities as a pharmaceutical manufacturer and its duty to continue business in times of a natural disaster, terrorism, a pandemic, or other disasters. Accordingly, the Company maintains safety stock in line with its risk management and business continuity plans.

The safety stock includes emergency-use products that have no substitutes, and therefore, are crucial for sustaining the lives of patients. The Company has designated these products as important pharmaceuticals and carefully monitors their inventory levels.

As a result of these measures, Mitsubishi Tanabe Pharma was able to fulfill its responsibility of maintaining a stable supply of pharmaceuticals in the aftermath of the Great East Japan Earthquake that struck on March 11, 2011.

# **Inventory and Quality Controls**

Mitsubishi Tanabe Pharma has implemented inventory and quality control systems as well as transport and risk management systems at its distribution centers with the ultimate objective of maintaining a stable supply of highquality pharmaceuticals to patients.

Through its inventory control system, the Company ensures a speedy and stable supply by storing products by item and lot and practices shipment controls based on the principle of first-in and first-out.

The Company maintains quality throughout the distribution process by monitoring who enters and exits the storage facilities, regulating storage temperatures, cleaning regularly, and inspecting storage facilities for insects and rodents.

Through its transport control system, the Company makes contractual agreements with transport companies regarding appropriate handling during transport, and the prevention of damage, theft, loss of goods, and misdirected or late deliveries. The Company periodically monitors these activities to ensure conformity with the agreements.

For its risk control system, the Company employs two distribution centers on both sides of the country, the East Japan Distribution Center and the West Japan Distribution Center, which are able to provide backup functions during emergencies. This was demonstrated in the aftermath of the Great East Japan Earthquake, which caused a temporary suspension the East Japan Distribution Center. At that time, the Company used the West Japan Distribution Center to supply replacement items, enabling it to deliver orders

from drug wholesalers around the country on time and successfully maintain a stable supply of pharmaceuticals.

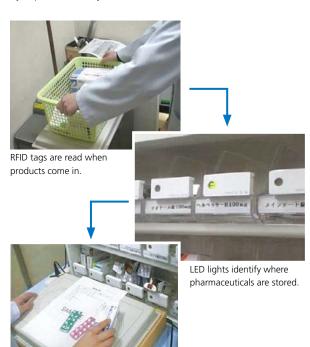
# **Export of Pharmaceuticals**

In fiscal 2010, Mitsubishi Tanabe Pharma exported its pharmaceuticals to approximately 50 countries around the world. To obtain permits for these exports, pharmaceuticals must be inspected to determine compliance with laws and customs regulations.

Therefore, the Company works to ensure that its products for export meet all pharmaceutical-related regulations effective in destination countries as well as export controls and regulations concerning the international transport of hazardous materials. Mitsubishi Tanabe Pharma intends to continuously work to improve its export operations to maintain a stable supply of pharmaceuticals to patients around the world.

# **Conducting Verification Tests on a Pharmaceutical Traceability System Designed to Assist Pharmacies**

In fiscal 2010, Mitsubishi Tanabe Pharma was outsourced by Japan's Ministry of Internal Affairs and Communications



Patients' medication histories can be digitized and stored.

Verification tests are carried out with the cooperation of Teiyu-kai Pharmacies.

to conduct verification tests on a pharmaceutical traceability model system that the ministry is developing to promote ubiquitous medical and healthcare technologies.

In the project, the Company tested a traceability control system that utilizes radio frequency identification (RFID) tags, designed for pharmacies that dispense drugs. The Company checked the system's ability to read en masse the data recorded in the tags on inventories of different types of pharmaceuticals, and to identify where the pharmaceuticals are stored when they are needed to fill prescriptions. The Company also demonstrated that the system could digitally record and store patients' medication histories. After completing these tests, Mitsubishi Tanabe Pharma confirmed that the system contributes to making operations at pharmacies simpler and more efficient and significantly lowers the chances of medical malpractice by improving the authentication of pharmaceuticals.

The importance of having a system like this for safely storing medication histories of patients, even if only temporarily, was underscored by experiences in the aftermath of the Great East Japan Earthquake. In disasteraffected areas, medical institutions could not confirm the past illnesses or medication histories of patients because neither paper nor digitized medical records were available or worked properly.

# **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. To ensure compliance with export security control, in fiscal 2008 Mitsubishi Tanabe Pharma established the Export Management Secretariat within the Environment and Safety Department, overseen directly by the president. The secretariat examines whether export products and technologies conform to regulations, investigates client companies, provides employees with information on revised regulations, carries out training programs, conducts onsite inspections of departments in charge of exporting, and verifies the proper operation and effective management of these activities.

To dependably maintain compliance with export security control systems, the Company exchanges related information with other member companies of the Mitsubishi Chemical Holdings Group.



# Providing Prompt and Accurate Information to Ensure Pharmaceuticals Are Used Appropriately

Providing medical professionals with comprehensive information about the efficacy and safety of pharmaceuticals is essential to ensure that the products are used appropriately. Accordingly, the 2,200 medical representatives (MRs) employed across the Mitsubishi Tanabe Pharma Group are responsible for promptly and accurately presenting all necessary information to medical institutions. Toward this end, the Group's MRs work to collect data related to the effectiveness and safety of pharmaceutical products that have been released in the marketplace.

# The Responsibility of MRs to Collect Data and **Provide Information to Medical Institutions**

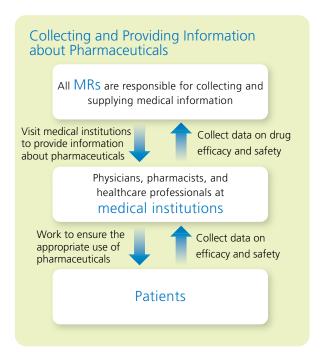
In its role to provide patients with pharmaceuticals that can effectively improve their health, the Mitsubishi Tanabe Pharma Group recognizes the importance of actively supplying a full array of information on pharmaceutical products to physicians, pharmacists and other medical professionals.

In Japan, the Group's general and specialized MRs supply medical institutions with information on the benefits of products as well as their possible side effects. In their efforts to ensure that products are used appropriately, the MRs collect data on the efficacy and safety of the drugs at the usage stage—information that was not available during the R&D stage—to provide databased evaluations to medical institutions. Specialized MRs are responsible for products that require a high level of knowledge about the targeted illness and drug treatment. General MRs, on the other hand, coordinate meetings between the specialized MRs and medical professionals to facilitate effective communication.

To support these activities, Mitsubishi Tanabe Pharma has created an exclusive website called Medical View Point for medical professionals, providing them with a constant source of useful information. Featuring news on drug products and diseases, the website offers an e-mail magazine along with information on various medical practices to subscribers.



Medical View Point—an exclusive website for medical professionals



# The Role of MRs in Helping Ensure the Safe Use of New Drugs

The number of patients that use a new drug after it has been released on the market is far greater than during the clinical-trial period. Since these patients use the new drug under a greater variety of circumstances, potentially serious side effects that were undetected during the clinical trials may be discovered.

Recognizing this fact, Mitsubishi Tanabe Pharma relies on its MRs to continuously collect data on the safety of its pharmaceutical products through post-marketing surveillance (PMS) based on doctors' reports. In Japan, the Minister of Health, Labour and Welfare requires pharmaceutical companies to conduct PMS for six months following the release of a new drug, for the purposes of encouraging cautious usage of the new product and collecting information about newly discovered side effects that may be serious. The Company fully cooperates in these measures for ensuring the safety of drugs by providing all required information.

As Mitsubishi Tanabe Pharma launches a number of new pharmaceutical products in 2011, MRs are playing a vital role in helping ensure the safe use of these new drugs as they carry out their responsibilities in supplying medical institutions with the information needed to use the Company's products appropriately.

# **Providing Comprehensive Product** 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 Japan through its overseas subsidiaries.

In the United States, Mitsubishi Tanabe Pharma's subsidiary based in Warren, New Jersey, makes all necessary preparations for launching new drugs in the American market. Meanwhile, the Company's subsidiary in Dusseldorf, Germany, handles marketing and sales of pharmaceutical products in Europe. MRs involved in sales must have a wealth of knowledge and skills to communicate effectively with physicians and pharmacists. Therefore, they are provided with monthly training to keep abreast of pharmaceutical information and related laws and regulations. MRs also make use of this training to improve their ability to provide comprehensive information to medical facilities. To supplement activities carried out by MRs, these subsidiaries send direct mail to

physicians and pharmacists on a regular basis to provide information on products and the illnesses

In Asia, Mitsubishi Tanabe Pharma provides a wide array of useful information to medical professionals through its group companies operating in China, South Korea, Taiwan and Indonesia. These subsidiaries provide support to medical professionals by sending MRs to visit medical facilities and physicians, participating in academic conferences, exchanging views with opinion leaders, engaging in scientific research, and creating and distributing informative publications.

MRs working at subsidiaries outside Japan play an important role as pharmaceutical experts with extensive knowledge about the increasing complexity and variety of medical treatments. As such, they have gained the trust of physicians and pharmacists around the world.

Through these global operations, the Mitsubishi Tanabe Pharma Group is providing comprehensive information on its pharmaceutical products with the overarching goal to contribute to people's health worldwide.

# Proud of Our Mission at Mitsubishi Pharma Deutschland to Provide Comprehensive Information

As the team leader in charge of MRs in Germany, I am involved in expanding our pharmaceutical business in Europe, mainly through sales of the direct thrombin inhibitor, Argatroban. We constantly challenge ourselves and view our team as having harmony as well as the ability to consider the viewpoints of others.

We are continuously striving to deepen our knowledge of both academic literature and product-related information. When working with medical professionals, we pay close attention to

the principles in the "Pride and Sense of Mission" section of Mitsubishi Tanabe Pharma's Corporate Behavior Charter.

Dr. Tobias Scheer Field Service Manager Sales Marketing Department Mitsubishi Pharma Deutschland GmbH



# Working for Both Patients and Medical Professionals at Taiwan Tanabe Seiyaku and Tai Tien Pharmaceuticals

At both Taiwan Tanabe Seiyaku and Tai Tien Pharmaceuticals, we support patients and medical professionals based on the following three basic principles.

Professionalism: Constantly striving to improve our professionalism, we use an academic approach to provide accurate pharmaceutical information to medical professionals.

Accountability: We maintain our commitment to accountability and service, listening to views and opinions that will help us meet the needs of patients and medical professionals as we strive to be product experts.

Integration: As MRs, we make the most of our sales support system to fulfill our roles and mission to gain the trust of medical professionals.

Chu Hung Hsiang Sales Director Sales & Marketing Department Taiwan Tanabe Seiyaku Co., Ltd. Tai Tien Pharmaceuticals Co., Ltd.

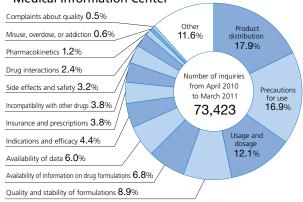


# **Providing Information through the Medical Information Center**

The Medical Information Center responds to inquiries from patients, consumers, and health care professionals including physicians and pharmacists. A highly unique information source in the private sector, the Medical Information Center provides callers with responses that are prompt, respectful, and clearly explained. In its role to ensure that Mitsubishi Tanabe Pharma products can be trusted, the center offers explanations related to product safety and quality issues.

When responding to inquiries, the Medical Information Center provides information based on drug approval documents, objective evidence and data, and scientific knowledge. However, it is careful to not provide the type of medical advice that should only come from a physician.

Breakdown of Types of Inquiries Received by the **Medical Information Center** 



#### Examples of Inquiries Made to the Medical **Information Center**

- What is the expiration date for this product? (Distribution management)
- Is it safe to take this medicine if I am pregnant? (Precautions for use)
- What is the dosage for a patient on dialysis? (Usage and dosage)
- My doctor instructed me to crush this medicine before taking it. Can you tell me if that would cause any problems? (Quality and stability of formulations)
- Can I use a vaccine stored in the refrigerator after it shut off due to a blackout? (Quality and stability of formulations)
- Is there something I can use in place of a product that has been discontinued? (Information on drug formulations)
- How long does it take for the drug to start to take effect and how long does the effect last? (Indications and efficacy)
- May I receive a long-term prescription for this drug? (Insurance and prescriptions)
- Can I bring this prescription medicine with me when I travel abroad? (Other)

# **Providing Information on Generic Drugs**

Under the slogan, "Providing Generics Reliably," Mitsubishi Tanabe Pharma maintains a stable supply of high-quality generic pharmaceuticals throughout Japan via its subsidiary, Tanabe Seiyaku Hanbai Co., Ltd. This company employs MRs with extensive experience and expertise in generic medicine to provide precise information on generic drugs to medical practitioners and facilities. Furthermore, Tanabe Seiyaku Hanbai's website is designed to make it easy for medical personnel to obtain the latest information on products at any time.

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

In order to assist people suffering from dermatological problems in obtaining accurate information and finding treatment as quickly as possible, the Company has conducted a variety of educational programs under the theme of "Thinking about skin problems" since fiscal 2009. These initiatives include TV commercials,

magazine ads, and website content aimed at informing people about the causes, symptoms and treatment of skin problems.



The Company's website on dermatological

# **Providing Information through Websites**

Mitsubishi Tanabe Pharma has set up websites to provide information on the various conditions that its products treat. The Company currently operates nine health support websites covering the following topics: Rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriasis, vaccines, cerebral infarction, sleep disorders, hemorrhoids and liver function. These websites provide

clear and accurate information on symptoms, diagnosis and treatment.



The Company's website, Ulcerative Colitis Frontier

# Recent Efforts to Improve Quality Control

Mitsubishi Tanabe Pharma sincerely regrets the fact that certain mandatory quality tests were not conducted for some products at the Ashikaga Plant, operated by Group company Mitsubishi Tanabe Pharma Factory Ltd., resulting in a loss of public trust. The Company's management offers its deepest apologies to all patients and medical professionals who experienced troubles and difficulties in relation to this incident

#### Overview of the Incident

In January 2011, it was discovered that a person in charge at the Ashikaga Plant failed to perform certain items of mandatory quality tests on products shipped between the spring of 2007 and the spring of 2010. The Company and the plant's operator, Mitsubishi Tanabe Pharma Factory Ltd., immediately filed a detailed report to Japan's Ministry of Health, Labour and Welfare, the Osaka Prefectural Government and the Tochigi Prefectural Government. The Company then decided to voluntarily recall all the affected lots. The required tests were performed on samples taken from the recalled lots, and no problems were found with the quality of the products. The Company held a press conference on January 26, where it apologized for the incident and announced plans to investigate what happened, determine the cause, and quickly implement preventative measures and correct any problems, with the intention to start afresh and regain the trust of society.

#### **Establishment of a Crisis Management** Committee

On January 26, the Company established the Risk Management Committee for Quality Control Problems, comprised of experts, for the purpose of providing guidance on handling the incident, uncovering its cause, and formulating measures to prevent a recurrence. The Group also set up the Emergency Countermeasure Committee as an in-house organization to carry out emergency countermeasures to deal with the incident, including comprehensive quality inspections, customer relations, and cooperation with government agencies.

The Risk Management Committee met a total of 11 times between January 26 and April 25, during which it requested a legal team to conduct a study and provided recommendations concerning comprehensive quality inspections

of Group products. On April 20, the committee met with the Company's Board of Directors and then reported its findings on the cause of the incident and recommended measures to prevent a recurrence.

#### **Comprehensive Quality Inspections Undertaken Group-Wide**

In order to respond to suspicions and concerns regarding the quality of the Group's products, and as part of comprehensive quality inspections, the Company ordered all Group factories to check their inspection records and supplementary records to verify that quality inspections had been properly carried out. Based on these findings, divisions involved in quality control were requested to submit voluntary reports on any discovered procedural problems with quality control.

To check the records, most inspection items could be confirmed by automatically analyzing raw data; otherwise, direct checks were made using analysis equipment of the Laboratory Information Management System. When no raw data was available, inspection items were verified using chemical reagent preparation records or other supplementary data and records. These results revealed that some plants had made minor omissions of necessary entries in supplementary records. However, there was no evidence that any of the plants had failed to carry out quality inspections.

Regrettably, however, the review of the voluntary reports submitted by divisions found that testing on some lots had been performed using weakened reagent. Therefore, tests were performed on sample items from these lots, determining that no problems with product quality existed.

The results of these comprehensive quality inspections were verified by the Crisis Management Committee and reported to the appropriate authorities.

# **Relation to the Medway Incident**

The Company had experienced quality control problems in the past with respect to its Medway products, and in April 2010, received an order to suspend production of these products from Japan's Ministry of Health, Labour and Welfare for violations of the Pharmaceutical Affairs Law. In June 2010, the Company was also handed a separate order to improve operations from the ministry, and accordingly, submitted

a report on its business improvement plan and implemented the plan throughout the Group.

The Medway incident publicly exposed the Group's quality control problems and the Company's efforts to put forward a series of Group-wide measures to improve operations and prevent a similar recurrence. Having carefully considered the similarities and differences between the problems involving Medway and the Plant, Mitsubishi Tanabe Pharma is placing the highest priority on completely solving all quality control problems by strengthening its Medway-related business improvement plan and bolstering it with effective and comprehensive preventative measures.

#### **Rectification Measures and Recurrence Prevention Measures to Recover Trust**

On April 27, 2011, the Company compiled the results of its comprehensive quality inspections and the recommendations of the Crisis Management Committee in the Comprehensive Report on the Quality Control Problem. The report presents the following measures aimed at preventing a recurrence of quality problems and regaining the trust of the public.

#### 1. Business management initiatives

#### 1) Improvement of training

As a result of the Medway incident, the entire Group reinforced its quality control training. To further improve basic compliance with quality inspection procedures at the Ashikaga Plant, training procedures already in place should be strictly carried out.

#### 2) Organizational and systemic reforms

# i. Improvement of the management

Management personnel in the Ashikaga Plant's Quality Control Division were increased or replaced. Mitsubishi Tanabe Pharma Factory Ltd. will assign personnel and ensure they receive the proper training as soon as possible.

#### ii. Promotion of multi-skill development among personnel in charge of inspections

The Ashikaga Plant's Quality Control Division now requires more personnel during inspections, with single-person inspections changed to two people or more and smallgroup inspections enlarged so personnel can check each other's work.

#### iii. Appropriate assignment of sufficient numbers of personnel

The amount of inspection work as well as the skills and abilities of the personnel in charge of inspections at quality control divisions at all plants, including the Ashikaga Plant, will be surveyed and personnel will be assigned as necessary.

3) Improvement of workplace communication Management personnel from the Ashikaga Plant's Quality Control Division are required to make rounds at inspection areas every day to improve communication with employees in charge of inspections, and are expected to improve their supervision of all employees in charge of carrying out inspections. The Company has also introduced weekly liaison conferences to supplement morning assemblies and monthly meetings.

#### 4) Workplace rotation to facilitate understanding and interaction

The Company will rotate personnel between the five factories operated by Mitsubishi Tanabe Pharma Factory Ltd. to facilitate a broader understanding of operations and encourage interaction among employees. The Company will also rotate more personnel between it and Mitsubishi Tanabe Pharma Factory.

#### 2. Quality Inspection Initiatives

- 1) Measures to improve the reliability of quality inspections
  - i. Preventative measures for emergencies A system of double-checking inspection items by inspection supervisors and other personnel in charge of inspections has been implemented for cases when no raw data is available
  - ii. Regular procedures to ensure inspections Supplementary records will be compared and checked when inspections are to be carried out. To ensure that the inspections are conducted, the supplementary records and inspection worksheets will be inputted into the Laboratory Information Management System.
- 2) Revised quality control management and stricter rules
  - i. Reassignment of line supervisors and clarification of responsibilities Operational tasks will be reassigned according to the responsibilities and authority of managers, supervisors, and persons in charge to achieve optimum organization. Personnel will be increased as necessary.
  - ii. Streamlining operations All quality control operations will be inventoried with redundant operations subject to revision. Certain operations will be outsourced both within and outside the Group as necessary.
  - iii. Optimization and standardization of inspections

The thoroughness and substance of standard operating procedures required in all quality control operations will be reviewed. Some inspection items will be partially simplified or modified as necessary through regulatory procedures to improve the efficiency of inspection operations.

#### iv. Implementation of new quality controls and appropriate methods for handling defects

All Group plants will strictly follow new quality controls and appropriate methods for handling defects in accordance with the Good Manufacturing Practice standards implemented at the Ashikaga Plant under directions from the government of Tochiai Prefecture.

#### 3. Management-level initiatives throughout the Mitsubishi Tanabe Pharma Group

1) Revision of in-house quality control operations

In its re-assessment of the Group's corporate governance, particularly in relation to the management of manufacturing operations, the Company aims to optimize the division of responsibilities and cooperation between it and Mitsubishi Tanabe Pharma Factory Ltd. by conducting a review that considers several perspectives, including business management, technology, and reliability assurance.

2) Improvement of compliance

The position of chief compliance officer in charge of supervising the Group's compliance promotion system will be assigned to Representative Director Kuniaki Kaga. Mr. Kaga will oversee a new department in charge of internal control and compliance, which will work to improve the daily operations and coordination of compliance promotion systems in place at all Group divisions and subsidiaries.

- 3) Improvement of the follow-up system for operational improvements As a result of the quality control problems at the Ashikaga Plant, the Company accelerated the implementation of business improvement initiatives it had initiated in the wake of the Medway problems. To improve the effectiveness of these initiatives, the Company strengthened the functions of three key organizations: its committee, overseen by the president, for following up on business improvements in relation to the Medway incident; an external committee that monitors these measures from a thirdparty viewpoint with the objective of restoring public trust in the aftermath of the Medway quality control problems; and the secretariat for both of these committees, the Medway Issue Management Department.
- 4) Specification of responsibility to society and response through organizational and personnel-related measures The Company has appointed an independent external director in an effort to make management more transparent.

Furthermore, the Company has replaced the former head of the Pharmacovigilance & Quality Assurance Division, who was ultimately responsible for the problems at the Ashikaga Plant, as well as the former president of Mitsubishi Tanabe Pharma Factory Ltd. Finally, severe disciplinary action has been taken against relevant people in charge and other personnel responsible for the inadequate testing at the plant.

#### **Business Suspension and Improvement** Orders Issued against the Ashikaga **Factory of Mitsubishi Tanabe Pharma Factory Ltd.**

On July 19, 2011, the Ashikaga Factory of Mitsubishi Tanabe Pharma Factory Ltd. was issued an order to suspend its business operations from the Tochigi prefectural government for a period of ten days, from July 20 to 29, 2011, in accordance with Article 75. Clause 1, of the Pharmaceutical Affairs Law for a violation of the Good Manufacturing Practice (GMP) ministerial ordinance. On the same day, the Company was issued an Improvement Order by Japan's Ministry of Health, Labour and Welfare in accordance with Article 72-4, Clause 1, of the Pharmaceutical Affairs Law for its violation of the Good Quality Practice (GQP) ministerial ordinance, as its business operations had deviated from GQP standards.

In response to the former problems concerning Medway products, the Company had already submitted a business improvement plan in June 2010 and implemented preventative measures. These measures were considered insufficient, so more effective measures were created in accordance with the improvement plan. Mitsubishi Tanabe Pharma Factory Ltd. was ordered to revise its improvement measures. and report this activity to the Ministry of Health, Labour and Welfare. This report was submitted in August 2011. The Company will make periodic reports on the progress of these measures to the appropriate authorities. In addition, reports on the measures will be issued to the external committee that monitors these measures so that the Company can receive recommendations and evaluations of the progress of the improvement plan from outside parties. Finally, reports submitted to and verified by this committee will be posted on the Company's website.

The Company is striving to prevent similar cases of quality control problems in the future by strengthening the preventative measures laid out in its business improvement plan. Driven by these efforts, the entire Mitsubishi Tanabe Pharma Group is fully dedicated to regaining the trust of society.

# Corporate Governance

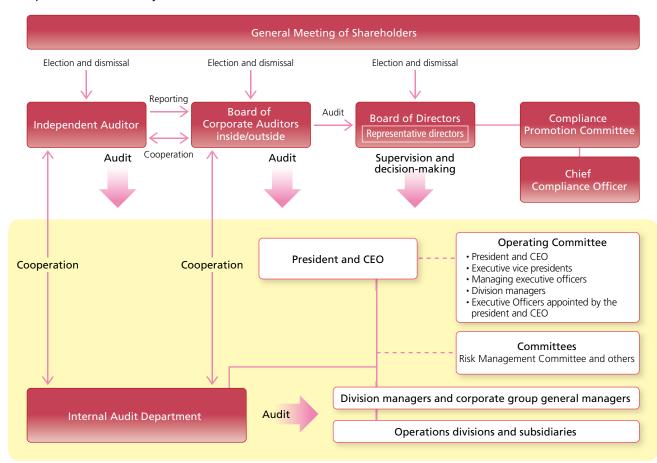
# Management

With the aim to earn the public's trust, Mitsubishi Tanabe Pharma is working to develop and maintain a highly transparent and objective corporate governance system. To this end, the Company has set up a system of internal controls designed to raise employees' awareness of the importance of compliance, and a risk management system for dealing with the risks involved in its business activities.

# **Management System**

Mitsubishi Tanabe Pharma has adopted a Corporate Officer System to clearly distinguish business executive functions of management from policymaking / supervisory functions. Important issues for the execution of business operations as well as basic policies and strategies are discussed and deliberated by the Operating Committee, comprised of the President and CEO, Managing Executive Officers, and Executive Officers appointed by President and CEO. Important matters discussed by the Committee are brought before the Board of Directors for final deliberation, thereby ensuring speedy and effective decision-making. As a general rule, meetings are held twice per month by the Operating Committee and once per month by the Board of Directors, as well as whenever necessary.

### ■ Corporate Governance System



# **Auditing System**

Mitsubishi Tanabe Pharma's auditing system is centered on its Board of Corporate Auditors, the members of which audit the execution of corporate activities by: attending important meetings, including those of the Board of Directors and the Operating Committee; interviewing directors, executive officers, and each division manager regarding business operations; reviewing documents related to major decisions; and investigating the operations and assets of principal business sites and subsidiaries, including their internal control systems and compliance and risk management.

Corporate auditors also review briefings from the independent auditor concerning its plans and policies, and exchanges views with the independent auditor on quarterly audit reports. At the end of each fiscal year, corporate auditors receive a report from the independent auditor concerning its system for ensuring the correct execution of duties. Furthermore, corporate auditors regularly receive information regarding the auditing plans, internal audit status, and monthly results of the Company's Internal Audit Department. The auditors exchange opinions with this department and review interim reports on the assessment of internal controls for financial reports.

Moreover, to support the duties of corporate auditors and outside corporate auditors, the Company has established a Corporate Audit Office with three full-time members, independent from business operations.

The Company has an Internal Audit Department that is independent from the executive divisions, and which audits the internal control status of each executive division. Ernst & Young ShinNihon LLC has been appointed as the independent auditor. Every effort is made to provide them with accurate managerial information in an environment in which proper auditing can be conducted.

# **Outside Directors**

On June 22, 2011, two additional outside directors were appointed to the Board of Directors with the aim to better ensure managerial transparency and objectivity. One appointee has a wealth of business administration experience while the other has wide-ranging knowledge of science, technology, and corporate governance. They joined the two current outside auditors, one of whom has abundant experience as an attorney while the other has abundant

financial institution experience. The addition of these outside directors has further strengthened the Company's external auditing and management supervision functions.

# **Accountability to Stakeholders**

Mitsubishi Tanabe Pharma publicly discloses important information concerning its corporate activities encompassing managerial policies, operational goals, and financial performance in a fair, prompt, and appropriate manner, to provide a basis for its stakeholders—including patients, medical professionals, shareholders, investors, and society at large—to evaluate its performance.

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 it is listed, in accordance with in-house information disclosure regulations. On the basis of these regulations, the Company ensures appropriate content and timing of information disclosure to stakeholders. The Company regards feedback from all stakeholders with the utmost seriousness and strives to share information in an effort to deepen mutual understanding.

Mitsubishi Tanabe Pharma holds guarterly meetings for institutional investors to present information on its financial performance, development of new products, important managerial policies, and business expansion. Briefings are held as necessary to discuss research and development as well as certain business issues. For individual and overseas investors, video and audio recordings of these meetings along with details of Q&A sessions are available on the Company website. The Company also issues its annual report to shareholders and investors to provide information on each fiscal year's performance.



Annual Report 2011

# Compliance and Risk Management

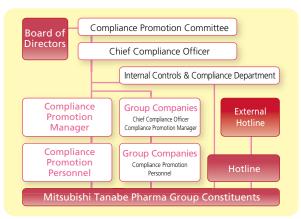
# **Promoting Compliance**

The Mitsubishi Tanabe Pharma Group has created a Group-wide compliance promotion system overseen by the Compliance Promotion Committee, chaired by the Chief Compliance Officer.

Through this system, the Group carries out compliance-related activities, such as conducting training on compliance and raising awareness of its hotlines and consultation services, in line with its Compliance Code of Conduct, which sets forth specific behavioral guidelines in accordance with the Mitsubishi Tanabe Pharma Group Code of Conduct.

In June 2011, Mitsubishi Tanabe Pharma newly established the Internal Controls & Compliance Department, under the direct supervision of the President and CEO, for the purpose of regaining public trust and confidence in the Company's quality control, and strengthening the promotion of compliance groupwide. The department is determined to enhance the understanding of compliance among all executives and employees of the entire Group.

# ■ Mitsubishi Tanabe Pharma Group Compliance Promotion System



#### Mitsubishi Tanabe Pharma Group 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 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.

#### **Hotlines**

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

To improve accessibility to the hotlines, the Group has provided toll-free numbers and made them available outside of business hours. It has also set up a system to allow customers and suppliers to directly contact the Group when they have suspicions or doubts about products or how the Group is handling compliance-related problems.

#### Number of Hotline Cases in Fiscal 2010

Laws or in-house regulations	Labor management	Preliminary consultation	Other	Total	
38	27	6	5	76	

# **Compliance Training**

Mitsubishi Tanabe Pharma Group holds a variety of training programs throughout the year with the aim of clarifying the behavior expected of pharmaceutical company employees and raising awareness of compliance issues among all Group employees.

Training sessions were held for all employees at each Group company in the first half of fiscal 2010, and for specific divisions shared by the Company and its subsidiaries in the second half of the fiscal year. In the divisional training, sessions focused on matters relevant to respective divisions, covering pertinent laws and regulations as well as case studies.

#### List of Training Sessions Held during Fiscal 2010

	Type of training	Times Held	Number of participants
	Common Company-wide (all employees,including part-time and temporary workers)	90	8,109
Compliance training	Division sessions (all employees, including part-time and temporary workers)	60	7,720
	Top seminar (directors, executive officers, and presidents of domestic affiliated companies)	1	34
Human rights	Director, Block (managerial posisions) training	37	773
awareness training	General training (employees in posisions of responsibility, including part-time and temporary)	102	6,515
New managem	2	108	
Management t	3	142	
New employee	1	68	

# **Group-Wide Meetings on Quality Risks**

In light of problems that arose in relation to the Company's Medway products in the past, the Mitsubishi Tanabe Pharma Group has been conducting meetings at each of its workplaces as an initiative to regain the confidence of its employees. Senior managers have been speaking directly with employees about the Medway problem in the meetings, which aim to share information and raise employees' awareness of potential problems. The meetings were held a total of 90 times between September 2010 and November 2010.



A speaker gives a presentation at a meeting on quality risks

# **Code of Conduct Day**

Taking into account the seriousness of the Medway problem, the Group established the "Code of Conduct Day" to provide an opportunity for all executives and employees to reflect upon compliance, with the overall aim of preventing any recurrence of such an incident.

On the Code of Conduct Day in fiscal 2011, the president offered a message to employees, and lectures were held featuring experts who sit on compliancerelated committees from outside the Group.

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

The Mitsubishi Tanabe Pharma Group has established risk management regulations with the objective of implementing appropriate management of risks associated with its business activities. Based on these regulations, the Group operates its risk management system under the supervision of the Risk Management Committee. Chaired by the president and CEO, the committee meets once every interim period and otherwise as necessary to identify and monitor risks faced by the Company and the

Group as a whole. Moving forward, the Risk Management Committee intends to implement even stricter risk management throughout the Company.

The Mitsubishi Tanabe Pharma Group has stated clearly in its Code of Conduct that it will not engage in any form of patronage with organized criminal groups. In the event such a group causes a problem, the Company has stipulated specific measures to be taken. Furthermore, to ensure that it does not become involved with customers that have relations with organized criminal groups, the Group manages a database of information on buisiness partners and has established operating procedures for assessing buisiness partners.

#### Mitsubishi Tanabe Pharma Group Risk Management System



## **Crisis Management**

In times of crisis such as disasters, accidents, or pandemics, or when there is the threat of such a crisis, Mitsubishi Tanabe Pharma takes measures in accordance with its risk management regulations and emergency communication procedures to keep damage and injury to a minimum. Depending on the circumstances, the Company may set up an emergency response headquarters to handle the crisis.

Immediately following the Great East Japan Earthquake, the Group confirmed the whereabouts of all employees and their families and collected information on damage and other problems from all facilities. The Group also set up a temporary risk management team and an earthquake response headquarters, which determined countermeasures in phases.

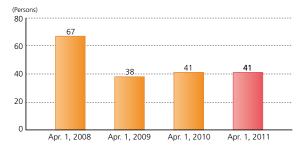
During the initial emergency phase, the Group worked to restore operations at factories and distribution centers to ensure a steady supply of pharmaceuticals and offered relief supplies, monetary donations, compensation payments, emergency loans, and other forms of support for people in the disaster areas. It continued this support in the second phase, during which it also introduced countermeasures to deal with the aftershocks and electricity shortages.

# **Providing Training** and Creating a **Positive Workplace Environment**

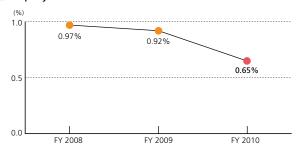
### Number of Employees

	Mar. 31, 2008	Mar. 31, 2009	Mar. 31, 2010	Mar. 31, 2011
Consolidated	10,361	10,030	9,266	9,198
Unconsolidated	6,266	5,715	5,186	4,957
Males	5,021	4,563	4,152	3,968
Females	1,245	1,152	1,034	989

## Number of New Graduates Hired (Unconsolidated)



#### **Employee Turnover Rate**

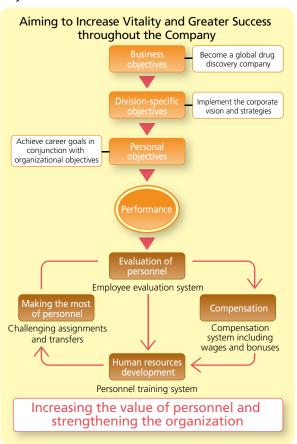


# **Fundamental Approach to Human Resources**

Mitsubishi Tanabe Pharma places paramount importance on requiring its employees to follow high standards of ethics, fairness, and integrity. In this regard, the Company has established the Corporate Behavior Charter that specifies four standards for conduct—Pride and a Sense of Mission, Challenge and Innovation, Trust and Teamwork, and Harmonious Co-existence with Society—on the basis of the Mitsubishi Tanabe Pharma Code of Conduct. These standards are applied as an integral part of daily work activities and specific business operations with the objective to cultivate employees that are dedicated to their work.

In an effort to be a flexible and dynamic organization, Mitsubishi Tanabe Pharma established its Comprehensive Management System for Human Resources to create a corporate culture in which employees can work toward personal success while channeling their energies toward strengthening the Company.

# Overview of the Comprehensive Management System for Human Resources



# **Improving Personnel Training and Enhancing Training Seminars**

As it strives to become a global drug discovery company, Mitsubishi Tanabe Pharma offers employees systematic career planning from a medium- to long-term perspective to foster the development of employees who are highly motivated to contribute to the vitality and growth of the Company. Building on this approach, the Company established its Human Resources Development Department in April 2011 to integrate activities from recruitment to training. The Company also worked to enhance its management and career-track training programs in fiscal 2010, and it plans to improve its graded and career-track training programs as well as its support for career management and individual skills development going forward.

# Training Programs

Level	Targeted staff		Career- track training		Career manage- ment support		Individual skills development		
	Executives								
Man highly	Directors Newly appointed directors								
Managers and highly skilled staff	Managers				Self-impi			ш	
staff	Newly appointed managers Promoted managers	ext-genera	Global l		ovement tı	Option	Corr	nglish and	In-
	Staff eligible for K1 Training	ion leade	eader trai	Education leave	aining fo	nal trainir	esponder	Chinese o	ouse TO
Regula	Employees eligible for New E-Level Training	Next-generation leader training programs	Global leader training programs	n leave	Self-improvement training for developing valuable skills	Optional training programs	Correspondence courses	English and Chinese conversation courses	In-house TOEIC course
Regular Employees	Third-year employees	ns			able skills			ses	
ees	New employees								

# **Initiatives to Promote Human Rights**

The Mitsubishi Tanabe Pharma Group respects the United Nations Global Compact's ten principles in the areas of human rights, labor, the environment, and anti-corruption, as it conducts its business activities as a responsible corporate citizen on the basis of its Code of Conduct.

The Company's Human Rights Awareness Promotion Committee, chaired by the president, plays a key role in Company-wide human rights training programs. The committee conducts regional training sessions for executives and managers as well as general training sessions for all employees in positions of responsibility, including temporary personnel. In anticipation of Human Rights Week in December every year, the committee holds a contest in which it solicits human rights slogans from employees to encourage them to think about human rights issues and increase their general awareness. In fiscal 2010, a total of 329 entries from throughout the Group were submitted.

#### **Relations with Labor Unions**

In April 2009, the labor unions of the former Tanabe Seiyaku Co., Ltd. and the former Mitsubishi Pharma Corporation merged and established the Mitsubishi Tanabe Pharma Labor Union. The union then completed 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 they exchange an array of information concerning workplace conditions. The Company's Labor and Management Committee also contributes views on specific issues to facilitate communication between labor and management and promote a better working environment.



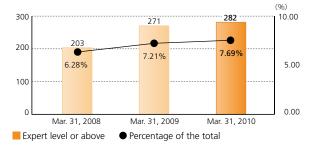
A labor and management meeting in progress

# Providing Training and Creating a Positive Workplace Environment

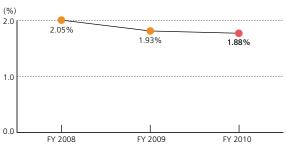
# Valuing Diversity in the Workplace

In response to Japan's shrinking workforce, caused by a decreasing birthrate and aging population, as well as to increasingly diverse values among individuals, Mitsubishi Tanabe Pharma has introduced working conditions that accommodate diverse work styles aligned with employees' lifestyles, including flextime, discretionary work, recognition of work offsite, and shortened work hours. Through these efforts, the Company is striving to help employees develop their abilities and work to their full potential. In this context, Mitsubishi Tanabe Pharma is creating more opportunities for female employees. As an example, the Company is assisting female employees in acquiring the expertise needed for promotion to managerial positions and other leadership roles. The Company is encouraging older employees who desire to work to continue utilizing their wealth of experience and skill. To this end, it introduced a re-employment system for retired employees in fiscal 2009, open to employees over the age of 60 who fulfill certain requirements. The Company also makes efforts to actively employ people with disabilities. The proportion of people with disabilities in its workforce is currently higher than the 1.8% legally mandated in Japan.

# Percentage of Female Employees with Expert Qualifications



# **Employment Rate of People with Disabilities**



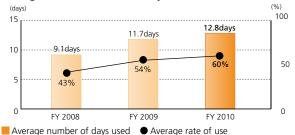
# **Promoting Work-Life Balance**

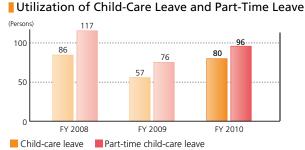
Mitsubishi Tanabe Pharma strives to create an environment in which every employee can easily balance work with personal life and family commitments, so that they can gain satisfaction and pride from their work while fully experiencing meaningful life events, such a birth of child and caring for children and family members. Taking this approach, the Company has formulated general business owner action plans pursuant to Japan's Law for Measures to Support the Development of the Next Generation. Since 2007, the Company has been certified for three consecutive periods as a "general business owner conforming to standards," earning it the "Kurumin" Certification Mark.

In addition, the Company has been promoting time management since 2009, with the goal to increase awareness of more efficient work methods to improve employees performance over short periods of time.

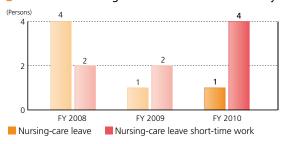
The "Kurumin' Certification Mark

# Usage of Paid Vacation Days





Utilization of Nursing-Care Leave/Short-Time Work System



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

In accordance with its belief that safety is the foundation of a company's existence, Mitsubishi Tanabe Pharma is taking initiatives aimed at completely eliminating workplace accidents or disasters. In particular, the Company has established an occupational health and safety management system to promote ongoing efforts to assist employees in maintaining their health and ensure safe working environments, and is applying the plan-do-check-act (PDCA) cycle to minimize safety risks in the workplace.

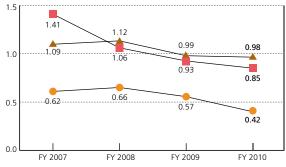
Through the occupational health and safety management system, Mitsubishi Tanabe Pharma is working to raise awareness of occupational risks among all employees. Specifically, every year the Company carries out safety training covering hazard prediction, human error prevention, and experience-based activities, with the goal of improving employees' ability to recognize unseen hazards in the workplace.

As a result of these efforts, the rate of lost work time in the Group's manufacturing and research divisions decreased year on year in fiscal 2010, dropping to 0.42 persons every 1 million work hours.



Employees learn about the dangers of organic solvents through experiments with absorption canisters .

#### Rate of Lost Work Time Due to Accidents



 Mitsubishi Tanabe Pharma Group
 Pharmaceutical industry average ▲ Manufacturing industry average

#### Safety Management of Chemical Substances

Mitsubishi Tanabe Pharma's factories and laboratories handle a variety of chemical substances. In fiscal 2010, the Company enhanced its internal system to ensure that necessary legal procedures are completed upon handling new chemical substances in all relevant operations, including research and manufacturing, in accordance with Japan's Act on the Evaluation of Chemical Substances and Regulation of their Manufacture, and the Industrial Safety and Health Act. Based on these laws, the Company implements chemical substance management procedures through cooperation between its divisions that handle chemicals.

#### Measures to Prevent Traffic Accident of New MRs

Mitsubishi Tanabe Pharma holds driver safety training sessions at driving schools for new MRs before assigning them to their posts in an effort to reduce their chances of having traffic accidents. With the goal to eliminate traffic accidents altogether, the Company improved its safety measures in fiscal 2010 by raising driver skill examination standards and requiring inexperienced drivers to achieve a certain level of skill. Consequently, work-related traffic accidents decreased by almost half compared to the previous fiscal year. Continuing from this result, Mitsubishi Tanabe Pharma will continue efforts to reach its goal of zero traffic accidents.

#### **Addressing Mental Health Issues**

Mitsubishi Tanabe Pharma is continuously working to address mental health issues among employees by giving them assistance in dealing with stress caused by interpersonal relations and the demands of the workplace. The Company has established a comprehensive followup system, increasing the number of offices where employees can meet and consult with visiting contracted medical specialists, and offering guidance for returning to work. Mitsubishi Tanabe Pharma is also working with health insurance associations to provide opportunities for employees to discuss health plans with representatives directly or by telephone. Furthermore, the Company provides opportunities for employees working more than 80 overtime hours a month, which can cause considerable mental fatigue, to meet with industrial medical advisors, as a measure that surpasses legal requirements in Japan. Finally, the Company is taking steps to reduce long work hours.

# Social Contribution **Activities**

#### **MSC Volunteer Salon**

Mitsubishi Tanabe Pharma sponsors the MSC Volunteer Salon, an event featuring seminars and small concerts. Held on a bimonthly basis, the salon provides opportunities for people interested in volunteer activities to interact with active volunteers. In fiscal 2010, the salon focused on issues concerning elderly nursing care and cancer.

The MSC Volunteer Salon also collaborates with volunteers from outside the Company to collect used stamps and prepaid cards to donate to welfare and other organizations. The donated items are used to support the activities of organizations such as the Japan Committee Vaccines for the World's Children, which provides vaccines to countries and regions where many children die of infectious diseases that can be prevented with existing vaccines.

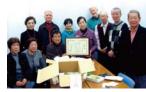
In fiscal 2010, the salon presented a volunteer activity club at Sainokuni Ikigai University with an official letter of appreciation for its participation in these activities

over many years. At the presentation ceremony, a representative of the club announced the following: "All of our members are very delighted to receive this letter of appreciation. We will



A seminar organized by the MSC Volunteer Salon

publicize it in our public relations magazine to increase awareness of this initiative. We intend to continue our participation to help needy people in the future."



The presentation of the letter of appreciation

#### **Supporting Activities of Patients Associations**

As a means to foster patient-centered healthcare, the Company supports volunteers of patients' associations by sharing useful information and providing assistance in holding general meetings and medical lectures. In fiscal 2010, Mitsubishi Tanabe Pharma offered support to the following patient associations: the Japan

Rheumatism Society, the Japan Spinocerebellar Degeneration & Multiple System Atrophy Society, the Fukusei Asebi Society, the IBD Network, and the Behcet's Disease Society.



A meeting of a patients association

#### Feedback from a Patients' Association

Our association has been receiving a wide range of support from Mitsubishi Tanabe Pharma since the company released Ceredist, a drug for treating spinocerebellar degeneration, in 2000. Mitsubishi Tanabe Pharma has provided grants to support our activities, assisted with lectures and consultations on healthcare, organized employee volunteer activities, and donated informational pamphlets to patients and their families. These activities help patients suffering from this incurable disease and their families face the challenges of daily life with a more positive outlook.

We are thankful for this support, as it is extremely helpful for expanding the society's activities. We look forward not only to Mitsubishi Tanabe Pharma's continued support for our activities, but also to the day when their drug development efforts result in a treatment for spinocerebellar degeneration.

Ryoji Saito, Chairman Japan Spinocerebellar Degeneration & Multiple System Atrophy Society

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

Mitsubishi Tanabe Pharma provides financial aid to the Mitsubishi Pharma Research Foundation<sup>1</sup> and the Japan Foundation for Applied Enzymology<sup>2</sup> as a means to fund research in a broad range of fields including medicine, pharmaceuticals, agriculture, and the physical sciences. Through the activities of both foundations, the Company is working to promote research and provide information that benefits medical treatment and public health.

#### Grants Provided to the Mitsubishi Pharma Research Foundation in Fiscal 2010

Total		113 projects	140 million yen
Research grants for special projects		2 projects	2,000 million yen
medicine	Financial aid for education abroad	3 projects	600 million yen
in the field of cardiovascular	New research areas	10 projects	1,000 million yen
Research grants	Basic research	24 projects	2,400 million yen
(blood)	Financial aid for education abroad	3 projects	600 million yen
in the field of hematology	New research areas	10 projects	1,000 million yen
Research grants	Basic research	24 projects	2,400 million yen
pharmacotherapy	Financial aid for education abroad	3 projects	600 million yen
in the field of	New research areas	10 projects	1,000 million yen
Research grants	Basic research	24 projects	2,400 million yen

#### Grants Provided to the Japan Foundation for Applied Enzymology in Fiscal 2010

Research grants	Applied research on enzymes and enzyme research related to life science	30 projects	2,250 million yen
	The Japanese Society of Applied Glycoscience	1 projects	30 million yen
Grants for specific	Research group focused on determining the causes and conditions of adult-onset diseases	40 projects	1,500 million yen
groups and	Vascular Biology Innovation Conference	20 projects	1,050 million yen
activities	Research group focused on determining the causes and conditions of systemic inflammation	10 projects	1,000 million yen

#### Notes:

- 1. The Mitsubishi Pharma Research Foundation obtained authorization from the Japanese government in April 2011 as an incorporated foundation.
- 2. The Japan Foundation for Applied Enzymology has applied for authorization as an incorporated foundation, with the outcome pending as of August 2011.

#### **Donations to Assist Victims of the Great East Japan Earthquake**

In the aftermath of the Great East Japan Earthquake, Mitsubishi Tanabe Pharma donated 100 million yen to the Japan Red Cross Society and pharmaceuticals to the Japan Pharmaceuticals Manufacturers Association as a way to assist victims of the disaster and the recovery of the affected areas. The Company also donated over-the-counter drugs, including gargling preparations, gastrointestinal drugs, and drugs for intestinal disorders. Mitsubishi Tanabe Pharma Group company, Choseido Pharmaceutical Co., Ltd., donated an additional 10 million yen.

#### River Cleanup Campaign Sponsored by P.T. Tanabe Indonesia

In June 2010, Mitsubishi Tanabe Pharma Group company, P.T. Tanabe Indonesia, sponsored a river cleanup campaign in Bogor, West Java. The company provided beverages to participants, and its employees worked together with volunteers to clean up the river and plant trees.

The river cleanup campaign is part of a series of environmental conservation activities that have a different theme each year, with "protect our rivers" designated as the theme in 2010. About 1,000 people joined the event from 75 organizations and companies, including P.T. Tanabe Indonesia and four other major pharmaceutical companies in the area, as well as the government of West Java.





Volunteers work together to clean Beverages are loaded for delivery

#### **Donating Over-the-Counter Drugs to a Children's Park**

As part of its social contribution activities, since 1971 Mitsubishi Tanabe Pharma has been donating overthe-counter drugs to Kodomo-no-kuni (Children's Land), a children's park in Yokohama City operated by the Kodomo-no-kuni Association, an organization that promotes social welfare. According to the park's director, Katsuhide Yasuzawa, "These pharmaceuticals benefit not only the children who play in the park, but also their parents

and guardians."



A representative officially offers donations on behalf of the Company.

# **Environmental Activities**

In order to contribute toward preserving the global environment and creating a sustainable society, Mitsubishi Tanabe Pharma must be cognizant of how every aspect of its business operations impacts the contributing to the environment and society.

#### 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 safety.

#### Basic Policy on Environmental Safety

- 1. Evaluate the environmental impact of all of our corporate activities in Japan and overseas, and continuously strive to reduce environmental burden.
- 2. Give precedence to safety considerations for all of our workers and prevent occupational accidents.
- 3. Establish clear objectives regarding environmental safety activities, and uphold and improve effective systems to achieve such objectives.
- 4. Comply with laws and regulations relating to environmental safety, and act in compliance with internally or externally established management standards more stringent than those stipulated in the laws and regulations.
- 5. Conduct systematic education and training to raise the environmental safety consciousness of each and 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.

## **Environmental Safety** Management

#### **Environmental Safety Management**

The Mitsubishi Tanabe Pharma Group has a strong sense of mission and ethics because its business activities—all carried out in accordance with the law—are deeply related to life itself. The Group's commitment to actively and aggressively protecting the natural environment and the safety of communities is part of the Mitsubishi Tanabe Pharma Group Code of Conduct. To promote related activities, the Group established the Basic Policy on Environmental Safety, which stipulates fundamental guidelines for the implementation of environmental and safety-related measures under the Environmental Safety Philosophy.

#### **Management Structure**

Mitsubishi Tanabe Pharma has instituted an environmental and occupational safety management system overseen by the president. 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. Meanwhile, 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 the Environmental Safety Division promotes the management of environmental issues both in and outside Japan. Furthermore, under its Medium-Term Voluntary Action Plan for Environmental Safety that commenced in fiscal 2011, the Group is pursuing objectives in four major areas, as outlined below.

#### Goals of the Medium-Term Voluntary Action Plan for **Environmental Safety**

Area	Goal
Energy conservation and global warming prevention	Reduce fiscal 2015 CO <sub>2</sub> emissions to 30% or less that of fiscal 2005
Waste reduction, reuse and recycling of resources	Aim for zero emissions and continuously reduce the amount of waste generated and the amount of final disposal Assume responsibility for waste matter and ensure that it is properly disposed of, both directly and by subcontracted disposal companies
Chemical substance emission reductions	Manage chemicals properly and continuously reduce the amount of chemical substances emitted into the environment
Enhanced environmental safety management	Improve the management of risks in workplace environments Maintain a record of zero environmental accidents

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

Mitsubishi Tanabe Pharma Group collects and discloses information regarding the manufacturing, research, and distribution facilities of consolidated subsidiaries and unconsolidated associate companies (under equity-method accounting), and environmental information pertaining to the manufacturing facilities of consolidated subsidiaries located outside Japan.

#### **Companies That Collect and Disclose Environmental Information**

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.

#### 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, Tianjin Tanabe Seiyaku Co., Ltd., in China acquired ISO 14001 certification in February 2010, following Mitsubishi Tanabe Pharma Korea, Co., Ltd.; Mitsubishi Pharma (Guangzhou) Co., Ltd.; and P. T. Tanabe Indonesia.

Other research institutes, distribution centers, and offices manage environmental and safety issues in ways that are appropriate to their locations and business activities, with the view to improve their environmental performance.

#### **Environmental Safety Risk Management**

The Group's production, research, and other divisions maintain constant awareness of the risks posed to environmental safety if harmful chemical substances used in business activities are leaked or allowed to disperse in the natural environment. The Group strictly abides by all relevant laws, establishes measures that take into account a variety of environmental safety hazards, and conducts activities in such a way as to prevent risks to the environment. Procedures for handling environmental problems are laid out in the Company's Environmental Safety Risk Management Regulations, which are studied in employee training.

#### **Environmental Safety Audits**

In fiscal 2010, environmental safety audits were conducted at 20 Mitsubishi Tanabe Pharmaceutical Group sites both in and outside Japan to ensure that their environmental safety activities and related regulations were in compliance with local laws.

In Japan, interviews with personnel in charge, inspections of environmental safety facilities and equipment, and onthe-spot checking of production, testing, and research divisions were carried out based on an initial examination of documents related to the environment and safety. Compliance with environmental laws and ordinances was assessed, and risk and safety assessment systems were evaluated.

Outside Japan, interviews with personnel in charge of risk management and on-site inspections are carried out in accordance with auditing practices in Japan with the aim of implementing improvements. Mitsubishi Tanabe Pharma is committed to promoting continuous improvement

through environmental safety audits, raising Group-wide awareness of the importance of environmental safety management, and thorough legal compliance.



Implementation of environmental safety audits

#### **Soil Contamination Control**

The Company has completed a cleanup operation of contaminated soil and is proceeding with an anaerobic bio groundwater cleanup operation at the former site of API Corporation's Kusu Plant, which closed in March 2009, located in Yokkaichi City, Mie Prefecture. In areas where contamination exceeded regulatory standards, the efficacy of cleanup operations, including the use of biodegradation to reduce the total contaminated area, is being checked. Efforts will be made to continue to carry out proper measures, including monitoring the effect of contamination on areas outside the plant's grounds, under the guidance of government agencies.

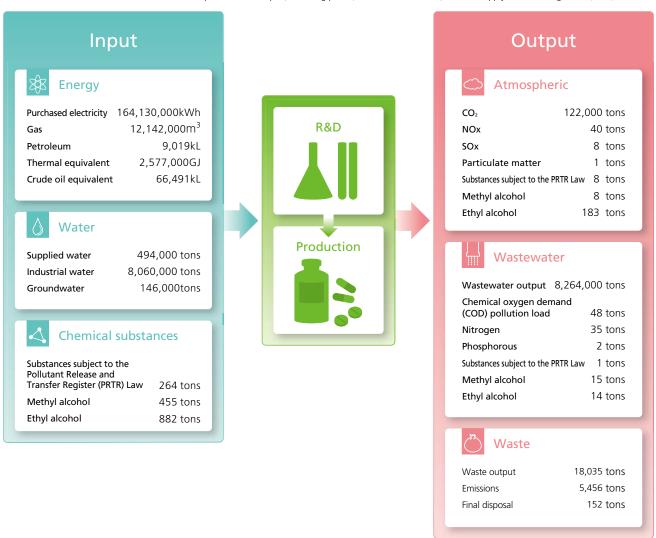
In the future, when changes are made to or on company-owned land as a result of reorganization to the scope of consolidation, the Company will submit reports detailing the reorganization and other required paperwork and conduct inspections in accordance with the revised Soil Pollution Control Act. The Group will release inspection results and take full and immediate responsibility for incidents involving contamination.

#### Overview of Environmental Burden

#### Input / Output

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

Data is for Mitsubishi Tanabe Pharmaceutical Group worksites in Japan, including plants, research laboratories, and the Supply Chain Management (SCM) Center



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

	Electricity	11.56 million kWh
Energy consumption	Gas	388,000 m³
	Petroleum	242 kL
Water consumption		428,000 tons
CO <sub>2</sub> emissions		8,000 tons
Waste output		470 tons

- ◆Data is for Taiwan Tanabe Seiyaku Co., Ltd.; Tianjin Tanabe Seiyaku Co., Ltd.; Mitsubishi Pharma (Guangzhou) Co., Ltd.; P.T. Tanabe Indonesia; and Mitsubishi Tanabe Pharma Korea, Co., Ltd.
- ◆Data was collected from January 1, 2010 to December 31, 2010
- ◆CO<sub>2</sub> emissions 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 the Ministry of the Environment and the Ministry of Economy, Trade and Industry of Japan. The electricity output coefficient was set at 0.000561 t-CO<sub>2</sub>/kWh.

#### Medium-Term Voluntary Action Plan for Environmental Safety

#### Objectives and Fiscal 2010 Results of the Medium-Term Voluntary Action Plan for Environmental Safety

Area	Objectives	Fiscal 2010 results
Energy conservation and global warming prevention	• Reduce CO <sub>2</sub> emissions for FY10 to 95% or less of FY2007	Reduced CO <sub>2</sub> emissions to 66.3% of the FY2007 level Completed integration of headquarters and surrounding buildings; thereby reducing CO <sub>2</sub> emissions to 45% of the FY2008 level Increased number of hybrid vehicles used by sales personnel to 700 from 76 in FY09; maintained 50 electric vehicles Performed energy conservation diagnosis at the Benesis Corporation Kyoto Factory
Waste reduction, reuse and recycling of resources	Promote zero emissions and keep final waste disposal ratio for FY10 below 0.5%	Achieved final waste disposal ratio of 0.84%     Promoted recycling and effective use of resources
Chemical substance emission reductions	Optimize chemical substance management and continuously reduce discharge of chemical substances into the environment, both in terms of concentration and total amount	Reduced atmospheric emissions of PRTR substances to FY09 levels     Continued with measures to control atmospheric emissions
Enhancement of environmental safety management	Develop and improve environmental safety management systems in accordance with the scale of work performed at company facilities     Improve environment, safety risk management, and emergency response measures at worksites     Conduct environmental safety audits     Promote environmental education and awareness-raising     Employ efficient environmental accounting	Introduced environment-related legal compliance management tools     Conducted environmental safety audits at 20 Group worksites both in and outside Japan     Conducted environmental training courses online
Occupational health and safety	Ensure that employees and workplaces undertake sufficient planning before carrying out projects     Review and promote safety measures for using machinery and equipment     Cultivate a corporate culture of safe driving	Conducted education and training to improve basic knowledge and awareness of health and safety     Conducted traffic safety education and driving training for new employees
Environmentally responsible product development	Develop environmentally responsible products     Introduce environmentally responsible containers and packaging	Reduced the volume, quantity, and weight of packaging for pharmaceuticals
Office environment measures	Conduct energy-saving campaigns     Promote green purchasing	Encouraged employees to follow campaigns to wear light clothes in the summer and heavy clothes in the winter to reduce office air conditioning and heating     Promoted power and water conservation through energy-saving campaigns
Environmental information disclosure	Improve the contents of the CSR report and disclose appropriate information     Contribute to local environmental protection efforts through interaction with local communities and volunteerism     Raise employee awareness of environmental issues at home	Issued the CSR Report 2010     Participated in the Mt. Ikoma Flower Screen forestation campaign organized by Osaka Prefecture     Participated in Biodiversity Declaration Promotion Partners initiated by Keidanren (Japan Business Federation)

#### **Environmental Accounting**

Mitsubishi Tanabe Pharma works to raise employees' environmental awareness and promote effective and efficient environmental management by clearly specifying and analyzing the costs and effects of environmental conservation and the impact these activities have on economic performance.

#### **■** Environmental Conservation Costs (Millions of yen)

Item	Invested	Expended
Pollution prevention	33	666
Global environmental protection	8	37
Recycling and reuse of resources	0	419
Upstream and downstream activities	0	33
Administrative activities	0	281
Research and development	0	0
Community activities	0	3
Environmental damage compensation	1	42
Total	42	1,480

#### Environmental Conservation Effects

Reduction of envi	Quantity reduced	
Global environmental protection	Greenhouse gas emissions	1,017 tons-CO <sub>2</sub>
Recycling and reuse of resources	Amount of generated waste	2 toms
Recycling and reuse of resources	Water consumption	425 toms

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

Material economic effects	Amount saved
Sales of valuable materials	12
Electricity consumption reduced through energy-saving measures	28
Reduction of the cost of waste disposal and treatment via resource conservation and recycling	1
Total	41

Notes regarding calculations for fiscal 2010 data:

Notes regarding calculations for fiscal 2010 data:

1. Data was calculated in line with the Environmental Accounting Guidelines (2005 edition) published by the Ministry of the Environment. 2. Data was collected from April 1, 2010 to March 31, 2011. 3. Data is for worksites in Japan. 4. Calculation methods: (1) simple method for amount invested (25%, 50%, 75%, 100%); (2) depreciation was calculated based on the service life of respective items as defined in financial laws; (3) the full amounts for non-amortization costs were 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 were calculated and assessed; (2) effects observed within the fiscal year were calculated 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).

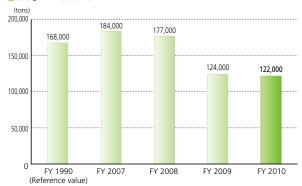
## Energy Conservation and Global Warming Prevention

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

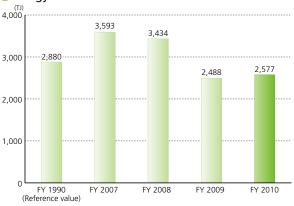
The Mitsubishi Tanaba Pharma Group considers initiatives to conserve energy consumption and curb global warming as two of its top-priority environmental activities. In its efforts to reduce greenhouse gas emissions, the Group implements energy-conservation initiatives encompassing both quantitative targets and qualitative reforms, and in consideration of the size and location of its various worksites, including plants, research facilities, distribution centers, and offices.

Under the Medium-Term Voluntary Action Plan for Environmental Safety, the Group targeted a reduction of CO<sub>2</sub> emissions in fiscal 2010 to 95% or less of the fiscal 2007 level. The Group was successful in significantly beating this target, as CO<sub>2</sub> emissions totaled 122,000 tons in fiscal 2010, equivalent to 66.3% of the fiscal 2007 level, and 98.4% of the level in the previous fiscal year. Energy consumption in fiscal 2010 increased by 3.6% over the previous fiscal year due to an unusually hot summer. Nevertheless, the Company reduced its emission factor, which determines CO<sub>2</sub> emissions related to the purchase of electric power, thereby contributing to lower CO2 emissions.

#### **■** CO<sub>2</sub> Emissions



#### Energy used



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

In fiscal 2010, Japan's Amended Act on the Rational Use of Energy went into effect, requiring that Specified Business Operators implement energy management. Under the law, Mitsubishi Tanabe Pharma and three Group companies— Mitsubishi Tanabe Pharma Factory Ltd., Benesis Corporation, and Bipha Corporation—have been designated as Specified **Business Operators.** 

In fiscal 2010, the Kashima, Toda, and Yokohama sites were designated as Class I Designated Energy Management Factories, and the Kazusa Office was designated as a Class II Designated Energy Management Factory. Combined energy usage at the four sites in fiscal 2010 totaled approximately 22,700 kL, a 4% increase over the previous fiscal year, while CO<sub>2</sub> emissions totaled approximately 36,900 tons, down 2% year on year. This accounts for 86% of the Company's energy consumption and 88% of its CO<sub>2</sub> emissions. In addition, the Kazusa Office is expected to receive designation as a Class I Designated Energy Management Factory based on its performance in fiscal 2010.

To further enhance the Group's energy management system, in fiscal 2010 the Company appointed an energy management control officer and an energy management planning promoter, and launched an energy conservation promotion liaison committee.

Energy Consumed by Mitsubishi Tanabe Pharma in Fiscal 2010

Sites	Crude oil equivalent (kL)	CO <sub>2</sub> emissions (tons-CO <sub>2</sub> )
Kashima Office	7,050	10,610
Toda Office	5,760	10,050
Yokohama Office	3,680	6,240
Kazusa Office	3,050	5,500
Osaka Headquarters	740	840
Tokyo Head Office	670	1,000
Branches and Sales Outlets	1,070	1,750
Other	700	900
Total	22,720	36,890

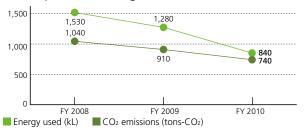
#### Mitsubishi Tanabe Pharma Energy Management Promotion System



#### **Energy Conservation from Consolidating Headquarters Buildings**

In October 2010, seven buildings that comprised the Company's headquarters complex in Chuo Ward, Osaka, were consolidated into two buildings, namely the Yodoyabashi Square Building and the Hiranomachi No. 1 Building. This allowed headquarters to reduce its consumption of electricity and city gas, as well as cut CO<sub>2</sub> emissions. Specifically, in fiscal 2010, energy consumption decreased 29% compared to the fiscal 2008 level, and 19% compared to the fiscal 2009 level. CO<sub>2</sub> emissions were reduced 45% and 34% compared to the fiscal 2008 and 2009 levels, respectively.

#### ■ Energy Consumption and CO<sub>2</sub> Emissions of **Headquarters Buildings**



#### **New System for Company Vehicles**

In fiscal 2010, the Company abolished its system that allowed the use of personal vehicles for business, and began leasing all company vehicles under a company contract. This resulted in an increase of 322 leased company vehicles, or 19.4%, compared to the previous fiscal year, for a total of 1.983 vehicles. Of the total, 50 were electric vehicles.

In an effort to reduce CO<sub>2</sub> emissions, the Company increased the number of hybrid vehicles from 76 to 700 compared to the previous fiscal year. It also promoted environmentally friendly driving practices, encouraging smooth acceleration and prohibiting unnecessary idling. As a result, gasoline consumption and CO<sub>2</sub> emissions were both reduced by 0.6%, respectively, compared to the previous year.

#### Company Vehicle Gasoline Usage and CO<sub>2</sub> Emissions

			FY 2008	FY 2009	FY 2010
		No. of company vehicles	1,616	1,661	1,983
		Electric vehicles	0	50	50
		Hybrid vehicles	0	76	700
Gasoline use CO <sub>2</sub> emissions		soline use	2,578kL	2,505kL	2,490kL
		2 emissions	5,986 tons-CO2	5,815tons-CO2	5,781tons-CO2

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

The Group's production plants and research facilities have been improving their energy conservation measures by upgrading equipment, such as pump inverters, and installing high-efficiency fluorescent lamps and LED lighting fixtures.

The Mitsubishi Tanabe Pharma Factory's Kashima Plant has revamped its methods for using materials in its pharmaceutical manufacturing process to reduce the burden placed on air conditioning and lighting equipment. The plant has also made renovations to the physical layout of its facilities by, for example, lowering the height of ceilings.

These efforts have resulted in reductions of 31 tons per year of CO<sub>2</sub> emissions from air conditioning equipment and 19 tons per year of CO<sub>2</sub> emissions from lighting fixtures.



The Kashima Office after renovations were

In recognition of its ongoing efforts to promote commuting by public transportation and bicycles instead of cars and motorcycles, the Kashima Office was approved and registered as an Eco-Commute Leading Business by Japan's Ministry of Land, Infrastructure, Transport and Tourism in September 2009.

All Company offices, including those at headquarters, strictly control room temperatures during summer and winter, and promote the national government's Cool Biz and Warm Biz campaigns for dressing accordingly. They also participate in the Light Down Campaign, which encourages companies to turn off both outdoor and indoor lights, promoted by the Ministry of the Environment and the city of Osaka. In addition, the offices are engaged in a campaign to increase awareness of their energy conservation activities.

The Company is undergoing continuous energy conservation assessments by outside organizations in order to gain an objective understanding of the further potential of energy conservation. In fiscal 2010, Benesis Corporation's Kyoto Plant underwent an energy conservation assessment of its air conditioning and electric equipment, encompassing a review and improvement of maintenance standards; upgrades of existing equipment and the introduction of energy-saving equipment and machinery; and the introduction of highefficiency machinery, reorganization of the facilities, and improvement of systems. As a result, the factory received various proposals in these areas, and is currently studying ways to efficiently operate as an energy-conserving facility.

## Special Feature Environmental Initiatives at the Yokohama Office's New Research Wing

The Yokohama Office's Pharma Research Building 2 is a new wing housing the Drug Discovery Chemical Research Facility, whose offices and labs were previously distributed throughout several wings of the Yokohama Facility and the Kashima Facility in Osaka. The design of the new wing took into account energy conservation and other environmental issues, and received a Rank A certification from Yokohama City's Comprehensive Assessment System for Built Environment Efficiency (CASBEE Yokohama).\*

\*CASBEE Yokohama is a procedure for assessing the level of environmental efficiency of buildings and assigning a rank based on the assessment. CASBEE Yokohama assesses the total environmental efficiency of a building, including the measures it has taken to prevent global warming and heat islands, increase its longevity, and contribute to the local scenery. The five available ranks are: S (excellent), A (very good), B+ (good), B- (somewhat unsatisfactory), and C (unsatisfactory).



The new research wing at the Yokohama Office

#### Reduction of Air Pollutant Discharge

All air discharged from laboratories is treated with activated charcoal to remove harmful substances. and the air from some laboratories is further treated

in scrubbers with alkaline water in a two-step process. A clean-air environment is maintained throughout the entire wing via a 100% fresh air system used in all locations where organic solvents and reagents are stored.



Air ventilation system

conservation effect of wet scrubbers

Wet scrubbers eliminate over 90% of the acid and odorous components that cannot be removed by activated charcoal, compared to Business as Usual (Bau).\*

\* Business as Usual (BaU) comparisons

The reduction in the environmental burden as compared to the situation before environmentally friendly measures were implemented

#### Energy conservation

Energy efficiency was greatly improved by introducing high energy-efficient exhaust ventilation equipment and highly efficient air conditioning equipment, including an inverter control, fewer units, a large temperature difference water supply, air-cooling chillers, air-cooling heat pumps, and pervaporation devices.

A draft chamber for exhaust ventilation is essential for environment maintenance in places where chemical research takes place, but discharging an enormous amount of air requires a high level of energy consumption and accounts for a substantial proportion of the total energy consumption at a facility. The latest push-pull type of low air capacity exhaust ventilation equipment was installed to reduce the amount of

discharged air by half. Energy was further conserved by using the door panel sensor that controls the amount of air, operating the variable air volume (VAV), installing motion sensors to prevent the door valve from being left open by mistake and establishing a centralized monitoring system.



High-efficiency local exhaust ventilation system

Environmental conservation effect of reducing the electrical consumption of air conditioning systems

CO<sub>2</sub> emissions 903 tons-CO2 (in comparison with BaU)

#### Lighting and Consideration for the **Surrounding Area**

Open spaces within the wing, such as hallways and local exhaust ventilation chambers, are lit with LED lighting fixtures. In addition, energy conservation has been improved through the use of highly efficient

fluorescent lights, automatic lighting, and automatic light-level adjustment systems. Consideration is paid to the environment and scenery surrounding the buildings by adjusting the coloring used on the outside of buildings and taking noise-reduction measures for roof-top machinery.



Use of LED lighting in hallways

Environmental conservation effects of reducing the electricity consumption of lighting fixtures

CO<sub>2</sub> emissions 13 tons-CO<sub>2</sub> (in comparison with BaU)

#### **Waste Reduction Initiatives**

The Medium-Term Voluntary Action Plan for Environmental Safety sets as its goals the promotion of zero emissions and the reduction of the ratio of final waste disposed to the total amount generated to less than 0.5%. The Company is reducing the amount of waste it disposes by reinforcing compliance with rules for separating types of waste material, promoting the reuse of materials, and turning harmful waste into something valuable. It is also reducing both the amount of waste generated and the final amount of waste disposed by reducing the number of defective products and reducing the amount of packaging materials used in the manufacturing process of pharmaceuticals.

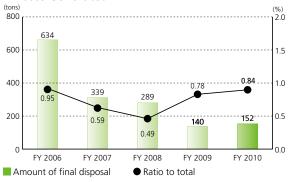
In fiscal 2010 the amount of sludge discharged was reduced through improvements that were made in the management of the activated sludge treatment of wastewater at Benesis Corporation's Kyoto Plant, and by improving the efficiency of water removal from waste sludge via renovation of the water removal and treatment equipment at Mitsubishi Tanabe Pharma's Onoda Plant.

The fiscal 2010 goal of a final waste disposal ratio of 0.84% was not reached, but aggressive efforts to reduce the amount of waste and final waste disposed are continuing.

#### Amount of Waste Generated



#### Amount of Final Waste Disposal and Ratio to Total Waste Generated



#### **Environmentally Friendly Packaging for Pharmaceuticals**

Packaging for pharmaceuticals must preserve the quality of the product, have clearly written labeling, and contribute to the reduction of generated waste. The Company has been making strenuous efforts based on the understanding that reducing the volume, amount, and weight of packaging also reduces the burden placed on the environment by the medical facilities that use the Company's products.

In fiscal 2010, the Company was able, with the cooperation of manufacturing subcontractors, to reduce the size of shipping containers for IV solutions—soft bag formulations for use as total parenteral nutrition infusions consisting of fluids contained separately in three chambers within the bag—and partially reduce the amount of cushioning material. The Company was also able to reduce the weight of its cardboard shipping boxes by approximately 25%, for a reduction of approximately 8.8 tons per 100,000 bags of product.

#### **Environmentally Friendly Ways to Transport Pharmaceuticals**

Remicade 100 mg for use in infusions is formulated outside Japan and then imported by air transport. In order to maintain the quality of this pharmaceutical, a constant temperature must be maintained, so it has been shipped with large amounts of cold insulating packs in insulated boxes. This type of packaging could not be reused, however, so it was disposed of in Japan after the product was removed. With the goal of reducing the amount of waste material it generates, in fiscal 2010 the Company reviewed the ways it transports products and switched to shipping Remicade in refrigerated air transport containers. As a result, the cold-insulating packs became unnecessary and the amount of waste generated was



Refrigerated air transport containers

#### Proper Management of Chemical Substances

#### **Reducing Air Pollutant Emissions**

One of the Company's objectives in its Medium-Term Voluntary Action Plan for Environmental Safety is managing chemical substances in a suitable manner and continuously reducing both the concentrations and total amount of emissions into the environment. To this end, the Company is making efforts to curb emissions of various pollutants, including those classified as Class I Designated Chemical Substances by the PRTR law.

As a result of revisions made to Japan's PRTR Law in fiscal 2010, the number of Class I Designated Chemical Substances was increased from 354 to 462. This meant that the amount of such substances that the Group as a whole handled increased by 83% over the previous year. However, air pollutant emissions remained at eight tons, unchanged from the previous year.

#### ■PRTR air pollutant emissions



#### Management of the Atmosphere and **Water Systems**

The Company complies with all standards stipulated by laws, ordinances, and agreements, including the Air Pollution Control Law and Water Pollution Control Law. In addition, there are protocols in place to deal with incidents in which harmful substances leak from outdoor tanks, 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.

#### **Initiatives to Protect Biodiversity**

Mitsubishi Tanabe Pharma is a participant in the Declaration of Biodiversity by Nippon Keidanren Promotion Partners. The Company promotes activities to preserve the natural environment and strives to maintain biodiversity by understanding the relationship to its business activities.

Mitsubishi Tanabe Pharma Factory Ltd.'s Ashikaga Factory has been ranked as Excellent Stage 2 of the

Social & Environmental Green Evaluation System (SEGES) for its activities that promote the preservation of the natural environment.

As part of its environment preservation efforts, the Yokohama Office, Mitsubishi Tanabe Pharma Factory's Kashima Plant, Bipha Corporation, and Hoshienu Pharmaceutical use water resources efficiently, with cyclicuse systems in place for experimental wastewater, humanuse wastewater, water recovered from steam traps and other devices, coolant water for distillation equipment, and water that drains from air conditioning equipment.

#### Efficient Use of Rainwater at P.T. Tanabe Indonesia

In accordance with regulations pertaining to the use of rainwater set by Indonesia's Environment Agency, P.T. Tanabe Indonesia's Bandung Factory uses rainwater to improve and maintain soil fertility via two absorption wells and 24 biopores installed on its grounds. The absorption wells have holes that filter rainwater, and the biopores, which have holes 10 to 15 centimeters across and one meter deep, are filled with organic waste material.





An absorption well

**Biopores** 

#### **Environment-Related Incidents**

In fiscal 2010, the Mitsubishi Tanabe Pharma Group experienced four environment-related problems. Three of these incidents were related to water quality, including one in which untreated wastewater was discharged with rainwater outside facility grounds due to a mistakenly operated wastewater valve. Another incident involved an offensive odor caused by the incomplete combustion exhaust fumes of a poorly maintained boiler. Thankfully, none of these incidents caused serious damage to the environment, but the Company filed reports with relevant government agencies and established measures designed to prevent recurrences after reviewing the procedures in place to deal with emergencies.

#### Promotion of Environmental Communications

#### **Environmental Education**

The Company provides a wide range of information on its intranet, including results of employee environmental awareness surveys, monthly amounts of CO<sub>2</sub> generated and energy consumed by each office, and explanations of environmental issues and terms.

Employee education includes e-learning programs for medical representatives to convey environmental information in a prompt and clear manner. This promotes the understanding of environmental problems both inside and outside the Company and increases environmental awareness.

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

As a model corporate citizen, Mitsubishi Tanabe Pharma values interaction with the local community. The Company is involved in environmental and social contribution activities, such as tree planting and cleanups of office surroundings and forests.

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

Each year, both Headquarters and the Kashima Office participate in a cleanup effort in Osaka City called "Clean Osaka," with employees cleaning up the area surrounding the offices. The Kazusa Office helps to restore and maintain the natural habitats of plants and animals and maintains greenery on grounds and at buildings that are suitable to

the landscape in Kazusa Akademia Park, in order to preserve the bountiful natural environment of the Kazusa



kyuryo hills area. Cleanup activities in conjunction with the Clean Osaka campaign

#### Participation in Forestation Campaign

In November 2010, 34 Mitsubishi Tanabe Pharma Group employees and their families participated in the Mt. Ikoma Hana-byobu (flower folding screen) forestation campaign sponsored by the Osaka prefectural Government. They walked along the old Tatsutagoe Kodo road through the Toge mountain pass area in Kashiwara City along with 250 prefectural residents. When they reached the Kameno-Se district, the Group employees and their families helped plant wild cherry and white oak trees.





Ikoma Mountain Range flower folding screen activities

#### Participation in the Tokyo Grass Support Group

The Tokyo Metropolitan Government is promoting the planting of grass lawns on the grounds of public elementary and junior high schools via its Tokyo Grass Support Group to reduce the heat island effect, increase the green areas of the city, and promote both children's education and local community exchanges. Mitsubishi Tanabe Pharma has participated in this event along with many other businesses since 2008 by helping with lawn maintenance.

As part of its assistance to the Tokyo Grass Support Group, the Company presented its Aspara Drink to everybody taking part in the lawn maintenance activities in July 2010, and sent its employees to participate in the activity management work at an elementary school.



Volunteers cut grass at a school.

## Independent Verification Report

#### 第三者検証報告書

田辺三菱製薬株式会社御中



ビューローベリタスジャ

#### 検証の目的

ビューローベリタスジャパン株式会社(以下 BV)は、田辺三菱製薬株式会社(以下田辺三菱製薬) の責任において発行される「田辺三菱製薬 CSR レポート 2011」(以下レポート)に記載される 2010 年度環境パフォーマンスデータの評価を実施した。BV の責任はレポートに記載される環境パフォー マンスデータについて独立した立場から客観的証拠に基づいて正確性を検証することである。

#### 訪問サイト

BV は以下のサイトを訪問し、レポートの" 環境報告"に記載される 2010 年 4 月から 2011 年 3月までの環境パフォーマンスデータの正確性を評価した。

田辺三菱製薬株式会社

本社 環境安全部

統括機能

田辺三菱製薬工場株式会社 小野田工場

横浜事業所

医薬品の研究 医薬品の製造

長生堂製薬株式会社

本社工場

医薬品の製造

#### 検証方法

BVは、田辺三菱製薬との合意に基づき、以下の評価を実施した。

- ・データの収集・集計システム及び関連するプロセスの信頼性
  - ・内部検証プロセスの有効性
- ・本社で集計された環境データ及び環境関連の記載内容の正確性

#### 各サイト

- ・データ集計範囲の適切性
- ・データの計測方法、収集方法、集計方法の有効性
- ・ 内部検証プロセスの有効性
- ・データ集計結果の正確性

この業務は、現時点での最良の事例に基づき、BVが定める非財務情報報告に対する第三者検 証手順とガイドラインに拠って行われた。加えて「国際保証業務基準 (ISAE) 3000 (2003 年 12月改訂 国際会計士連盟)」を参考にし、限定的保証業務を行った。

#### 検証結果

BVは上記検証の結果として、以下のとおり意見を述べる。

- 1. レポートに記載される環境パフォーマンスデータに重大な誤りは確認されなかった。
- 2. 検証の過程において認められたすべての誤りは、適切に修正された。
- 3. データの計測、収集、集計システムには信頼性があり、本社と訪問した全てのサイトにおい て適切に運用されている。

ビューローベリタスは、全社員の日々の活動における高い品質を保つためにビジネス全般にわたる倫理規定を定め、特に利害の対 立を避けることに配慮しています。田辺三菱製薬株式会社に対するビューローベリタスの活動は、CSR レポートの検証のためだけ に行われ、その検証業務がなんら利害の対立を引き起こすことはないと考えます。

## Third-Party Opinion

## Comments on the Mitsubishi Tanabe Pharma Corporation CSR Report 2011

The Mitsubishi Tanabe Pharma Corporation CSR Report 2011 was markedly different from the Group's CSR report in the previous year. For example, the overall organization changed. Whereas the 2010 report organized CSR activities into the three main sections of "Management," "Sociality Report," and "Environmental Report," the 2011 report presents corporate activities in the order of the pharmaceutical supply chain, with sections covering R&D, reliability assurance, the manufacturing system, supply system, and provision of information. The Report then goes on to discuss management and environmental activities. This organization reflects the fact that the Mitsubishi Tanabe Pharma Group has returned to its original mission to be a creator of pharmaceuticals, and that achieving this mission will itself lead to the fulfillment of its corporate social responsibility.

CSR reports are generally filled with descriptions of philanthropy-related activities and corporate patronage of the arts and culture. A European Commission white paper published in 2002, however, defined CSR not as adjuncts to primary business activities, but rather as a company's very way of doing business. In this light, the main criterion for evaluating a company's CSR activities is the extent to which it embeds it CSR concepts in its core business activities. The revisions made to the organization of the 2011 report appear to reflect this concept of CSR.

In the report's main sections from "R&D" through to "Provision of Information," research activities are described not from a business perspective but rather around the theme of unmet medical needs. The report goes on to discuss reliability assurance, the stable supply of high-quality pharmaceuticals, and the provision of accurate and timely information about pharmaceuticals. Numerical data related to environmental information and targets is also presented. In this way, readers can fully understand the substance and results of the Mitsubishi Tanabe Pharma Group's recent CSR activities.

Unfortunately, however, it is difficult to gain from the 2011 report a clear picture of the problems the Group is facing, the goals it has yet to achieve, and how it is dealing with these

challenges. A CSR report should fully disclose all corporate realities, both positive and negative, in the same way as a securities report or annual report. I would hope that the Group considers this aspect of CSR reporting in the future.

Following the Medway problem, which was covered in the 2010 report, the Company announced a voluntary recall of drugs owing to inadequate testing at a plant operated by Mitsubishi Tanabe Pharma Factory Ltd. This is highly unfortunate, since the public was led to believe that the Group had implemented improvements and preventative measures after all of its members, from senior management down, had seriously reflected on the Medway problem. What both of these incidents have in common is that the problems occurred at consolidated subsidiaries.

Today's large corporations are far more difficult to manage than in the past due to their increased scale of consolidation, the size of their subsidiaries, and their increasing complexity. These increases in size and complexity are the result of expanding business activities, mergers and acquisitions, globalization, the lengthening of the supply chain, and other common trends. If a problem arises, however, the party held most responsible is the parent company. In other words, the former approach to corporate governance, which was exclusively focused on the relationship between external stakeholders and management, has become insufficient. Attention must also be paid to the corporate group's internal governance, which encompasses the relationships between the holding company and its group companies, and the parent company and its consolidated subsidiaries or affiliated companies.

While Mitsubishi Tanabe Pharmaceutical Corporation is a member of the Mitsubishi Chemical Holdings Group, it is also a company with many consolidated subsidiaries and affiliated companies. I hope that all members of the Group consider corporate governance with this fact in mind, because incidents that can occur in large corporations are intrinsically linked to internal corporate governance at the group level.

## Dr. Matao Miyamoto

Professor, Institute of Business and Accounting, Professional Graduate School, Kwansei Gakuin University

Matao Miyamoto holds a Ph.D. in Economics, and specializes in Japanese business history, the history of the Japanese economy, and corporate ethics, among other topics. He assumed his present post in April 2006 after retiring as a professor in the Graduate School of Economics at Osaka University. Dr. Miyamoto has served in a variety of high-ranking posts, including the president of the Business History Society of Japan, chairman of the Forum for Entrepreneurial Studies, and director of the Japan Academic Society for Ventures and Entrepreneurs.



## Explanation of Terms

#### Alliance

Cooperation and coordinated action by several firms

#### 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.

#### Appropriate use of pharmaceuticals

Prescribing and preparing pharmaceuticals in their optimum form in regards to drug selection, formulation, appropriate administration and dosage, based on a precise diagnosis. Also, a cycle in which the patient has satisfactory understanding of the above-prescribed drug, and after the patient takes the prescribed drug according to instructions, its effects and side-effects are evaluated and reflected in subsequent prescriptions.

#### Informed consent

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

#### Orphan drug

A pharmaceutical drug designed to treat a specific rare disease or disorder. Although there is high medical need for these drugs, the number of patients requiring these drugs is small.

#### Development pipeline

A series of processes and goods in such processes within the pharmaceutical company from the initial development stage to marketing.

#### 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. The term "generic" encompasses meanings of "Rcommon' and "general," and in the Western world, such drugs are often prescribed by their active ingredients, or "generic names," instead of their product names. This is why they are referred to as a generic drugs.

#### **Self-medication**

To maintain and enhance health or to prevent illnesses at one's own risk using products, information, and knowledge related to health and medical care available in their immediate surroundings. This includes well-informed utilization of over-the-counter (OTC) drugs to prevent or alleviate mild symptoms.

#### **Electronic chart**

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

#### Intractable diseases

Diseases for which the cause is unknown, for which there is no treatment, and which cause long-term debilitation. For some incurable diseases diagnostic standards exist to some extent, but because they are very severe and the number of patients suffering from them is relatively low, public funding is necessary to determine their causes and develop treatments. Thus, in Japan they are known as "specific diseases (or, diseases with specific conditions)." Prefectural governments in Japan partially or completely cover out-ofpocket patient costs for these diseases.

#### 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.

#### Good manufacturing practice (GMP)

Standards concerning manufacturing control and quality control for pharmaceuticals and non-medicinal products.

#### Good Quality Practice (GQP)

Standards concerning quality control for pharmaceuticals, non-medicinal products, cosmetics, and medical equipment.

#### Good x Practice (GxP)

A casual designation to mean standards 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. Other designations include: GCP (Good Clinical Practice: standards for clinical trials for pharmaceuticals and medical instruments), GLP (Good Laboratory Practice: standards for non-clinical tests of pharmaceuticals and medical instruments), GMP, and GQP.

#### ICH Q10

Guidelines for pharmaceutical quality systems that are under consideration by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

#### Medical representative (MR)

Person in charge of medical information. An MR visits medical institutions as a pharmaceutical company sales person and provides and collects 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. They are called overthe-counter (OTC) drugs because they can be purchased over a pharmacy counter.

#### Quality of Life (QOL)

Criteria used to evaluate 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 and without placing a priority on the effect of the treatment.

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 Mitsubishi Chemical Holdings Group

