



Sharing wellness.  
Fostering happiness.

# CSR Report 2013

Mitsubishi Tanabe Pharma Corporation



Mitsubishi Tanabe Pharma

Good **Chemistry** for Tomorrow Mitsubishi Chemical Holdings Group

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

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**We contribute to 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

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**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

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

### Pride and Sense of Mission

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

### Trust and Teamwork

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

### Challenge and Innovation

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

### Harmonious Coexistence with Society

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

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

## Editorial Policy

This report is intended to provide a wide variety of information on the Group's CSR activities carried out in fiscal 2012, from April 2012 to March 2013, to stakeholders, including patients, medical professionals, shareholders, investors, local communities, and employees. Editors sought to present specific initiatives taken in relation to the Company's philosophy according to the ISO 26000 Core Subjects structure.

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

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

## About the Mitsubishi Tanabe Pharma Corporation CSR Report 2013

- This report covers the period from April 1, 2012 to March 31, 2013. Certain activities and policies undertaken after this period are also included.
- This report covers Mitsubishi Tanabe Pharma Corporation and its Group companies both within and outside Japan. Some included information may be different in scope.
- Applied Guidelines  
Global Reporting Initiative (GRI) *Sustainability Reporting Guidelines*, 3.1 version;  
*Environmental Reporting Guidelines*, 2012 version, published by the Ministry of the Environment of Japan; ISO26000
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## CONTENTS

Message from the President	04
Business Overview of Mitsubishi Tanabe Pharma Group	06
Major Products of Mitsubishi Tanabe Pharma Group	07

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### Organizational Governance

Corporate Governance	09
Risk Management	11
Compliance	12

### Human Rights

Initiatives for Employees	15
Human Rights Issues in the Value Chain	16

### Labor Practices

Human Resources Development	19
Promoting Diversity	20
Occupational Health and Safety	21

### Environment

Environmental Management	23
Overview of Environmental Impact	25
Energy Conservation and Global Warming Mitigation	27
Waste Reduction & Proper Management of Chemical Substances	30
Promotion of Environmental Communication	31

### Fair Operating Practices

Fair Business Practices	33
-------------------------	----

### Consumer Issues

Research & Development— Contributing to Healthier Lives for People around the World	37
Manufacturing and Supply Chain— Reliably Delivering Pharmaceuticals	38
Information Provision— Providing Needed Pharmaceutical Information	40
Reliability Assurance— Ensuring Users Are Able to Trust in the Reliability of Mitsubishi Tanabe Pharma's Drugs	42

### Community Involvement and Development

Social Contribution Activities	45
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Independent Verification Report	48
Third-Party Opinion	49
Explanation of Terms	50

## We take a patient-centered approach to the creation of new drugs because we believe our pharmaceutical business can make the world a better place.

### Contributing to medical treatment by drug discovery and post-marketing services and activities

At Mitsubishi Tanabe Pharma, we are as committed as ever to implementing corporate activities that uphold our corporate philosophy of “contributing to healthier lives for people around the world through the creation of pharmaceuticals” and embody our vision of “striving to be a global, research-driven pharmaceutical company that is trusted by communities.”

Two years have passed since we introduced our Medium-Term Management Plan 2011-2015 based on the key concept of “new value creation.” Over this relatively short time, we have brought to the Japanese market a number of new products designed specifically to address unmet medical needs, including Simponi to treat rheumatoid arthritis and Imusera to treat multiple sclerosis. These products have had an impact on both patients and medical professionals. It has been 11 years since we launched our anti-human-TNF $\alpha$  monoclonal antibody Remicade, an intravenous drip infusion originally indicated for the treatment of Crohn’s disease. Since then, Remicade has benefited many more patients as it earned additional indications for the treatment of such intractable illnesses as rheumatoid arthritis, psoriasis, spondylarthritis ankylopoietica, and ulcerative colitis. Sales of Gilenya, a drug containing the same active ingredient as Imusera that is marketed by Novartis, have also grown significantly, and it is now used in the U.S., Europe, and countries around the world.

At Mitsubishi Tanabe Pharma, we believe that the best way to deliver on our goal of making the world healthier is to remain ever mindful that “everything we do is for patients.” Toward this end, we focus on two objectives: drug discovery, where we work as quickly as we can to address specific unmet medical needs; and post-marketing activities, where we keep striving to perfect the products we offer to make them ever safer and more effective.

### Discovering useful new drugs and getting them to patients as quickly as possible

Of course, we believe we can and should do more to contribute to the medical community. One way we do this is by keeping our focus on the patients who are battling with illness. Thinking of them, we challenge ourselves to create drugs in new areas to meet their treatment needs. A prime example is our TA-7284, a drug that works to treat type 2 diabetes mellitus with a novel mechanism of action. In May of this year, we submitted an application for approval for the Japanese market. In the U.S., this drug is already being marketed under the product name INVOKANA™, and the marketing authorization application has

been filed in Europe. In addition to blood glucose lowering effect, TA-7284 also has a weight reduction effect not seen in oral diabetes drugs with other mechanisms of action. This new drug is expected to provide more flexible treatment options for patients with type 2 diabetes mellitus. We hope that an expedited launch of this product on the Japanese and European markets will help with the treatment of patients suffering from this disease.

Our three priority areas for research & development are autoimmune diseases, central nervous system diseases, and diabetes and renal diseases. We recognize that, as the environment surrounding the pharmaceuticals industry continues to change dramatically, drug discovery itself will also have to change. In the past, all aspects of discovery from basic research through development took place exclusively at Mitsubishi Tanabe Pharma, but this will not necessarily be the case in the future. Collaboration and coordination with companies, universities, and other entities in and outside of Japan will be the key to ensuring that we can enter new sectors that we are unable to tackle alone. We also look for opportunities for out-licensing and joint development after we have achieved proof of concept (POC). All this is to say that we are going to be as creative as we can to get new drugs to market more quickly. In striving to position Mitsubishi Tanabe Pharma as a global, research-driven pharmaceutical company, we hope to discover as many new drugs as possible to help improve quality of life of people around the world.

While contributing to society through our pharmaceutical business itself, we also provide support for associations of patients with incurable diseases. To better facilitate this support, we marked our fifth anniversary in 2012 by establishing the Mitsubishi Tanabe Pharma Tenohira Partnership Program. Through this program, we provide financial assistance for associations and support groups for patients with incurable diseases. We support these groups’ efforts to improve medical treatment and career prospects for patients to enhance their quality of life.

### Aiming to be an inspiring company that brings joy to patients

I have called on all of our employees to help make Mitsubishi Tanabe Pharma an inspiring company as we move toward becoming a global, research-driven pharmaceutical company. An inspiring company creates inspiring new drugs that help patients. It helps people around the world live healthier lives. The secret to being an inspiring company is employees who are themselves inspired to help patients overcome illness and live out their dreams. This is the single aspiration we all share at Mitsubishi Tanabe Pharma.

We believe that we can make this dream a reality by building on the vibrant corporate culture we already have, fostering an atmosphere where people are proud to work for a visionary industry leader. We are currently working to further invigorate the corporate culture as one of our business challenges. We envision a culture and a dynamically structured organization that encourage free and open communication, reward employees with a drive for self-improvement, and proactively address whatever issues we face.

Human resource development and training is crucial for building the kind of dream company I'm talking about. For instance, we are transferring employees to different positions and taking other steps to foster dynamic communication and exchange. The goal is to foster new interaction that will generate innovative ideas, values and desires. By giving our young employees and mid-level managers the opportunity to work at subsidiaries outside Japan, we hope to develop the talent that will prove successful on the global stage. We also believe in providing women with equal opportunities to demonstrate their skills and capabilities. In all these ways, we are shaping an enterprise where every employee is able to experience the joy that comes from helping patients the way only a pharmaceutical company can. This is what it means to be an inspiring company.

## Strengthening activities to attain *KAITEKI*

As a member of the Mitsubishi Chemical Holdings Group, Mitsubishi Tanabe Pharma is the Group's core healthcare company. The Group is focused on the attainment of *KAITEKI*, which refers to a truly sustainable society in which people are comfortable, society is comfortable, and the planet is comfortable. We view dialogue and working in concert with all of the entire Group's stakeholders as we work to attain *KAITEKI* as one of our social responsibilities.

True to the Mitsubishi Chemical Holdings Group's philosophy, "Good Chemistry for Tomorrow—Creating Better Relationships among People, Society, and our Planet," we are committed to fostering the public's embrace of the idea and value of *KAITEKI*. To do this, we will continue to ensure that all of our corporate activities deliver on the Mitsubishi Chemical Holdings Group's three priorities of ensuring environmental sustainability, supporting people's health and enhancing the comfort of life.

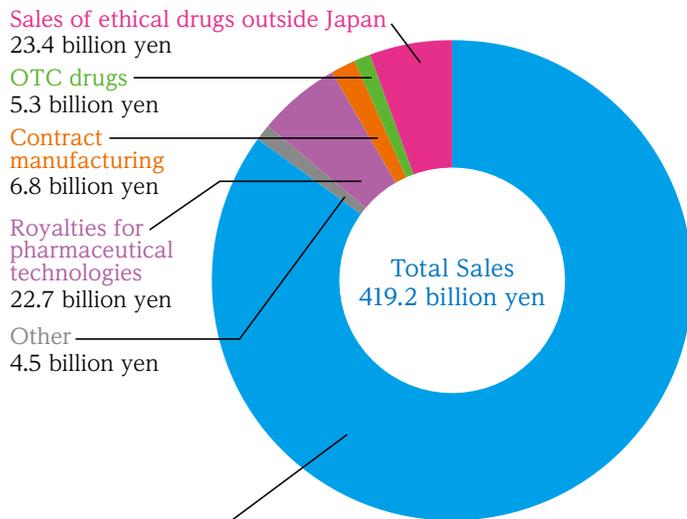
As we pursue these endeavors, we ask all stakeholders of the Mitsubishi Tanabe Pharma Group for their continued support and understanding.

Michihiro Tsuchiya  
President and Representative Director  
Chief Executive Officer



# Business Overview of Mitsubishi Tanabe Pharma Group

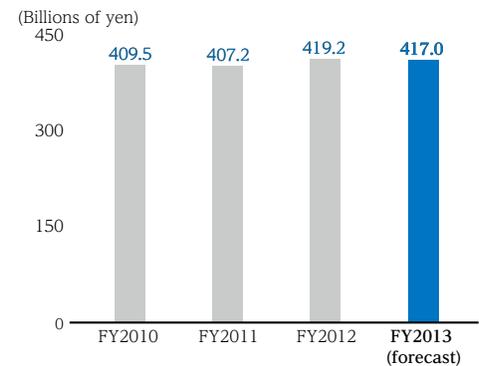
## Sales in Fiscal 2012



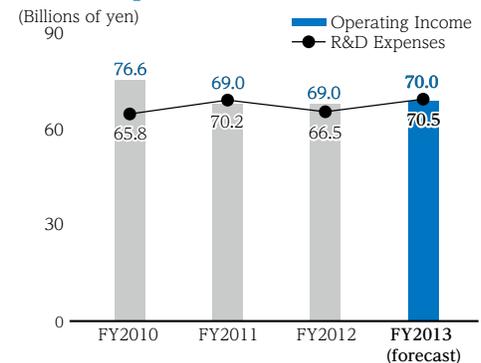
### Sales of ethical drugs in Japan

356.6 billion yen	
• Remicade	73.5 billion yen
• Ceredist	18.4 billion yen
• Talion	14.3 billion yen
• Maintate	14.1 billion yen
• Radicut	13.3 billion yen
• Urso	13.3 billion yen
• Anplag	13.0 billion yen
• Kremezine	12.2 billion yen
• Venoglobulin IH	11.0 billion yen
• Depas	10.4 billion yen
• Vaccines	28.8 billion yen
• Generic medicines, etc.	19.0 billion yen

## Consolidated Net Sales



## Operating Income and R&D Expenses



## Corporate Data

Company Name	Mitsubishi Tanabe Pharma Corporation
Representative	President and Representative Director Michihiro Tsuchiya
Paid-in Capital	50 billion yen
Number of Employees	8,835 as of March 31, 2013
Headquarters	2-6-18 Kitahama, Chuo-ku, Osaka 541-8505, Japan
Establishment	October 1, 2007
Business Activities	Manufacture and sales of pharmaceuticals

## Network

Headquarters	Osaka Headquarters, Tokyo Head Office
Sales Network	Hokkaido, Tohoku, Kita-Kanto, Koushinetsu, Tokyo, Chiba, Saitama, Yokohama, Tokai, Kyoto, Osaka, Kobe, Chugoku, Shikoku, and Kyushu branches
Research Centers	Toda, Kazusa, Yokohama, and Kashima offices
Overseas Network	Shanghai Office

## Group Companies in Japan

Mitsubishi Tanabe Pharma Ltd., Tanabe Seiyaku Yoshiki Factory Co., Ltd., Bipha Corporation, API Corporation, Yoshitomi-yakuhin Corporation, Tanabe Seiyaku Hanbai Co., Ltd., Tanabe R&D Service Co., Ltd., Tanabe Total Service Co., Ltd.

## Group Companies outside Japan

**Europe**  
Mitsubishi Pharma Europe Ltd., Mitsubishi Pharma Deutschland GmbH, Synthelabo-Tanabe Chimie S.A.

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

**United States**  
Mitsubishi Tanabe Pharma Holdings America, Inc., Tanabe Research Laboratories U.S.A., Inc., Mitsubishi Tanabe Pharma Development America, Inc., Mitsubishi Tanabe Pharma America, Inc., MP Healthcare Venture Management, Inc., Tanabe U.S.A., Inc.

# Major Products of Mitsubishi Tanabe Pharma Group



Treatment of rheumatoid arthritis (RA), Crohn's disease, psoriasis, ulcerative colitis, Behcet's disease with refractory uveoretinitis, and ankylosing spondylitis

**Remicade**



Treatment of rheumatoid arthritis

**Simponi**



Treatment of spinocerebellar degeneration

**Ceredist**



Treatment of depression

**Lexapro**



Treatment of allergic disorders

**Talion**



Treatment of type 2 diabetes mellitus

**Tenelia**



Treatment of hypertension, angina pectoris, extrasystole, chronic heart failure, and atrial fibrillation

**Maintate**



Treatment of multiple sclerosis (MS)

**Imusera**



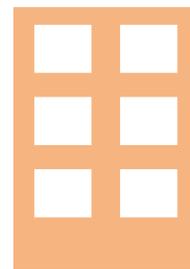
Adsorbed Diphtheria-purified Pertussis-tetanus inactivated polio (Sabin strain) Combined Vaccine

**Tetrabik**



OTC drug for eczema and dermatitis

**Flucort f**



# Organizational Governance



**Kuniaki Kaga**  
Chief Compliance Officer  
Senior Managing Executive Officer,  
Representative Director

## Highly motivated employees working together to build a company the public trusts

The management practices of corporations today are being subjected to increasing scrutiny. Companies are no longer evaluated merely by their financial performance and corporate value. A company's contribution to the public good has become a very important factor, and it is only by upholding its social responsibilities that a company can earn society's trust. At Mitsubishi Tanabe Pharma, we believe that this trust is the foundation for continuous corporate growth.

At Mitsubishi Tanabe Pharma, the key to continuous growth is ensuring that employees experience their work as deeply rewarding. Relationships of trust between the company and employees are critical in this regard. We strive to raise awareness among our employees of the ways in which their work contributes to society and do all we can to ensure that they take pride in the positive impact they have. Finally, we seek to foster a sense of solidarity among employees by encouraging them to share their work-related challenges and support one another in solving them. Every person has an innate desire to do meaningful work, and I believe that it is my responsibility to help all employees to fully realize this aspiration.

As business becomes increasingly global in nature, corporate governance will be subjected to even more rigorous scrutiny. At Mitsubishi Tanabe Pharma, we will respond by drawing on our employees' enthusiasm to bring renewed vigor to our organization and ensure that everything we do helps people around the world lead healthier lives.





# Corporate Governance

## Basic Stance on Corporate Governance

Mitsubishi Tanabe Pharma contributes to society by pursuing a corporate philosophy of creating pharmaceuticals that help people around the world lead healthier lives, aspiring to its corporate vision as a global, research-driven pharmaceutical company that the public trusts.

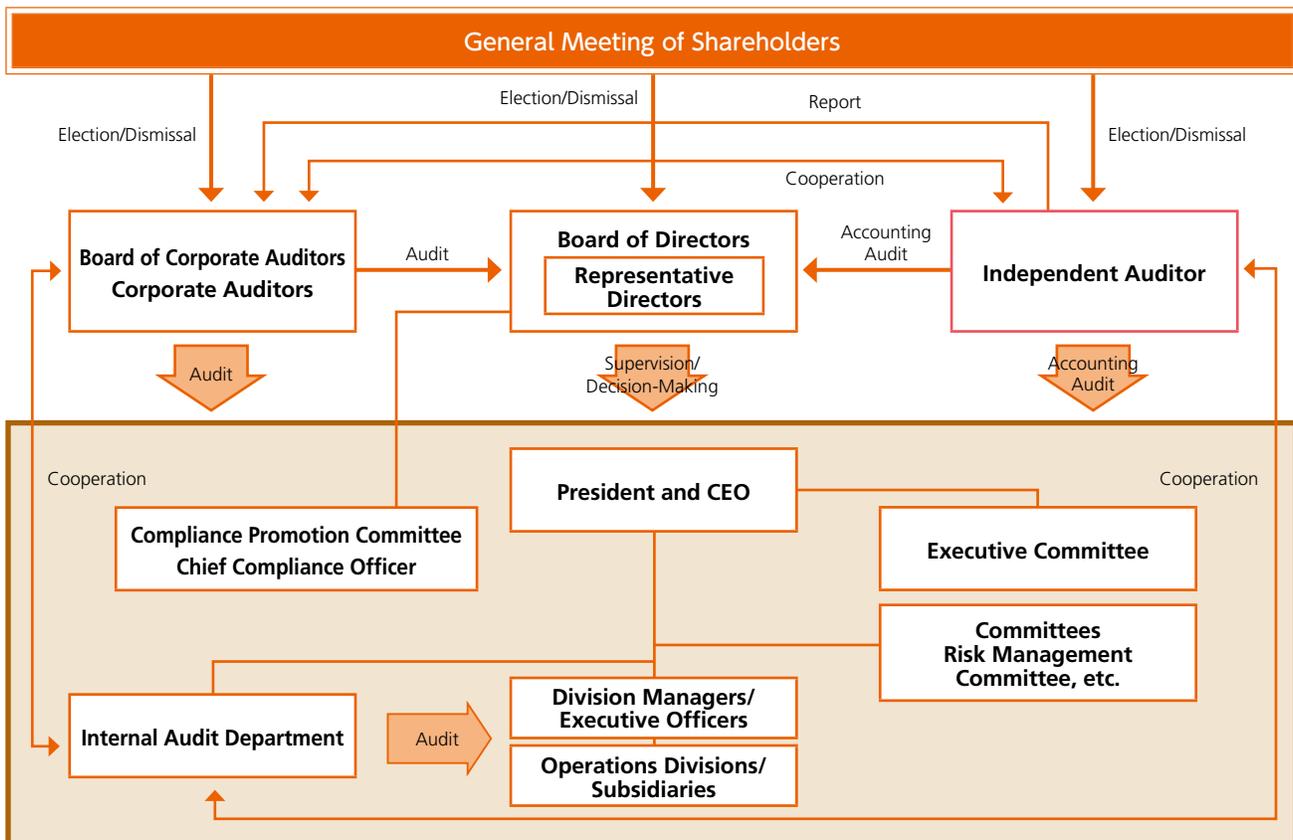
The Company operates under a system of corporate governance designed to ensure that it fulfills all of its responsibilities to shareholders and other stakeholders in order to maximize corporate value. This system facilitates transparency, objectivity, and effective, timely decision-making related to business management by ensuring systematic oversight and supervision that incorporate robust auditing and the views of outside directors.

## Management System

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

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

### Corporate Governance Structure





# Organizational Governance

## Corporate Governance

### Auditing System

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

Corporate auditors receive audit information on a monthly basis from the Internal Audit Department, which is independent from operations divisions, concerning plans, progress and the results of their internal auditing. The corporate auditors also receive reports on the results of semiannual evaluations of the internal control system concerning financial reporting.

The Company has established a Corporate Auditors Office with three full-time members who operate independently from business operations to provide support to these internal corporate auditors and outside corporate auditors in the execution of their auditing duties.

Ernst & Young ShinNihon LLC has been appointed as Mitsubishi Tanabe Pharma’s independent auditor. Every effort is made to provide accurate managerial information and create an environment that facilitates the conduct of proper audits.

### Accountability to Stakeholders

Mitsubishi Tanabe Pharma recognizes the importance of public disclosure for providing an accurate basis upon which stakeholders—including patients, medical professionals, shareholders, investors, and the general public—are able to evaluate corporate performance. The Company therefore publicly discloses important information concerning all of its corporate activities, encompassing managerial policies, operational goals, and financial performance, in a fair, prompt, and appropriate manner. Mitsubishi Tanabe Pharma

complies with all applicable laws and ordinances, including Japan’s Financial Instruments and Exchange Law, and the information disclosure regulations of stock exchanges that list the Company. Compliance with these laws and ordinances is mandated by in-house information disclosure regulations to ensure appropriate content and timing of information disclosure to stakeholders. Mitsubishi Tanabe Pharma takes feedback from all stakeholders seriously and strives to share information in a way that fosters better mutual understanding.

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



Financial performance briefing



Business briefing



Annual Report 2013



Organizational  
Governance

# Risk Management

## Managing Risks Associated with Business Activities

The Mitsubishi Tanabe Pharma Group has established risk management rules to ensure that risks associated with its business activities are managed properly. Based on these rules, each of the divisions at Group companies works to accurately identify the presence, type, and importance of the risks associated with its activities and to take the necessary steps to manage these risks. The Group has also developed and established a group-wide structure for supervising and implementing risk management. This structure operates principally under the Risk Management Committee, which is chaired by the president and CEO and generally meets twice a year to discuss and deliberate issues related to mitigating risks that affect the entire Group.

Mitsubishi Tanabe Pharma has built a clear structure for reporting serious risks which have a Group-wide impact on the management team. The divisions primarily and peripherally responsible for managing these risks take steps to address them.

General business divisions and departments as well as Group companies also work to raise awareness within their organizations in order to increase sensitivity to risk in the workplace and ensure that individual employees are able to spot potential risks, inform their colleagues of possible problems, and trigger a response by the entire unit.

### Mitsubishi Tanabe Pharma Group Risk Management Structure



## Risk Control Adapted to Classification

### Management strategy risks

Corporate Planning Department supervises risk management to be implemented in individual divisions

Examples: Risks associated with moving into new sectors, development strategies, etc.

### Serious risks (risks that require Group-wide management)

Divisions primarily and peripherally involved coordinate to develop and carry out measures to mitigate risks

Internal Controls & Compliance Department supervises progress

Examples: Risks related to the Pharmaceutical Affairs Law of Japan, information management, large-scale disasters, etc.

### Other general risks (other than those listed above)

Individual divisions implement measures to mitigate risks

## Being Prepared for Large-scale Disasters

Society counts on the Mitsubishi Tanabe Pharma Group to do whatever it takes to maintain a stable supply of pharmaceutical products. To fulfill this trust, the Group has established its own Regulations on Managing Business Continuity in a Large-scale Disaster to ensure that its business will continue to operate even if risks like a disaster should materialize.

### Overview: Regulations on Managing Business Continuity in a Large-scale Disaster

#### Objective

To prepare to respond to a large-scale disaster and related risks which could lead to a serious disruption of the Group's business, in times of normal business operations.

#### Basic policy

The Group's basic policy focuses on the following measures.

1. Develop a comprehensive top-down structure during normal business operations to prepare for Group-wide response when disaster strikes
2. Identify potential degrees of damage and develop practical and effective measures to be implemented under each scenario
3. Draw up response for large-scale disaster emergencies (including recovery and reconstruction)

#### Assumed risks

Develop guidelines for each type of risk

1. Earthquake, tsunami, typhoon, snowstorm, flooding
2. Pandemics (new influenza strains, etc.)
3. Terrorism (conflicts and terrorism overseas, cyberterrorism)



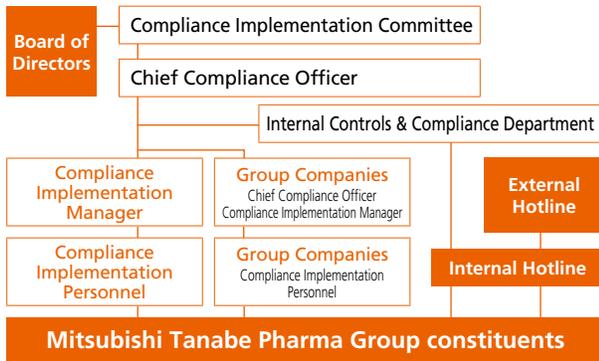
# Organizational Governance

## Compliance

### Compliance Implementation Framework

The Mitsubishi Tanabe Pharma Group has in place a Group-wide compliance implementation framework overseen by its Compliance Implementation Committee, which is chaired by the Chief Compliance Officer. A total of 210 compliance implementation personnel, including managers and staff, meet semiannually. These meetings are held to facilitate coordination among individual workplaces, heighten sensitivity to risk associated with compliance and potential scandals, share information on related problems, and enhance the capacity of workplaces to address compliance issues.

#### Mitsubishi Tanabe Pharma Group Compliance Implementation Framework



#### Compliance Code of Conduct

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

### Compliance Training

The Group conducts the following training programs each year for the purpose of fostering a strong sense of ethics, raising awareness of compliance requirements, and cultivating greater awareness of compliance-related issues among all employees.

- Group-wide compliance training: Participatory training based on active dialogue and discussion, rather than lectures or other forms of one-way information provision
- Divisional compliance training: Focuses on specific topics relevant to respective divisions as a supplement for Group-wide compliance training sessions

#### List of Training Sessions Held in Fiscal 2012

	Type of training	Times held	Number of participants
Compliance training	Company-wide sessions	241	7,866
	Divisional sessions	476	5,560
	Top mgmt seminars	1	32
New management training		2	67
New employee training		1	136

### Hotlines

The Mitsubishi Tanabe Pharma Group's internal and external hotlines allow employees and managers to obtain consultation and make reports about any violation of laws, ordinances, or social conventions. The purpose of these hotlines is to prevent or reduce risks that could lead to scandal by providing employees with an easily accessible channel for bringing up concerns or suspicions that they may have. The number of calls handled by these hotlines is posted on the Group's intranet at the end of each six-month period of the fiscal year. Reports on recent trends and issues warranting special mention are then included in Company-wide training sessions.

#### Number of Hotline Consultations Handled in Fiscal 2012

Regulations	Labor management	Preliminary consultations	Other	Total
13	35	2	5	55

### Compliance at Group Companies Outside Japan

The Group consults regularly with relevant departments at its Group companies outside Japan concerning their respective action programs. These programs outline concrete approaches and program timelines designed to enhance risk management and compliance systems at subsidiaries outside Japan.

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



Organizational Governance

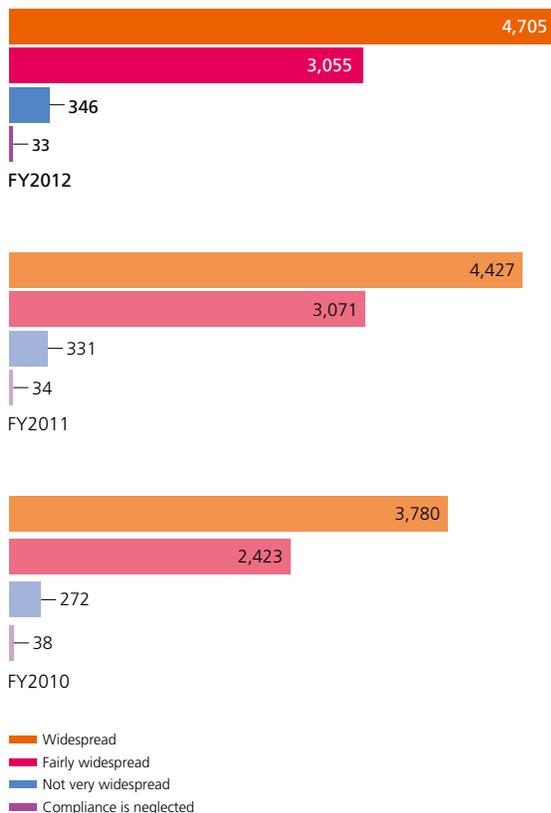
## Monitoring Compliance Awareness

In managing risk to prevent scandal, the Mitsubishi Tanabe Pharma Group recognizes the importance of monitoring progress in individual Group employees' awareness of compliance, and then continuing to strive to help it grow. To do so, the Group conducts a yearly compliance awareness survey among all employees and reports the survey findings back to each division. In fiscal 2011, the Group introduced an online format for the survey. In fiscal 2012, the response rate stood at 93.4%, with 8,237 responses.

In answer to the question, "Is awareness of the importance of compliance widespread throughout your workplace?" a combined total of 95.3% responded that awareness was "widespread" or "fairly widespread."

### Results of Compliance Implementation Survey

Is awareness of the importance of compliance widespread throughout your workplace?



## Corporate Behavior Charter Day

Taking into account the gravity of the Medway Issue and the related quality control problem, and recognizing the need to prevent any recurrence of similar incidents, the Mitsubishi Tanabe Pharma Group has introduced an annual Corporate Behavior Charter Day. This day offers employees the opportunity to review the Group's Charter and reflect on their individual conduct during compliance meetings at all Group workplaces in Japan. At these meetings, employees study the *Compliance Guidebook* and affix their signature to pledges in which they vow to conduct themselves in accordance with the Corporate Behavior Charter and Compliance Code of Conduct. For the 2013 Corporate Behavior Charter Day, Mitsubishi Tanabe Pharma invited outside experts to speak at



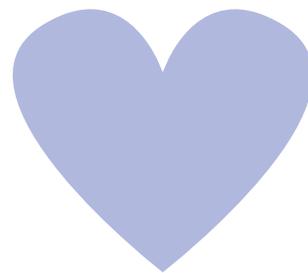
Outside expert speaks to Mitsubishi Tanabe Pharma employees

its Osaka Headquarters and Yokohama Office on April 12, the Tokyo Head Office on April 19, and the Yoshitomi and Ashikage Plants on April 26.

## Regaining Public Trust

In response to the Medway Issue and the related quality control problem, Mitsubishi Tanabe Pharma drew up improvement plans in June 2010 and again in August 2011, which were submitted to the Ministry of Health, Labour and Welfare. Since then, these plans have been implemented at all Group companies in a concerted effort to establish organizational, educational and business management structures and frameworks designed to ensure that no incident that could damage the public's trust in the Group ever occurs again. A committee comprised of experts from outside the Group has been set up to address specifically the issue of regaining public trust in relation to the Medway Issue and the quality control problem. This committee is tasked with objectively assessing progress made on the improvement plans, as well as advising when necessary to ensure that the Group's approach to these matters is highly effective.

The Group is committed to preventing the recurrence of similar incidents and to doing everything it can to regain public trust. To accomplish this, it is ensuring that these initiatives are fully integrated as quickly as possible across all Group companies and that robust efforts continue to be made to implement them.



## Human Rights



**Tomoaki Yoshimatsu**

Internal Controls &  
Compliance Department

### Raising Group-wide awareness of what respect for human rights means for a pharmaceutical company

Mitsubishi Tanabe Pharma focuses on individual employee awareness of human rights and employee behavior that reflects this awareness. In terms of the Group as a whole, we realize there is still room to improve employee awareness of human rights issues. We recognize the need to do more, going forward. Human rights issues must be addressed not only within the Group, but throughout the entire value chain, which includes all of our business partners.

An important element when addressing human rights issues is the ability to look at a given situation from the other's perspective. As a pharmaceutical manufacturer, Mitsubishi Tanabe Pharma recognizes the need to take even more seriously the views of the patients who take our medications and the medical professionals who prescribe them, and we want to ensure that employees listen better and share even more information.

With this in mind, in fiscal 2013 we are focusing on strengthening human rights and compliance training using e-learning programs. We are committed to fostering a corporate culture in which our employees take it upon themselves to think critically about these issues and actively seek to protect human rights.



# Initiatives for Employees

## Basic Stance on Human Rights

The Mitsubishi Tanabe Pharma Group recognizes the protection of human rights as part of its corporate social responsibility. In order to address the various human rights issues that can arise in a corporate environment, the Group has established Regulations for Promoting Awareness of Human Rights. The purpose of these regulations is to direct efforts to raise human rights awareness in order to raise executive and employee awareness of these issues and develop a corporate culture that is firmly committed to protecting human rights.

Under the Mitsubishi Tanabe Pharma Group Compliance Code of Conduct, the Group pledges to “respect our employees, encourage open and honest communication, and promote safe and healthy working conditions.” The Group views a positive environment in which each individual’s character and human rights are respected and all employees are able to openly discuss any subject to be the very foundation of sound corporate management.

## Initiatives to Raise Human Rights Awareness

The Mitsubishi Tanabe Pharma Group respects the ten principles of the United Nations Global Compact, which address human rights, labor, the environment, and anti-corruption, and upholds these principles in its business activities as a responsible corporate citizen in line with its Corporate Behavior Charter. The Company’s Human Rights Awareness Promotion Committee, chaired by the president,

plays a key role in both training for all employees and other Group-wide human rights training programs, which include collaborating with outside experts and employee participation in outside lectures. In anticipation of Human Rights Week in December each year, the committee sponsors a contest in which employees are encouraged to consider human rights issues and demonstrate their general awareness by composing human rights slogans. In fiscal 2012, a total of 181 entries were submitted by employees throughout the Group.

## Addressing Harassment

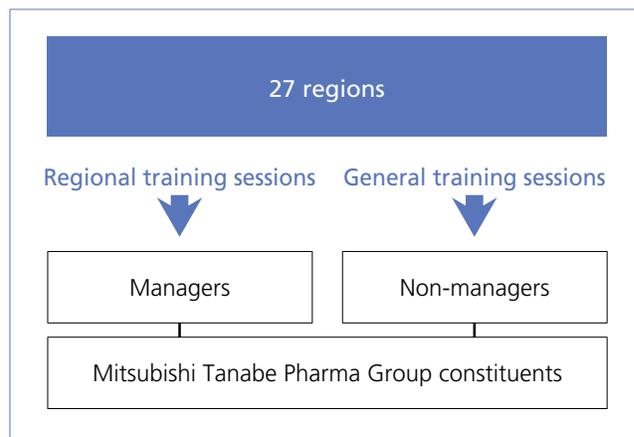
Under its Compliance Code of Conduct, the Mitsubishi Tanabe Pharma Group states clearly that the Group “does not tolerate discrimination, harassment or any behavior that violates basic human rights or inhibits the capabilities of any individual.” As part of its commitment to raising awareness and eliminating harassment in the workplace, this issue is addressed in both Group-wide compliance training and management training. In April 2013, the Group held e-learning training for all employees to increase understanding of the issue of power harassment.

Sexual harassment counseling services were expanded in May 2013. In response to recent requests, an external hotline was also set up to address difficulties and interpersonal relationships in the workplace. The Mitsubishi Tanabe Pharma Group believes that eliminating harassment is a key component of creating a comfortable work environment, which will in turn help boost the vitality and performance of the Group.

### Mitsubishi Tanabe Pharma Group Human Rights Awareness Promotion Structure

#### Article 4 of the Regulations for Promoting Awareness of Human Rights

The Group will establish a Human Rights Awareness Promotion Committee, which will determine Group-wide standards for human rights policy and raise awareness of these issues.





# Human Rights

## Human Rights Issues in the Value Chain

### Ethical Considerations in Research

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Animal experiments is an indispensable aspect of new drug research to confirm the efficacy and safety of pharmaceuticals prior to clinical studies. Research using human tissue and cells provided by patients is also increasingly important to gain a better understanding of the pathology of diseases and more accurately predict the efficacy and safety of new drugs.

In conducting tests on animals, Mitsubishi Tanabe Pharma applies as its basic principles the 4Rs, a program that adds the additional R of "responsibility" on the part of Company researchers to the conventional 3R international standards ("replacement" with alternative testing methods, "reduction" of the number of animals used, and "refinement" to relieve pain and distress). The Institutional Animal Care and Use Committee deliberates the validity of the animal experiment protocol based on international standards for animal experiments. In addition, Mitsubishi Tanabe Pharma carries out internal inspections and self-assessments to confirm that all animal experiments comply with its own management controls and in accordance with laws, regulations, and guiding principles. The Company's animal experimentation is also certified by Center for Accreditation of Laboratory Animal Care and Use of the non-profit Japan Health Sciences Foundation.

### Ethics Review Committee Approach

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Research into new drugs using samples of human origin plays an important role as a link between animal experiments and clinical trials. Ethical issues such as the informed consent of donors and the protection of their personal information must be given serious and careful consideration. Mitsubishi Tanabe Pharma has established a Human ES Cell Research Ethics Review Committee, Human Genome and Gene Analysis Research Ethics Review Committee, and a Human



Tissue Research Ethics Review Committee. These committees carefully consider the ethics and scientific validity of research protocols in these respective areas. To promote objectivity, impartiality, and transparency, each ethics review committee includes outside members to ensure that reviews are well balanced and respect is given to the range of differing opinion. Research into human ES cells and human genome/gene analysis warrants particularly serious consideration. To ensure full transparency in these areas, the Company posts the rules governing the Ethics Review Committees and the records of its proceedings on its website (currently in Japanese only).



### Human Rights and Bioethical Considerations in Clinical Testing

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All Mitsubishi Tanabe Pharma clinical trials are subject to strict standards. The Company follows the guidelines set by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use/Good Clinical Practices (ICH-GCP), based on the Declaration of Helsinki (June 1947). It also upholds the laws and regulations of the country in which the studies are conducted, as well as its own standards and clinical trial protocol. All volunteer participants in the trials give their informed consent to do so. The Company's highest priority is to ensure the safety of its subject, protect their human rights and safeguard their personal welfare.

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





## Ethical Considerations in Procurement

Mitsubishi Tanabe Pharma operates by a defined set of Purchasing Principles. Its basic purchasing policy calls for fair, equitable and transparent transactions with suppliers and CSR-oriented purchasing activities that comply with relevant laws and regulations, are environmentally friendly, and respect human rights.

The Company selects suppliers on a globally equitable and open basis with the aim of ensuring the quality of procured materials and their stable supply. Its own strict supplier selection standards are designed to ensure fairness, impartiality and transparency when evaluating and selecting suppliers. As part of its initiatives in CSR procurement, Mitsubishi Tanabe Pharma surveys its suppliers to gather information concerning these companies, including their CSR initiatives.

## Human Rights Considerations in Production

The Mitsubishi Tanabe Pharma Group acts with consideration for local communities in the manufacture of its products. Group initiatives include energy conservation and recycling, as well as maintaining ISO14001 certification, an international standard for environmental management, at major production sites.

Each Mitsubishi Tanabe Pharma plant carries out greening activities and local environmental cleanup campaigns, planting trees on factory grounds and collecting litter in the surrounding neighborhoods. Both the Yoshitomi and Ashikaga Plants are involved in activities to promote interaction with local communities, including hosting summer festivals in which local residents are invited to participate.

Mitsubishi Tanabe Pharma fully complies with all environmental laws and regulations associated with its business activities, including Japan's Water Pollution Control Act, Soil Contamination Countermeasures Act, and Noise Regulation Law. In addition, the Company is also in compliance with all special local laws and regulations, such as the Act on Special Measures concerning Conservation of the Environment of the Seto Inland Sea, which are relevant to operations at the Onoda and Yoshitomi Plants.

When investing in new facilities that involve the construction of buildings or other structures, the Company holds briefings for neighborhood residents before the project commences in an effort to help the local community better understanding how they will be impacted.

## Human Rights Considerations in Marketing

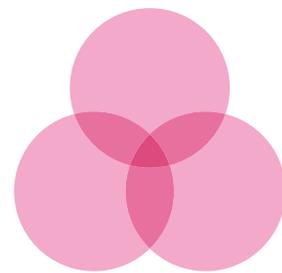
As a pharmaceutical manufacturer, the Mitsubishi Tanabe Pharma aspiration is to provide patients with medicines that can effectively improve their health. To achieve this, the Company takes as its mission the provision of accurate information on its valuable pharmaceutical products to physicians, pharmacists, nurses, and other medical professionals in order to improve the welfare and medical care of the public and help people live healthy, quality lives.

Mitsubishi Tanabe Pharma medical representatives (MR) conduct themselves with the high ethical standards and common sense befitting employees of a global healthcare company, placing the highest priority on fairness and integrity in all of their activities. An MR's goal is to carry out promotional activities in a manner that respects the human rights of all patients.

## Protecting Customer Privacy

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

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



## Labor Practices



**Shinichi Sakamoto**  
Human Resources Development  
Department

### Nurturing talent able to identify issues and take action to succeed on the global stage

As Mitsubishi Tanabe Pharma's business expands with increasing speed outside Japan, we recognize the importance of developing employees who are capable of doing business at a global level. We have designed a variety of training programs to achieve this. One such program focuses on helping the young employees who will handle the core of our operations outside Japan to develop the expertise and mindset needed to work successfully on the world stage. We have also introduced another training program designed to broaden the perspectives of employees who will work outside Japan. Under this program, young Japanese employees are sent to sites in North America, Europe and Asia for a one-year period during which time they sharpen their multicultural communication skills and learn the basics of doing business outside of Japan through firsthand experience.

We are also working to revitalize our organizational structure in order to address the strategic challenges laid out in the Medium-Term Management Plan 2011-2015, "New Value Creation." As part of this focus, we hold group dialogues that emphasize participant discussions during grade-specific training sessions. This type of training and similar programs help raise awareness so that employees are capable of identifying issues on their own and taking the steps needed to address them. Our aim is to develop human resources who are able to contribute to the local communities everywhere we operate.

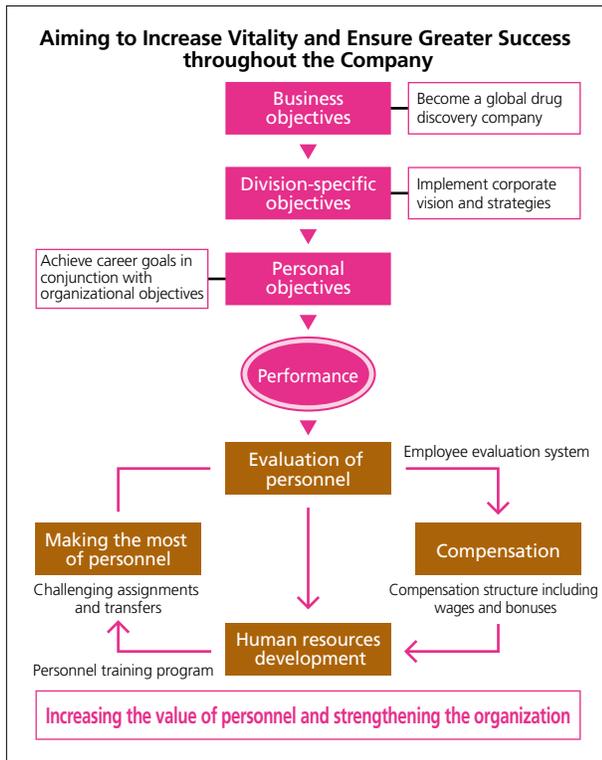


# Human Resources Development

## Basic human resources policy

In an effort to build a flexible and dynamic organization, Mitsubishi Tanabe Pharma has established a Comprehensive Management System for Human Resources to create an environment that encourages employees to pursue personal growth, while at the same time channeling their energies into strengthening the Company. Human resources training is focused on the Company's four standards for conduct: Pride and a Sense of Mission, Challenge and Innovation, Trust and Teamwork, and Harmonious Co-Existence with Society. In its Medium-Term Management Plan, Mitsubishi Tanabe Pharma aims to position itself as a company that continuously produces new value and does so by working to enhance its human resources and organizational structures to facilitate global development.

### Comprehensive Management System for Human Resources



### Number of Employees

	March 31, 2010	March 31, 2011	March 31, 2012	March 31, 2013
Consolidated	9,266	9,198	9,187	<b>8,835</b>
Unconsolidated	5,186	4,957	4,826	<b>4,850</b>
Men	4,152	3,968	3,869	<b>3,870</b>
Women	1,034	989	957	<b>980</b>

## Enhancing Personnel Training

As it strives to become a global drug discovery company, Mitsubishi Tanabe Pharma offers employees medium- to long-term career planning support. In fiscal 2012, the Company placed particular emphasis on training to enhance managerial skills, for instance training designed to shift fundamental attitudes among all general managers and section managers. In conjunction with the new Comprehensive Management System for Human Resources, the Company plans in fiscal 2013 to integrate career management support and individual skill development sessions. Mitsubishi Tanabe Pharma will continue to offer career track training for prospective managers and global leadership training programs in order to foster highly competent next-generation leadership.

### Training Program Structure

Grade	Targeted staff	Career track training	Career management support	Individual skills development
Managers and highly skilled staff	Directors General managers Newly appointed GMs Managers	Next-generation leadership training programs	Self-improvement training for developing valuable skills	English and Chinese conversation courses In-house TOEIC classes
Regular employees	Newly appointed managers Manager assessment promoted employees Employees eligible for new K1 training	Global leadership training programs Education leave	Optional training programs Correspondence courses	
	Employees eligible for new E-level training Third-year employees New employees			

\* Targeted staff training scheduled as of May 2013

### Number of New Graduates Hired (Non-consolidated)



### Employee Turnover Rate (Non-consolidated)



\* Figures for employee turnover include only cases of resignation or death (e.g., not dismissals)

# Labor Practices

## Promoting Diversity

### Securing Diverse Talent

Hiring and keeping the best human resources is essential to enhancing the Company's organizational functions. Mitsubishi Tanabe Pharma strives to open its doors ever wider to new hires, as well as to talent able to compete globally, career personnel with expert skills, and people with disabilities. The Company is also focused on expanding hiring opportunities by offering online seminars and participating in employment events. Mitsubishi Tanabe Pharma is committed to fulfilling its social responsibilities by providing employment opportunities for a diverse group of individuals and giving employees the opportunity to demonstrate their full potential.

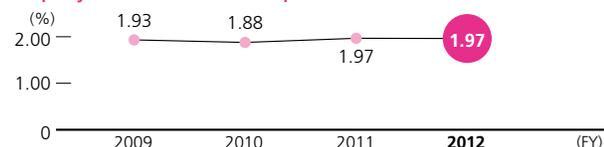
#### Percentage of Female Employees with Expert Qualifications



### Supporting People with Disabilities in the Workplace

As of March 31, 2013, Mitsubishi Tanabe Pharma employed people with disabilities at a rate of 1.97%, a figure that was higher than the 1.8% mandated by Japanese law. On April 1, 2013, the legally required rate was revised upward to 2.0%. The Company will work to ensure that it reaches that rate by continuing to take steps to proactively advance the employment of people with disabilities, such as providing employment opportunities and comfortable work environments that accommodate the nature and degree of specific disabilities.

#### Employment Rate of People with Disabilities

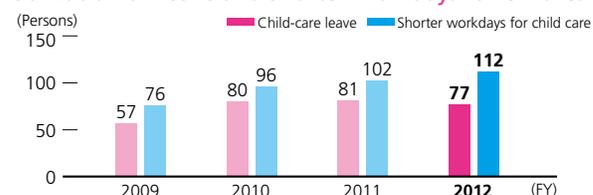


### Work-Life Balance Considerations

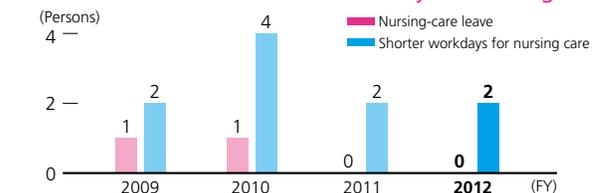
Mitsubishi Tanabe Pharma strives to help employees comfortably balance work with personal life and family commitments. The Company recognizes the importance of employees gaining satisfaction and pride from their work while

also being able to experience meaningful life events, such as the birth of a child or caring for children and family members. This approach has earned the Company "KURUMIN" accreditation every consecutive year since 2007. This accreditation mark is based on the Next Generation Nurturing Support Measures Promotion Law. In an effort to enhance its work environment to an even greater degree, Mitsubishi Tanabe Pharma has introduced its own unique Time Management Campaign to encourage more efficient working styles.

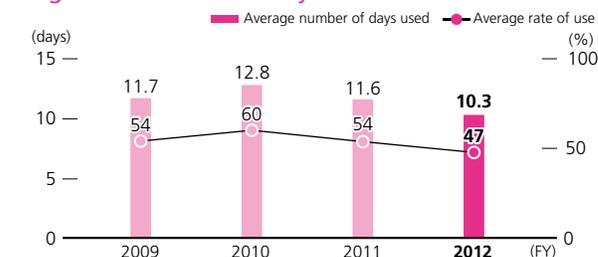
#### Utilization of Leave and Shorter Workdays for Child Care



#### Utilization of Leave and Shorter Workdays for Nursing Care



#### Usage of Paid Vacation Days



### Building Sound Labor-Management Relations

The labor agreement that Mitsubishi Tanabe Pharma has entered with the Mitsubishi Tanabe Pharma Labor Union guarantees the working conditions and rights of union members. Company management and the union regularly hold labor-management meetings where the Company communicates its management policy and the two parties exchange information on workplace conditions, seeking to more fully understand each other. The members of the Labor and Management Committee also contribute their views on such issues as work hours and human resource systems in order to promote a better working environment.



# Occupational Health and Safety

## Occupational Health and Safety Initiatives

Convinced that safety is fundamental to its very existence, the Mitsubishi Tanabe Pharma Group takes every measure to ensure the safety of all employees at its business sites, aiming to eliminate workplace accidents and disasters.

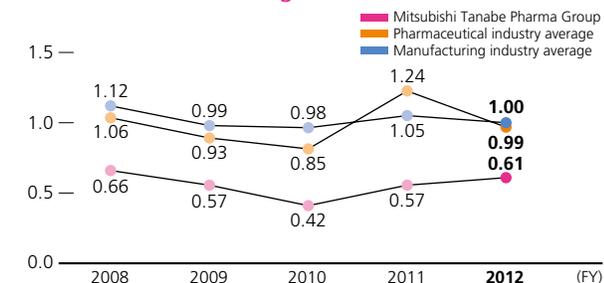
As part of its accident and disaster prevention efforts, the Company operates an occupational health and safety management system and implements an effective Plan-Do-Check-Act (PDCA) cycle. Despite these efforts, however, the rate of accidents causing absence from work has not decreased yet in the Mitsubishi Tanabe Pharma Group.

With this in mind, the Mitsubishi Tanabe Pharma Group recognizes that safety awareness is vital to risk reduction. Viewing efforts to raise safety awareness among all employees as a means of preventing accidents caused by unsafe practices, the main factor in work-related accidents, the Group conducts ongoing safety training for all employees. This training covers hazard prediction and the prevention of human error and also incorporates experience-based training. The latter utilize simulations of workplace accidents and disasters to raise awareness of the dangers involved and are designed to eliminate unsafe behavior and practices associated with workplace accidents and disasters.



Experience-based training simulates workplace accidents in which employees are caught between moving objects.

### Rate of Accidents Causing Absence from Work



Rate of accidents causing absence from work: Number of casualties due to accidents that require time off of work to one million actual work hours

## Safety Assessments

Mitsubishi Tanabe Pharma uses safety assessments to evaluate in advance potential risks related to environmental safety whenever changes to processes, raw materials, equipment, or personnel are scheduled. These assessments also help the Company devise the requisite preventative measures. Further, the Mitsubishi Tanabe Pharma Environmental Safety Assessment Guidelines were developed to help prevent accidents and disasters before they occur and guide the implementation of the Company's safety assessments.

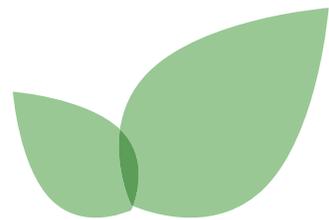
In order to mitigate problems and incidents arising from the chemical substances handled by the Company, safety assessments incorporate search tools to secure comprehensive verification of the laws and regulations related to these chemical substances. These assessments promote a thorough review of the laws and a careful and considered response on the part of the Company.

## Addressing Mental Health Issues

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

## Surveying Employee Attitudes

The Mitsubishi Tanabe Pharma Group introduced employee attitude surveys in 2011. Providing a comprehensive understanding of employee attitudes toward their jobs and a clear picture of the Company's workplace environments, survey findings are incorporated into the Group's management policies. Since fiscal 2012, the findings have also been reported back to individual departments. In terms of addressing Company-wide issues, the surveys help improve the capacity of managers to train subordinates as part of managerial training and provide a channel for communication between executives and employees. Responses to new items added to the fiscal 2012 survey will also be incorporated into future Company policy.



# Environment

## Successful in eliminating industrial waste, continuing to protect the global environment



**Yasutoshi Kameyama**  
Environmental Safety Department

At Mitsubishi Tanabe Pharma we are committed to making continuous efforts to reduce our environmental impact. In fiscal year 2012, the Group's Onoda Plant reduced its CO<sub>2</sub>, NO<sub>x</sub>, and SO<sub>x</sub> emissions by switching fuel from kerosene to city gas. Meanwhile, our final disposal rate for industrial waste fell below 0.5%, and thus we achieved zero emissions status.

I feel that environmental awareness within the Group has been increasing year by year, not only in terms of efforts to conserve energy and electricity but also in regards to protection of the natural environment. The number of participants in the Ikoma Mountain Range "Folding Screen of Flowers" Project, for example, which was held on the outskirts of Osaka in November 2012, nearly doubled from 2011. We are planning similar activities for Eastern Japan in fiscal 2013 in addition to ongoing events in Western Japan and hope to see more participants.

In the future we are thinking to put more effort into the preservation of biodiversity in addition to the reduction of environmental impact. Moreover, we will continue to value communication with local communities through each of our business sites and will engage in environmentally friendly initiatives that meet local needs in pursuit of the creation of a *KAITEKI* (comfortable) society.



Environment

# Environmental Management

## Environmentally Friendly Corporate Activities

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

As a member of the Mitsubishi Chemical Holdings Group, the Mitsubishi Tanabe Pharma Group is pursuing the creation of a *KAITEKI* (comfortable) society. In particular, it is reducing its global environmental impact through measures such as the reduction of greenhouse gases.

### Mitsubishi Tanabe Pharma Environmental Safety Philosophy

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

## Policy on Environmental Safety Activities



The Mitsubishi Tanabe Pharma Group is committed to implementing and continuously improving measures for the environment, safety, and health across the entire lifecycle, from product R&D through manufacture, distribution, and use, to disposal. The Group also practices active information disclosure in an effort to embody **its vision of being a company that is trusted by communities.**

## Management Structure

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

### Mitsubishi Tanabe Pharma's Environmental Safety Management Structure



## Scope of Environmental Information Collection and Disclosure

Mitsubishi Tanabe Pharma Group collects and discloses information in its CSR reports regarding the manufacturing, research, and distribution facilities of Mitsubishi Tanabe Pharma, its consolidated subsidiaries, and equity method-applicable subsidiaries in Japan, as well as the manufacturing sites and research facilities of its overseas consolidated subsidiaries.

### Companies Subject to Environmental Information Disclosure

In Japan: Mitsubishi Tanabe Pharma Corporation, Mitsubishi Tanabe Pharma Factory, Ltd., Benesis Corporation, Bipla 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., Tianjin Tanabe Seiyaku Co., Ltd., Mitsubishi Tanabe Pharma Korea Co., Ltd., Mitsubishi Pharma (Guangzhou) Co., Ltd., P.T. Tanabe Indonesia, Tanabe Research Laboratories U.S.A., Inc.

\* Due to a change in the scope of disclosure for consolidated subsidiaries and equity method-applicable subsidiaries in Japan, information for Benesis is current as of September 2012 and information for Choseido Pharmaceutical and Hoshienu Pharmaceutical is current as of October 2012.



# Environment

## Environmental Management

### Environmental Compliance

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The Mitsubishi Tanabe Pharma Group is committed to proactively protecting the global environment and coexisting in harmony with society. The Group makes active efforts to conserve resources, save energy, and reduce, reuse, and recycle waste. It also works to strengthen its environmental compliance by routinely checking, through environmental audits, to ensure that the Plan-Do-Check-Act (PDCA) cycle is being implemented appropriately and smoothly.

### Environmental Risk Management

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The Mitsubishi Tanabe Pharma Group has established risk management rules and shares awareness within the Group to prevent risks from developing into incidents. As an added precaution, it has prepared specific procedures for handling emergencies, in order to minimize human, economic, and societal damage, and the Group makes every effort to reduce risks by practicing these procedures in routine employee training.

In particular, the Group has prepared for initial responses in emergencies by systematically installing and adopting equipment and systems for preventing environmental pollution in case of an unforeseen contingency, such as an accidental discharge of chemical substances to rivers or the sea.

### ISO 14001 Certifications

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The Mitsubishi Tanabe Pharma Group's principal production sites have acquired either ISO 14001 certification or other certifications established by relevant local municipalities. Research centers and offices manage environmental and safety issues and conduct environmental preservation activities in ways that are appropriate to their business.

### Environmental Safety Audits

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The Mitsubishi Tanabe Pharma Group has further enhanced the level of its environment- and safety-related activities through environmental safety audits conducted at plants and research centers in and outside Japan. No issues that could lead to a major environmental risk were identified in the audits conducted in fiscal 2012.

The Group has also commenced environmental audits

on legal compliance at production sites outside Japan. As part of that effort it uses auditors who are outside experts in local environmental laws. In this and other ways the Group has strengthened initiatives pertaining to compliance and environmental management at business sites outside Japan.



An environmental audit at Mitsubishi Tanabe Pharma Korea Co., Ltd.

### Soil and Groundwater Contamination Prevention and Control

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The Mitsubishi Tanabe Pharma Group proactively monitors soil and water contamination at all its production and research facilities and, in the remote chance that contamination is discovered, takes appropriate measures to prevent wide-area pollution dispersion.

At the former site of API Corporation's Kusu Plant (Yokkaichi City, Mie Prefecture), which closed in 2009, the Company completed a cleanup operation of contaminated soil, carried out anaerobic bioremediation of groundwater, and is now continuing to monitor the groundwater. It is also monitoring the effects of contamination on areas outside the plant, under the guidance of government agencies, and is reporting the absence of problems each time.

There were no new soil pollution sites identified in fiscal 2012. In the future, at events involving Company-owned land such as consolidating, decommissioning, or reconstructing facilities, the Company will continue to conduct appropriate investigations, make reports, and submit required paperwork in accordance with the Soil Pollution Control Act. The Group will release inspection results and take full and immediate responsibility for incidents involving contamination.

### Environment-Related Incidents

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In fiscal 2012, the Group experienced no incidents that would have had a major effect on the environment. There were, however, three minor incidents, such as an on-the-premises leak of chemical substances and excess chemical oxygen demand (COD) value in wastewater, due to defective installation of piping and flaws in operation and management. In each incident, the Group made an appropriate report to the authorities, took thorough recurrence prevention measures, and will make every effort to prevent similar accidents.



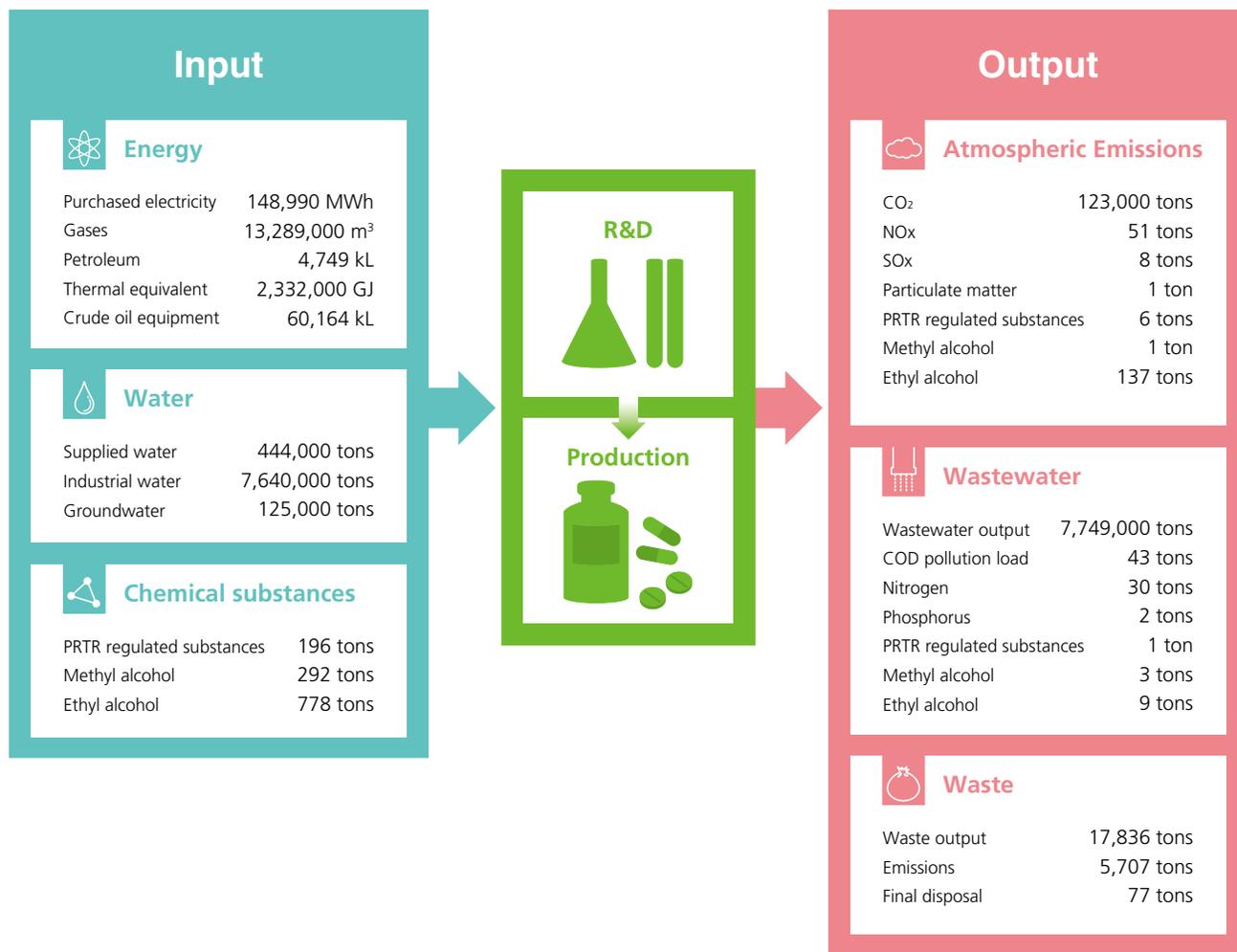


Environment

# Overview of Environmental Impact

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

Scope: The Mitsubishi Tanabe Pharma Group's business sites — plants, research centers, and distribution centers — in Japan



## Environmental Performance of Production and Research Sites outside Japan

Energy consumption	Electricity	14,530 MWh
	Gases	516,000 m <sup>3</sup>
	Petroleum	274 kL
Water consumption		301,000 tons
CO <sub>2</sub> emissions		10,000 tons
Waste output		283 tons

◆ Scope: Taiwan Tanabe Seiyaku Co., Ltd.; Tianjin Tanabe Seiyaku Co., Ltd.; Mitsubishi Pharma (Guangzhou) Co., Ltd.; P.T. Tanabe Indonesia; Mitsubishi Tanabe Pharma Korea, Co., Ltd.; and Tanabe Research Laboratories U.S.A., Inc.

◆ Period: January 1 to December 31, 2012

◆ CO<sub>2</sub> emissions were calculated with reference to the *Greenhouse Emission Calculation and Reporting Manual (Ver. 3.3)* and the *List of Calculation Methods and Emission Coefficients for Calculation, Reporting and Publication*, published by Japan's Ministry of the Environment and Ministry of Economy, Trade and Industry. The electricity output coefficient was set at 0.000550 t-CO<sub>2</sub>/kWh.



# Environment

## Overview of Environmental Impact

### Medium-Term Environmental Action Plan

#### Objectives and Fiscal 2012 Results of the 2011-2015 Medium-Term Environmental Action Plan

Area	Objectives	Fiscal 2012 results
Energy conservation and global warming mitigation	<ul style="list-style-type: none"> <li>Reduce CO<sub>2</sub> emissions for FY2015 by at least 30% compared to the FY2005 level</li> </ul>	<ul style="list-style-type: none"> <li>Reduced CO<sub>2</sub> emissions by 36.3% compared to the FY2005 level (a 2.4% reduction compared to the FY2011 level)</li> <li>Increased the number of hybrid vehicles used by sales personnel to 1,113 from 929 in FY2011</li> <li>Performed energy conservation analyses at Mitsubishi Tanabe Pharma Factory's Kashima Plant based on the CO<sub>2</sub> reduction and energy saving analyses developed by the Ministry of the Environment, and at Ashikaga Plant based on an external institution's diagnostic methodology.</li> </ul>
Reduction of waste, reuse and recycling of resources	<ul style="list-style-type: none"> <li>Promote a zero emissions strategy (final waste disposal rate of less than 0.5%) and continually reduce waste and emissions output and final waste disposal</li> <li>Fulfill the responsibility of a waste-discharging enterprise for handling waste correctly and ensuring proper treatment by contractors</li> </ul>	<ul style="list-style-type: none"> <li>Achieved a final waste disposal rate of 0.43%, compared to 0.68% in fiscal 2011</li> <li>Promoted recycling and the effective use of resources</li> <li>Performed on-site inspections of waste collection and transportation companies and intermediate and final disposal sites</li> </ul>
Chemical substance emissions reductions	<ul style="list-style-type: none"> <li>Properly manage chemical substances and continually reduce their discharge into the environment</li> </ul>	<ul style="list-style-type: none"> <li>Properly manage chemical substances and continually reduce their discharge into the environment</li> <li>Reduced emissions of PRTR substances into the air by 33% compared to the FY2011 level and maintained emissions of water at the same level as FY2011</li> </ul>
Enhancement of environmental management	<ul style="list-style-type: none"> <li>Improve environment-related risk management at company facilities</li> <li>Maintain zero environmental accidents</li> </ul>	<ul style="list-style-type: none"> <li>Conducted environmental safety audits at 20 Group worksites inside and outside Japan</li> <li>At overseas worksites, introduced environmental compliance audits by outside experts</li> <li>Conducted online environmental and safety training courses</li> <li>Had zero environmental accidents and only three minor incidents</li> </ul>

### Environmental Accounting

Mitsubishi Tanabe Pharma works to promote effective and efficient environmental management by ascertaining and analyzing the costs and effects of environmental conservation and the impact these activities have on economic performance. Environmental conservation costs for fiscal 2012 were ¥281 million in investments and ¥1.215 billion in running costs. The economic benefit of environmental conservation measures was ¥72 million.

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

Item	Invested	Expended
Pollution prevention	48	474
Global environmental protection	209	40
Recycling and reuse of resources	24	365
Upstream and downstream activities	0	37
Administrative activities	0	269
Research and development	0	0
Community activities	0	0
Environmental damage compensation	0	30
Total	281	1,215

#### Environmental Conservation Effects

Reduction of environmental impact		Quantity reduced
Pollution prevention	NOx load reduction	6.05 tons
	SOx load reduction	0.11 tons
	Particulate matter load reduction	0.03 tons
	PRTR regulated air emission reduction	0.71 tons
Global environmental protection	Greenhouse gas emission reduction	4,490 tons-CO <sub>2</sub>

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

Material economic effects	Amount saved
Sales of valuable materials	10
Electric consumption reduced through energy-saving measures	62
Total	72

Notes regarding calculations for fiscal 2012 data: 1. Data were calculated according to the *Environmental Accounting Guidelines* (2005 edition) published by the Ministry of the Environment of Japan. 2. Calculation period: April 1, 2012, to March 31, 2013. 3. Scope: All worksites in Japan. 4. Calculation methods: (1) Simple method for amount invested (25%, 50%, 75%, 100%); (2) Depreciation is calculated based on the legally defined service life of applicable items; and (3) The full amounts for non-depreciation costs are posted only if 100% environment related. 5. Calculation and evaluation methods for effects resulting from environmental conservation measures: (1) Only material effects based on conclusive grounds for each environmental measure are tallied and assessed; and (2) Effects observed within the fiscal year are tallied by converting them to a period of 12 months, and evaluated by comparing them to the year before the measures were implemented (or the previous fiscal year).



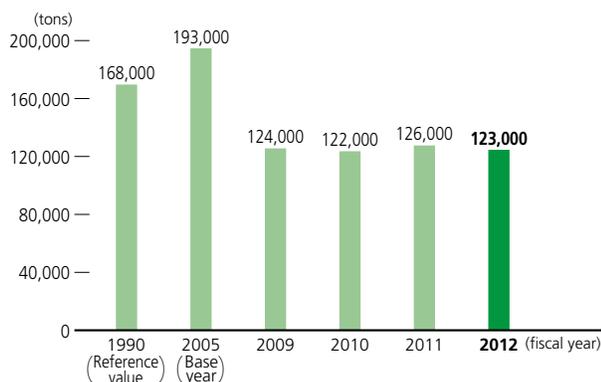
# Energy Conservation and Global Warming Mitigation

## CO<sub>2</sub> Emissions Reduction Targets and Results

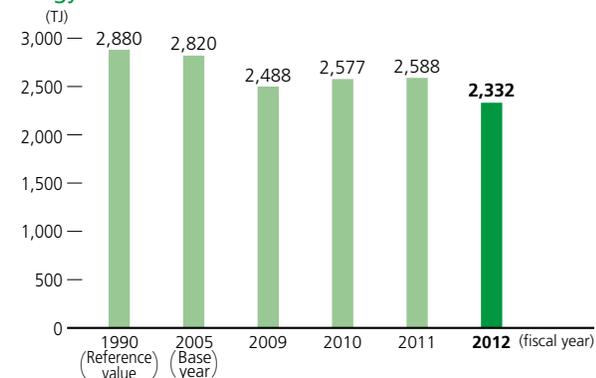
The Mitsubishi Tanabe Pharma Group has made the conservation of energy and the curbing of global warming two of its top-priority environmental objectives. In its efforts to reduce greenhouse gas emissions, the Group implements energy conservation initiatives based on the location and business of its various worksites, including plants, research facilities, distribution centers, and offices. These initiatives are aimed at reducing CO<sub>2</sub> emissions for fiscal 2015 by at least 30 percent from its fiscal 2005 level as stipulated in the Group's Medium-Term Environmental Action Plan.

The Group's CO<sub>2</sub> emissions in fiscal 2012 totaled 123,000 tons, a 36.3-percent reduction compared to the fiscal 2005 level. In fiscal 2012, many worksites were affected by an increase in the emission factor used to determine CO<sub>2</sub> emissions related to the purchase of electric power. However, changes in the scope of worksites subject to monitoring and fuel conversion at some sites resulted in CO<sub>2</sub> emissions decreasing by 2.4 percent compared to fiscal 2011.

### CO<sub>2</sub> Emissions



### Energy used



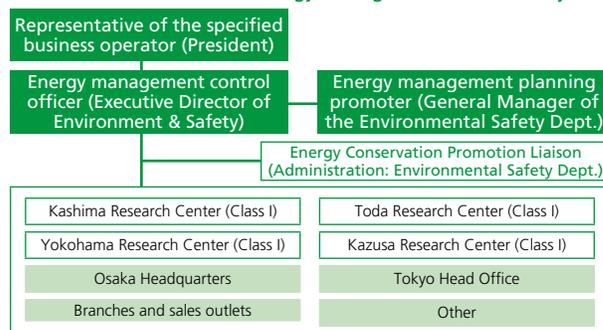
## Strengthening Energy Management

The Kashima, Toda, Yokohama, and Kazusa research sites were appointed as Class I Designated Energy Management Factories. Combined energy usage at the four sites in fiscal 2012 totaled 20,380 kL of crude oil equivalent, a 4-percent reduction from the previous fiscal year, while CO<sub>2</sub> emissions totaled 38,330 tons, up 11 percent from the previous year as a result of a change in the CO<sub>2</sub> emission factor for purchased electricity. These efficiency improvements at the four research sites account for 88 percent of both the Company's energy consumption and its CO<sub>2</sub> emissions at all worksites, including offices.

### Energy Consumed by Mitsubishi Tanabe Pharma's Worksites in Fiscal 2012

Sites	Crude oil equivalent (kL)		CO <sub>2</sub> emissions (tons-CO <sub>2</sub> )	
	FY 2011	FY 2012	FY 2011	FY 2012
Kashima Research Center	6,980	<b>6,210</b>	10,830	<b>11,500</b>
Toda Research Center	5,070	<b>5,380</b>	8,770	<b>10,240</b>
Yokohama Research Center	3,530	<b>3,320</b>	5,840	<b>6,230</b>
Kazusa Research Center	2,850	<b>2,900</b>	5,050	<b>5,560</b>
Osaka Headquarters	660	<b>640</b>	790	<b>1,120</b>
Tokyo Head Office	580	<b>300</b>	850	<b>550</b>
Branches and sales outlets	1,010	<b>1,070</b>	1,670	<b>2,150</b>
Other	560	<b>550</b>	740	<b>980</b>
<b>Total</b>	<b>21,240</b>	<b>20,380</b>	<b>34,540</b>	<b>38,330</b>

### Mitsubishi Tanabe Pharma Energy Management Promotion System



Three companies in the Mitsubishi Tanabe Pharma Group—Mitsubishi Tanabe Pharma, Mitsubishi Tanabe Pharma Factory Ltd., and Bipa Corporation—have been designated as Specified Business Operators under the Act on the Rational Use of Energy. These companies are enhancing their energy management by holding energy conservation promotion liaison committee meetings to monitor any transitions in energy consumption and CO<sub>2</sub> emissions and to discuss energy-saving measures for worksites.



# Environment

## Energy Conservation and Global Warming Mitigation

### Energy Savings through Office Consolidation

The Tokyo Head Office used to operate out of two offices, one in Chuo-ku and one in Chiyoda-ku, but in May 2012 the two offices were consolidated into the Nihonbashi Building in Chuo-ku, which has an environmentally friendly design. This resulted in a marked energy savings, with energy consumption in fiscal 2012 of 303 kL of crude oil equivalent, a 48-percent reduction compared to a total of 579 kL for the two buildings before the consolidation.

FY 2011		FY 2012	
Two offices		Nihonbashi Building*	
Electricity	569 kL	Electricity	302 kL
City gas	10 kL	City gas	1 kL

\* Including energy consumption needed for building management of the two old offices

### Energy Conservation Analyses

Plants in the Mitsubishi Tanabe Pharma Group are pursuing efficient energy use through energy conservation analyses and support for operation improvements. In fiscal 2012, Mitsubishi Tanabe Pharmaceutical Factory's Kashima Plant had its potential CO<sub>2</sub> reduction and electric power savings inspected by the Ministry of the Environment. The Ministry conducted the emergency inspection on business operators in areas affected by the Great East Japan Earthquake. The Company's Ashikaga Plant conducted an energy conservation inspection using an outside analytical organization.

Both plants have large energy consumption for maintaining clean rooms and other purposes in order to comply with good manufacturing practice (GMP) for pharmaceutical products. Going forward, the plants will continue to make steady efforts to improve energy efficiency in light of the results of the analyses, including installing efficient equipment.



Conducting an energy conservation analysis

### Initiatives with Company Vehicles

In fiscal 2012, there were 1,963 vehicles in Mitsubishi Tanabe Pharma's fleet, nearly the same as the previous year, but the number of hybrid vehicles had increased by 184 to 1,113. The Company will continue making every effort to reduce CO<sub>2</sub> emissions by promoting economical driving practices and moving toward its goal of converting its entire fleet of vehicles (excluding those for use in cold weather areas) to hybrid vehicles and other environmentally friendly vehicles by 2015.

#### Company Vehicles

	FY 2010	FY 2011	FY 2012
No. of company vehicles	1,983	1,966	1,963
Electric vehicles	50	49	46
Hybrid vehicles	700	929	1,113

### Third-Party Verification in Accordance with ISO 14064-3

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

Mitsubishi Tanabe Pharma had an outside certification body verify that the CO<sub>2</sub> emissions from its worksites in Japan were in accordance with ISO 14064-3 before

disclosing them in this report. The Company had the verification conducted with the purpose of obtaining a "limited assurance" for the greenhouse gas emissions it quantified.



Greenhouse gas emissions verification report



Environment

## Initiatives at Worksites and Offices

### Using Electric Vehicles

In fiscal 2012, the Kashima Research Center adopted an electric vehicle for the document-delivery vehicle used on the Center's premises. The Center has been certified and registered as an Excellent Ecological Commuter Office since



Electric vehicle used on the Center's premises

2009. Its employees do not commute to work using private cars or motorcycles; they all take public transportation or ride bicycles, and strive to reduce CO<sub>2</sub> emissions not only during their work commute but also during on-premises activities.



Excellent Ecological Commuter Office certification

### Energy Conservation Campaigns

Cooperating in the *KAITEKI* activities being promoted by the Mitsubishi Chemical Holdings Group, Mitsubishi Tanabe Pharma Group has been conducting energy conservation campaigns that include strict control of air conditioning / heating temperatures in the summer and winter, setting PCs to energy conservation mode, and following the principle of "two-up three-down" for the use of stairs instead of elevators. It also participates in "lights down" campaigns



Fan made for summer 2012

promoted by the Ministry of the Environment and local governments. In these ways the Group pursues reductions in energy consumption through efforts conducted within a scope that does not impede work or endanger safety.

### Promoting Energy Conservation through Energy Conversion

Mitsubishi Tanabe Pharma Factory's Onoda Plant previously used kerosene as boiler fuel but switched to city gas in fiscal 2012. This fuel conversion enabled a reduction in CO<sub>2</sub> emissions and also had a favorable effect on reducing the environmental load of NO<sub>x</sub>, SO<sub>x</sub>, particulate matter, and PRTR substances. It even resulted in an economic benefit of ¥56 million in environmental accounting in fiscal 2012.

#### Reduction in Greenhouse Gas Emissions

Kerosene: 16,094 tons-CO<sub>2</sub> /year  
 → City gas: 11,840 tons-CO<sub>2</sub> /year (26% reduction)

#### Reduction in NO<sub>x</sub>/SO<sub>x</sub> / Particulate Matter Load

NO<sub>x</sub> load Kerosene: 11.135 tons/year  
 → City gas: 5,083 tons/year (54% reduction)

SO<sub>x</sub> load Kerosene: 0.358 tons/year  
 → City gas: 0.243 tons/year (32% reduction)

Particulate matter load Kerosene: 0.096 tons/year  
 → City gas: 0.069 tons/year (27% reduction)

#### Reduction in Air Emissions of PRTR Class I Designated Chemical Substances

Air emissions of xylene (content: 1.1%) and 1,2,4-trimethylbenzene (content: 1.5%) in kerosene:  
 When using kerosene, 0.5% of handled amount was emitted  
 → Reduced to zero when using city gas

Tanabe Seiyaku Yoshiki Factory uses kerosene as a fuel for air conditioning equipment, but the fuel for the equipment that produces hot and cold water was switched from kerosene to electricity in fiscal 2012. While a complete fuel conversion, including boiler fuel, has not been made, the company is verifying the CO<sub>2</sub> emissions reduction effect of the conversion based on the actual operation results for fiscal 2013.



Electrical cold water chiller installed at Tanabe Seiyaku Yoshiki Factory in fiscal 2012



# Environment

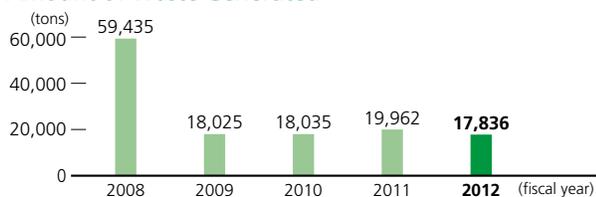
## Waste Reduction & Proper Management of Chemical Substances

### Waste Reduction Initiatives

Defining zero emissions as a final waste disposal rate (amount of final waste disposed / total amount of waste generated) of less than 0.5%, the Mitsubishi Tanabe Pharma Group's objective is to achieve continued reductions in both the amount of waste generated and the amount of final waste disposed. In fiscal 2012, the Mitsubishi Tanabe Pharma Factory's Onoda Plant was able to achieve zero emissions with a final waste disposal rate of 0.43%. This achievement was the result of various improvements, such as the recycling of the surplus sludge that is generated when wastewater is processed.

In addition, the Group visits waste treatment contractors and uses an original check sheet to confirm the status of legal compliance, contract fulfillment, and processing. In fiscal 2012, on-site inspections were made at 43 waste treatment facilities at Group worksites.

#### Amount of Waste Generated



#### Amount of Final Waste Disposed



### Dealing with PCB Waste

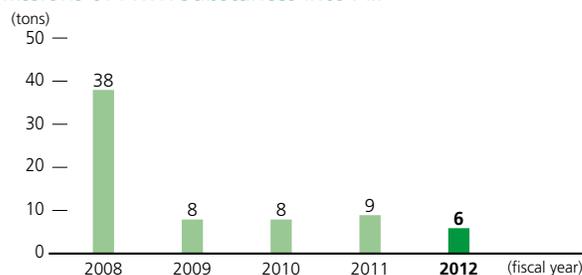
The Mitsubishi Tanabe Pharma Group ensures proper storage of polychlorinated biphenyl (PCB) waste and the filing of notifications based on the Act on Special Measures concerning Promotion of Proper Treatment of PCB Wastes. In fiscal 2012, the Onoda Plant disposed of all its PCB waste, including PCB-containing fluorescent light ballasts and waste with high concentrations and trace contamination of PCB. The Group is also treating PCB waste at other worksites.

### Reducing Air Emissions

Working toward its objective of proper management of chemical substances and the reduction of emissions into the environment, the Group is striving to ascertain and control its emissions of pollutant release and transfer register (PRTR) substances (Class I Designated Chemical Substances). These substances are specified in Japan's Law Concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management (PRTR Law). Also, the Group is working to control volatile organic compounds (VOCs) such as ethyl alcohol.

In fiscal 2012, the amount of Class I Designated Chemical Substances handled by the Group was 195.8 tons, down 36% from fiscal 2011, while the amount released into the air was 6.2 tons, a 29% decrease from the previous fiscal year. These substantial reductions were mainly attributable to the conversion of boiler fuel from kerosene to natural gas at the Onoda Plant. The Group is committed to continuing the proper management of chemical substances in its manufacture and research of pharmaceuticals, and will take effective initiatives to reduce the use of chemical substances and decrease emissions into the environment.

#### Emissions of PRTR Substances into Air



### Management of Air and Water Systems

The Group complies with all standards stipulated by the Air Pollution Control Law and Water Pollution Control Law as well as other regulations, and puts thorough measures to deal with incidents involving exhaust gas or wastewater drainage caused by the leakage of chemical substances from outdoor tanks or piping, so as to minimize the impact on the environment outside the facility where the accident occurs.

The Group strives to reduce water usage and reuse water at its plants and research centers, and is committed to taking biodiversity into account when discharging wastewater and to using water resources properly.



Environment

# Promotion of Environmental Communication

## Environmental and Social Contribution Activities

In striving to become a model corporate citizen, Mitsubishi Tanabe Pharma values interaction with the local community and engages in environmental and social activities with employees and their families.

### Greening of Office Surroundings and Nature Preservation Activities

Every year before the Osaka Marathon the Headquarters and Kashima Office participate in the Osaka Marathon Cleanup, conducting cleanup activities around worksites. Other worksites inside and outside Japan engage in greening and beautification around their sites.



November 2012  
Osaka Marathon Cleanup Campaign  
(Mitsubishi Tanabe Pharma headquarters)



November 2012  
Mitsubishi Tanabe Pharma Korea  
Hyangnam Plant

### Road Watering Event

In August 2012, the Tokyo Head Office held a "road watering" event using reclaimed wastewater provided by the Tokyo metropolitan government's Bureau of Sewerage, and wooden buckets and ladles borrowed from the ward, enjoying a cool moment with members of nearby companies and the neighborhood association.

The road watering reduced the surface temperature by 1.8 degrees Celsius, increasing awareness of how to live comfortably in an environmentally friendly manner, including mitigating the heat island effect and saving electricity.



Road watering event at the Tokyo Head Office

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

In November 2012, 66 Mitsubishi Tanabe Pharma Group employees and their families participated in the Ikoma Mountain Range "Folding Screen of Flowers" Project held by the Osaka Prefectural Government. The volunteers enjoyed a hike through autumnal woodlands near settlements, planted mountain cherry trees and helped thin cypress trees in Kurondo Park in Katano City. They also tried their hand at cutting logs and doing acorn crafts, allowing families with children to also enjoy themselves.

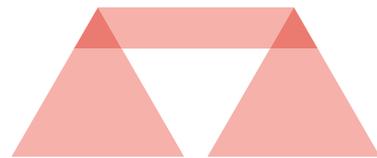


Ikoma Mountain Range "Folding Screen of Flowers" Project

### Environmental Education

The Group continues to provide education and training on the environment for new hires, e-learning programs for medical representatives, and training sessions on environmental compliance for employees in charge of environmental matters at plants and research centers. In fiscal 2012, it provided workshops for employees in charge of environmental matters at the Group's business sites on compliance with the revised Water Pollution Control Law. In July 2012, the Mitsubishi Tanabe Pharmaceutical Factory's Kashima Plant provided all employees with environmental education through an outside instructor on various topics such as countermeasures for environmental risk.

The Company also disseminates environmental information via different methods, including the use of its intranet to post changes in the amount of CO<sub>2</sub> generated and energy consumed at each worksite.



## Fair Operating Practices



**Shintaro Mimoto**

Kochi Sales Office,  
Sales and Marketing Division,  
Shikoku Branch

### Keeping compliance in mind while following good practice as a medical representative

So far I have worked as a medical representative (MR) in Ehime and Kochi prefectures in western Japan. Hoping to be of as much service as possible, I am committed to exchanging information with medical personnel who are working in community healthcare. While gaining deeper relationships of trust with healthcare providers, I take care to give sufficient attention to compliance. Sometimes there are cases in which I am unsure of the right decision, and at such times I always make sure to consult my boss, senior colleagues, or personnel in the compliance department.

On the annual Corporate Behavior Charter Day, everyone in the sales office reads through and signs the Compliance Guidebook. I feel that this exercise helps us share once again the importance of behaving properly as an MR. We also participate in periodic training in ethics, which gives us opportunities to learn the ethical norms that change with the times. It seems that the provision of medical information will become increasingly IT-based in the future, and so I would like to think about ethical standards and the give and take of informational programs in the new era.





Fair Operating Practices

# Fair Business Practices

## Initiatives for Fair Business Practices

The Mitsubishi Tanabe Pharma Group conducts its corporate activities with a fair and sincere attitude, exercises moderation, and strictly avoids any form of unethical behavior in order to contribute to sound social and economic development through fair competition in the market. For instance, the Group has established rules for compliance with antitrust legislation, to which it adheres in every area, from licensing and R&D to production, purchasing, product marketing, advertising, and promotion. In this way, the Group is committed to practicing fair and free competition and transactions.

All employees engaged in purchasing-related activities share in the main pillars of the Group's Compliance Code of Conduct for Purchasing Operations and always act with high ethical standards and social good sense.

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

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

The Group maintains a sound position in both its political stance and relationships with the government and shuns relationships with antisocial forces and organizations.

### Corporate Behavior Charter Card

**企業理念** 医薬品の創製を通じて、世界の人々の健康に貢献します

**めざす姿** 国際製薬企業として、社会から信頼される企業になります

**企業行動憲章**  
私たちは、一人ひとりが高い倫理観を持ち、公正かつ誠実であることをすべてに優先し、つぎのとおり行動します

田辺三菱製薬

Front

**使命感と誇り** 医薬品の創製に携わる者としての使命感と誇りを持ち、求められる医薬品の研究開発と製品の安全性・品質の確保に力を尽くします

**挑戦と革新** 鋭敏な感性と広い視野で進むべき方向性を見据え、より高い目標に果敢に挑戦し、革新的な価値を創出します

**信頼と協業** 自由闊達なコミュニケーションを通じて互いを理解・尊重し、深い信頼関係のもとで力を合わせ、成果の最大化を図ります

**社会との共生** 地域社会や地球環境に配慮した活動を通じ、社会との共生を図ります

田辺三菱製薬

Back

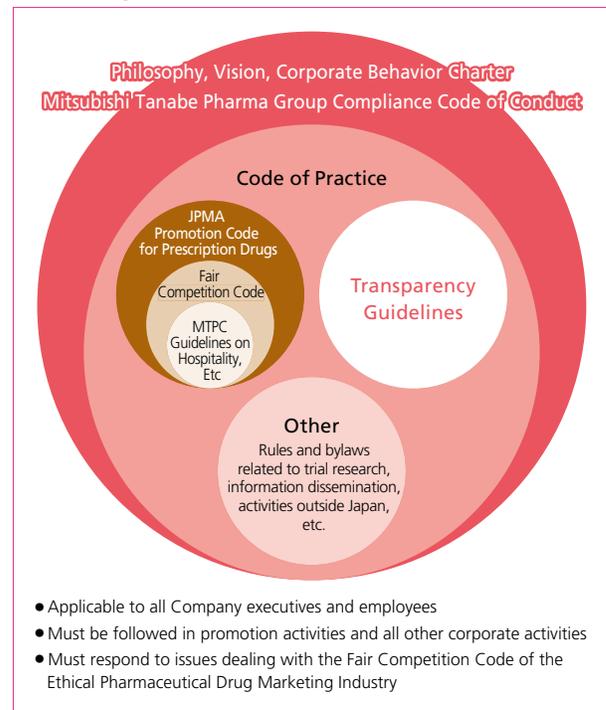
Corporate Behavior Charter Cards are distributed to all employees.

## Code of Practice

The Japan Pharmaceutical Manufacturers Association (JPMA), of which Mitsubishi Tanabe Pharma is a member company, established the JPMA Code of Practice in January 2013. This expanded upon the existing JPMA Promotion Code for Prescription Drugs to govern interactions between all of the executives and employees of the member companies with researchers, healthcare professionals, patient organizations, wholesalers, etc. This new code came into effect starting in April 2013.

In response, the Company established and put into effect in April 2013 the Mitsubishi Tanabe Pharma Corporation Code of Practice, which it developed based on its Philosophy, Vision, Corporate Behavior Charter, and the Mitsubishi Tanabe Pharma Group Compliance Code of Conduct. All executives and employees of the Company as well as its affiliated companies in Japan are required to follow this code not only in promotion endeavors designed for healthcare professionals, medical institutions, and others, but also in all other corporate activities. Of course, they are still expected to observe the JPMA Promotion Code for Prescription Drugs in all promotion activities intended for medical professionals and institutions.

### Positioning of the Code of Practice



# Fair Operating Practices Fair Business Practices

## Promotion Code

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“Promotion” in a pharmaceutical company does not mean sales promotion, as the term is generally used; rather, it is defined as the provision, collection, and transmission of information on the company’s own pharmaceuticals to and from healthcare professionals and the advancement of the proper use and spread of those pharmaceuticals based on that information. A “promotion code” is the explicitly written code of behavior and modality of promotion—the obligations that must be fulfilled as a matter of course and the moderation that naturally must be adhered to—when conducting promotion, as understood in terms of corporate ethics in the pharmaceutical industry.

The Mitsubishi Tanabe Pharma Group follows its Promotion Code in carrying out promotion activities aimed at advancing the proper use and spread of ethical drugs.

## Fair Competition Code of the Ethical Pharmaceutical Drugs Marketing Industry

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The pharmaceutical industry association has established the Fair Competition Code on Restrictions on Premium Offers in the Ethical Pharmaceutical Drugs Marketing Industry (hereafter the “Code”) with the aim of preventing unjust inducement of customers and ensuring autonomous and rational selection by general consumers as well as fair competition among businesses through restrictions on unjustifiable premiums. The Code has its legal basis in the Act against Unjustifiable Premiums and Misleading Representations. In addition to the Code, restrictions are in place on various matters relating to premium offers in the ethical pharmaceutical industry,



medical devices industry, and the clinical laboratories industry, based on Article 3 of the above act. The Code and these restrictions are mutually complementary. The ethical pharmaceutical industry restricts premium offers through the Code and sector-based restriction notifications.

The Mitsubishi Tanabe Pharma Group adheres strictly to the Code and other restrictions in order to practice fair medical information activities.



## Transparency Guidelines

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In March 2011, the Japan Pharmaceutical Manufacturers Association formulated and released the Transparency Guideline for the Relation between Corporate Activities and Medical Institutions, which addresses information disclosure for such matters as monetary payments from pharmaceutical companies to medical institutions. In response, in July 2011 the Company developed guidelines for transparency in relationships with medical institutions, etc. In accordance with these guidelines, from fiscal 2012 the Company will follow a policy of releasing related information on its website after the announcement of financial results for each fiscal year. This information includes payments from the Group to medical institutions as R&D expenses, support for academic research, manuscript writing fees, information provision related expenses, and hospitality and other expenses.

In regard to guidelines related to cooperation with patient organizations, the Company established on April 1, 2013 guidelines for transparency in such relationships as well as detailed rules. In accordance with these guidelines, from fiscal 2013, information regarding the funds and services provided to patient organizations will be disclosed on the Company’s website.



## Fair Operating Practices

### Rejecting Antisocial Forces and Checking Suppliers for Antisocial Affiliations

The Company's basic policy regarding corporate extortion, crime syndicates, and other antisocial forces is to shun all contact and cooperation with such groups. In the face of unreasonable demands, the Company will respond with a resolute stance that is unyielding and uncompromising.

The Company has also established a system for deciding whether to start transactions with new business partners by checking them for any possible affiliations with antisocial forces, including through the collection of information on the Internet and by other means. Moreover, the Company has established a code of conduct in which it avows that all executives and employees will adhere strictly to relevant laws and ordinances in all of their day-to-day business activities and act in accordance with social ethics.



### Protection of Intellectual Property

In line with its philosophy of contributing to the healthier lives of people around the world through the creation of pharmaceuticals, the Company files and maintains patents, trademarks, and other intellectual property rights, and prosecutes their infringement in order to protect its own pharmaceuticals. Furthermore, the Company respects third parties' valid intellectual property rights by managing intellectual property risks through investigations into the rights of third parties.

If a third party infringes upon the Company's intellectual property rights, the Company endeavors to strengthen legal protection and exploitation of intellectual property by taking appropriate legal action, while simultaneously establishing a framework that enable it to take such action quickly.



### Promoting CSR in the Supply Chain

The Mitsubishi Tanabe Pharma Group recognizes that a pharmaceutical company's duty is to provide pharmaceuticals to patients when they are needed. To fulfill this duty, it has been carrying out the following:

#### **Establishment of a solid supply chain**

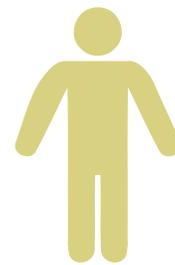
Conducting business with companies in good standing reduces the frequency of problems and minimizes the damage should any complications actually occur. The Company uses a CSR questionnaire and a supplier questionnaire concerning raw materials for evaluation and improvement in supply.

#### **Fair, impartial, and transparent supplier selection**

The level of a raw material manufacturer's quality assurance, technical capabilities, customer focus (readiness to respond flexibly), and management capabilities (continuity) are all important in procuring raw materials for pharmaceuticals. To evaluate these capabilities, the Company visits manufacturing sites for confirmation.

#### **Establishment of a BCM system**

The Company has established a business continuity management (BCM) system through the development of various rules concerning inventory management standards and information cooperation standards. It has built a system for the stable supply of pharmaceuticals so that it can securely deliver drugs to patients, even in the event of a disaster or other unforeseen problem.



## Consumer Issues



**Hiroyuki Taniguchi**

Department I, Pharmacological  
Research Laboratories II  
Research Division

### Bringing smiles to patients' faces—that is the motivating force behind our research

Our goal is to provide pharmaceuticals that have true value for patients. A deep understanding of the current state of medical care is needed to create pharmaceuticals that meet unmet medical needs. That is why we work together with sales personnel who are in daily contact with doctors, in order to listen to voices from the medical front and make use of them in our research. It is also important to understand the future, including upcoming global progress in medicine-related governmental policies and technology as well as political and economic trends, since it takes a very long time going through numerous clinical trials until a pharmaceutical is actually put on the market.

Many challenges are faced on the long road to a product launch, but the joy is all the bigger when those challenges are resolved thanks to everyone's efforts to overcome difficulties through companywide cross-department cooperation. After a product has been launched, researchers make sure to communicate to sales personnel the feelings put into that pharmaceutical to share the same feelings with them. We engage in our research work day in and day out with passion and in close cooperation with our colleagues so that patients can get their smiles back.

# Research & Development— Contributing to Healthier Lives for People around the World

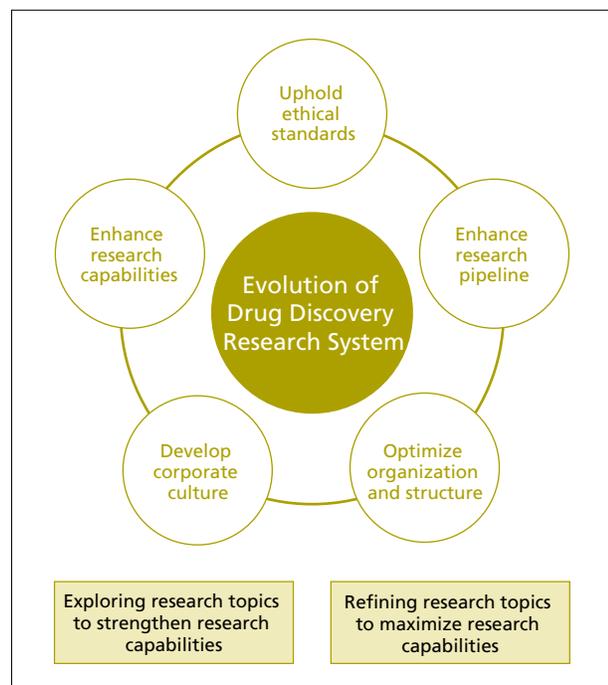


## Basic Approach to Discovery Research

Starting from its philosophy of “contributing to the healthier lives of people around the world through the creation of pharmaceuticals,” Mitsubishi Tanabe Pharma aims to explore research topics and enhance its development capabilities, in order to create new drugs that can meet unmet medical needs. That is why the Company enhances the drug discovery foundations of its research centers and implements optimal guidelines for research projects, including portfolio and resource allocation.

The Company also actively trail-blazes new research fields and pursues the acquisition of new drug discovery technology through cooperation with academic institutions and venture firms. These actions help build an R&D pipeline that will translate into the creation of future growth drivers. Moreover, the Company also actively participates in teamwork within the Mitsubishi Chemical Holdings (MCHC) Group, cooperating with other MCHC Group companies to tackle technical challenges. Mitsubishi Tanabe Pharma is committed to enhancing its R&D capabilities and developing a corporate culture that shares high ethical standards and values, creating new drugs and continuing to create new value.

## Evolution of Drug Discovery Research System



## New Drug Development in the Diabetes Field

In September 2012, the Company launched Tenelia, a treatment for type 2 diabetes mellitus. Then, in February 2013, the Company filed an application to partially change the drug’s efficacy based on a new combined therapy treatment with blood sugar lowering agents. Tenelia is the first DPP-4 inhibitor to originate in Japan. It improves blood sugar levels after every meal and when the stomach is empty, with a once-daily oral administration. Tenelia is eliminated from the body via two routes—through the kidneys and the liver.

In May 2013, the Company applied with the Ministry of Health, Labour and Welfare for manufacturing and marketing approval of TA-7284 for the treatment of type 2 diabetes mellitus. By inhibiting SGLT2, which is involved in glucose reabsorption in the tubules of the kidney, TA-7284 controls glucose reabsorption and promotes the excretion of excess glucose in urine, thereby improving blood sugar control. In the US, the product received approval in March 2013 as a treatment for adult type 2 diabetes mellitus through its licensee, Janssen Pharmaceuticals, Inc., which has started marketing it under the product name INVOKANA™.

By offering new options in the treatment of type 2 diabetes mellitus through the use of Tenelia and TA-7284, Mitsubishi Tanabe Pharma hopes to make a greater contribution to patients who are fighting diabetes.

## Spurring New Drug Development through Industry-University Collaboration

In April 2013, Mitsubishi Tanabe Pharma established a course in practical drug discovery science as an industry-academia cooperation research project in the Graduate School of Pharmaceutical Sciences at Nagoya University.

In this way, the Company will carry out drug discovery in an academic research environment and, by posting two of its employees as a specially appointed professor and associate professor for the course, it is making an effort to nurture researchers who have advanced research capabilities and who will lead drug discovery research from a different perspective.

Through this cooperative effort the Company and the Graduate School of Nagoya University aim to use drug industry know-how to translate the outcomes of basic research in the university into practical applications, creating innovative new drugs from groundbreaking drug discovery targets.



# Consumer Issues

## Manufacturing and Supply Chain—Reliably Delivering Pharmaceuticals

### Pharmaceutical Manufacturing Process

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

The Mitsubishi Tanabe Pharma Group's global manufacturing system is made up of 10 production plants in Japan and five outside the country, as well as subcontracted manufacturers that deliver the products worldwide.

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

### Measures to Prevent Medical Malpractice

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

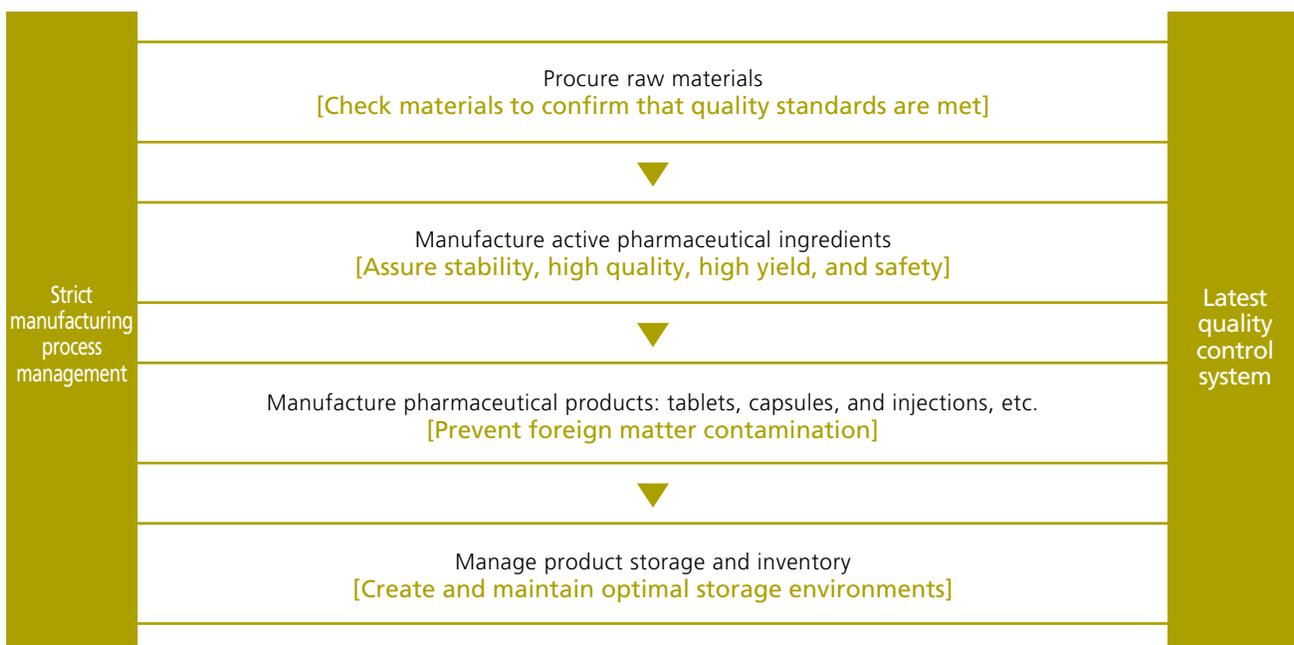
In an effort to guard against mistakes involving its products, Mitsubishi Tanabe Pharma has been modifying the brand names of its pharmaceuticals to make them easier to understand. Thus the brand names shown on the packaging for two medications marketed in Japan—oral spinocerebellar degeneration treatment Ceredist and

selective  $\beta_1$  antagonist Maintate—have been improved. In addition, there is now a clearer description of active pharmaceutical ingredients in each tablet unit dose.



Anplag tablets with the product name displayed

### Process from Raw Materials to Pharmaceutical Product





## Manufacturing System in Asia

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

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

The Group is also making efforts to comply with the GMP standards in countries throughout Asia. As a result of these efforts, in October 2011, Tianjin Tanabe Seiyaku Co., Ltd. became the first pharmaceutical company in Tianjin city to be certified under China's new GMP standards. The Mitsubishi Tanabe Pharma Group will make necessary investments to consistently and continuously improve the quality of its pharmaceuticals and ensure their stable supply.

## Managing Distribution to Ensure Stable Supplies

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

The Company has developed a dual-base delivery system featuring two Distribution Centers, which handle the shipping of the Company's pharmaceuticals to the market, one to eastern and one to western Japan. This ensures that even in an emergency in which one Distribution Center could become inoperable, such as due to a natural disaster, the remaining center will be able to provide backup for a stable supply of pharmaceuticals.

Each Distribution Center employs an inventory control system that carefully monitors product stocks and shelving and picking work down to individual lots. Under this warehouse management system, the Company is able to accurately control the diverse products it handles, ranging from medical pharmaceuticals and healthcare products to generic drugs and cold storage products. The system also enables efficient work without operational or shipping errors in the instruction data,

such as shipping instructions from the host system.

Additionally, the Company has developed manuals for all work procedures in the Distribution Centers, which it uses to provide regular employee training. In this way it makes an effort to raise employee awareness of the importance of pharmaceutical distribution and to maintain a stable supply by handling products responsibly.

## Quality Control in the Distribution Process

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

The Company works to maintain both the operational and physical aspects of distribution quality. While complying with the building and facility requirements under the Pharmaceutical Affairs Law of Japan and other relevant regulations as well as various operational requirements, Mitsubishi Tanabe Pharma's distribution policies and procedure manuals are designed in light of the features of the products it handles. The Company is particularly vigilant about regulating the temperature at which cold storage products are stored. In addition to measures such as periodic temperature validation and thermometer calibration in cold warehouses, the Company has designed a system that maintains product storage at a constant temperature, 24 hours a day, seven days a week. The system also has emergency response measures in place, including in-house power generators that can be used when electricity is interrupted, as well as a process that provides information when abnormal or emergency conditions are detected.

Mitsubishi Tanabe Pharma designed its entire transportation system with the focus on supplying high-quality pharmaceuticals. Products are shipped from the Distribution Centers via contracted transport companies that are in compliance with pre-determined qualifications. With an understanding of the importance of the pharmaceuticals that they are carrying, these companies strictly supervise the transport of this cargo, utilizing facilities and vehicles specifically designed for loading and unloading pharmaceuticals. The Company works to maintain quality during the distribution process by carrying out periodic inspections of its subcontracting transport companies, as well as using a comprehensive distribution method with precise temperature control validation and special insulated boxes for packing the products.



# Consumer Issues

## Information Provision—Providing Needed Pharmaceutical Information

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

The Mitsubishi Tanabe Pharma Group employs about 2,200 general and specialized medical representatives (MRs) in Japan. These MRs work each day to supply medical institutions throughout the country with scientific information concerning the benefits of Mitsubishi Tanabe Pharma's products, as well as their possible side effects, in order to ensure that the products are used appropriately. The Group's representatives are also responsible for collecting data on the efficacy and safety of the drugs at the usage stage—information that could not be gleaned during R&D—and providing medical professionals with data-based evaluations. Specialized MRs are responsible for products that require a high level of knowledge about specific illnesses and drug treatments. General MRs, on the other hand, cooperate with specialized MRs to provide quality information services based on the needs of medical professionals.

### Providing Comprehensive Information through Seminars

In November 2012, Mitsubishi Tanabe Pharma co-sponsored the Nikkei Health Seminar 21 held by newspaper publisher Nikkei Inc. In coordination with the National Health Promotion Movement in the 21st Century (Healthy Japan 21) promoted by the Ministry of Health, Labour and Welfare of Japan, the purpose of this educational seminar was to help prevent lifestyle diseases and other illnesses. The seminar featured a keynote speech and a panel discussion on influenza prevention and treatment. Mitsubishi Tanabe Pharma expects that promoting understanding of illnesses among the general public through this seminar to raise interest in general health issues is key to early detection and prevention. It is committed to sponsoring seminars as one of many ways in which it can provide comprehensive information on the diseases and illnesses that its products have been developed to treat.



Nikkei Health Seminar 21

### Supporting Proper Self-Medication for Skin Problems

Mitsubishi Tanabe Pharma believes it is important to help people suffering from dermatological problems to obtain accurate information and find a treatment as quickly as possible. Toward this end, it has been conducting a variety of educational programs in Japan since fiscal 2009 designed to motivate people to consider how to treat one's own skin problems. These initiatives include TV commercials and



Mitsubishi Tanabe Pharma's website on dermatological issues

website content that explain the causes, symptoms, and treatment of skin problems.

### Providing Information on Generic Drugs in Japan

Mitsubishi Tanabe Pharma applies the same strict quality control system and extensive distribution network that it has developed for its traditional brand-name drug businesses to generic drugs as well. Under the slogan "Reliable generics," the Company provides high-quality generic drugs in Japan through Tanabe Seiyaku Hanbai Co., Ltd., a Mitsubishi Tanabe Pharma Group company. Tanabe Seiyaku Hanbai employs MRs with extensive experience and knowledge in generic drugs so that patients can expect to receive comprehensive information regarding the Company's generic pharmaceuticals and the assurance that these drugs can be relied upon.

### Sales Efforts outside Japan

To ensure that its drugs are used properly around the world, Mitsubishi Tanabe Pharma strives to collect and provide its product information outside Japan through its overseas subsidiaries.

The Group has sales offices in the UK and Germany in Europe, and in China, South Korea, Taiwan, and Indonesia in Asia. The Group provides the MRs working in these countries with periodic training to improve their ability to provide comprehensive information.



## Providing Information through Websites

Mitsubishi Tanabe Pharma has set up health support websites in Japanese to provide clear explanations to patients and their families on subjects such as vaccines, as well as a number of different conditions and their symptoms, diagnoses, and treatment. These include rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriasis, Behcet's disease, cerebral infarction, liver failure, multiple sclerosis, spinocerebellar degeneration and



Health support website

multiple system atrophy (MSA), chronic kidney disease, sleep disorders, and hemorrhoids.

## Providing Comprehensive Information through the Medical Information Center

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

The center also plays a vital role in ensuring the reliability of the Company's products by accurately glean safety and quality information, including side effects, from the content of inquiries and relaying that information to the relevant Mitsubishi Tanabe Pharma department as feedback to be addressed.

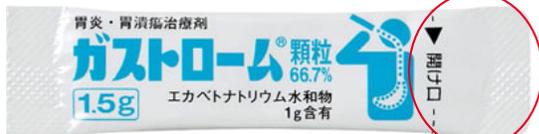
Receiving over 85,000 calls a year, the Medical Information Center staff helps ensure that the Company's products are used appropriately by sharing objective facts and data taken from drug approval documents and scientific evidence.

### Calls to the Medical Information Center improve products: A Case Study

Original packaging



Improved packaging

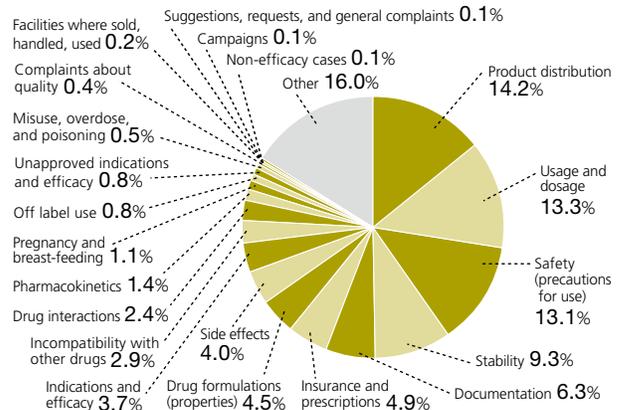


Easier to grasp when opening

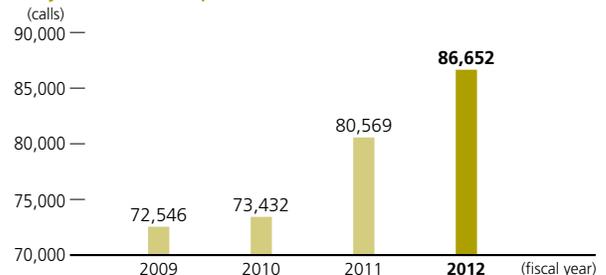
In 2010, the original transparent, flat envelopes for Gastro-Room, a Mitsubishi Tanabe Pharma drug for treating gastritis and gastric ulcers that is dispensed at clinics in granular form, were replaced with cylindrical, stick-type packets. Afterward, the staff at the Medical Information Center began logging calls from patients with complaints that the packages were difficult to open. The MRs received similar complaints at the medical facilities they visited, and the Company took action to remedy the situation.

Mitsubishi Tanabe Pharma's packaging planning, plant, formulation research, and other departments studied the issue and finally changed the location where the package is opened, making it easier to handle.

### Subject of Inquiries to Medical Information Center



### Yearly Increase in Inquiries to the Medical Information Center





# Consumer Issues

## Reliability Assurance—Ensuring Users Are Able to Trust in the Reliability of Mitsubishi Tanabe Pharma’s Drugs

### System to Assure the Reliability of Drugs

Mitsubishi Tanabe Pharma’s drugs must remain effective, safe and of high quality throughout their lifecycles, in order ensure that healthcare professionals and patients alike are able to trust in their reliability. One of the objectives of the Pharmaceutical Affairs Law of Japan is to ensure the efficacy, quality, and safety of pharmaceuticals. “Good practice” guidelines and regulations (GLP, GCP, GMP, GVP, GPSP) have been established based on laws to guarantee reliability. The Group complies with these laws and regulations in order to maintain the three important factors of efficacy, quality and safety. The supervisory units, namely clinical and research QA and product QA sections, provide objective appraisals of the Group’s compliance with these regulations. The Pharmaceutical Affairs Law is expected to be amended in the next fiscal year, and a new system for ensuring safety will be introduced. The Group will not only comply with the revised legislation but will also meet requests from society in an effort to establish an optimal reliability assurance system.

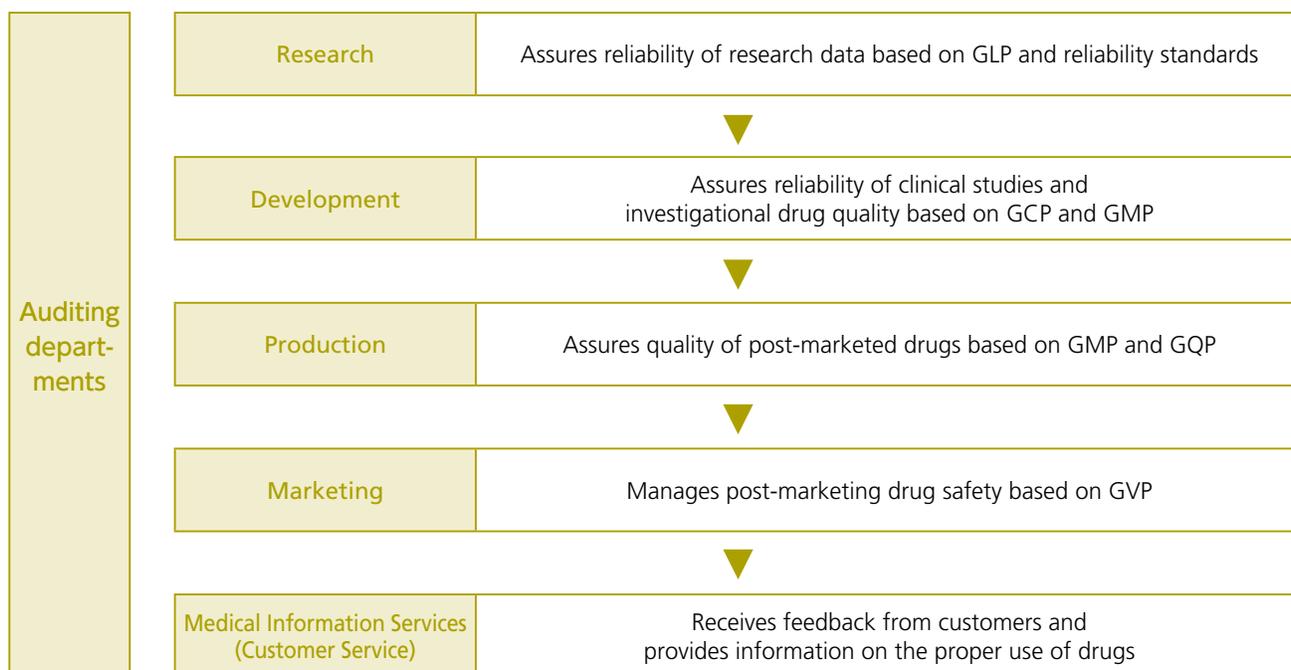
### Safety Measures for New Drugs

It is unavoidable that after a new drug is put on the market, a number of side effects will appear that were not noticed during clinical trials. It is an extremely important safety measure to identify these issues as soon as possible, analyze the data, and feed the results back to the medical front. The feedback of information makes it possible to prevent adverse reactions and reduce complications.

Telavic, which the Company launched in 2011 and is used by many patients, is a promising chronic hepatitis C treatment with a new mechanism of action. After Telavic was launched, however, many cases of impaired renal function appeared as an adverse reaction. The Company quickly analyzed the data in an effort to detect risk factors that could lead to renal dysfunction. Additionally, the Company revised the package inserts based on this information, prepared a notification, and provided medical institutions with detailed case studies and analytical results. This series of efforts resulted in a decrease in the development of impaired renal function.

Going forward, Mitsubishi Tanabe Pharma will continue to provide comprehensive information, in order to minimize product risks while maximizing benefits.

### System to Assure the Reliability of Drugs



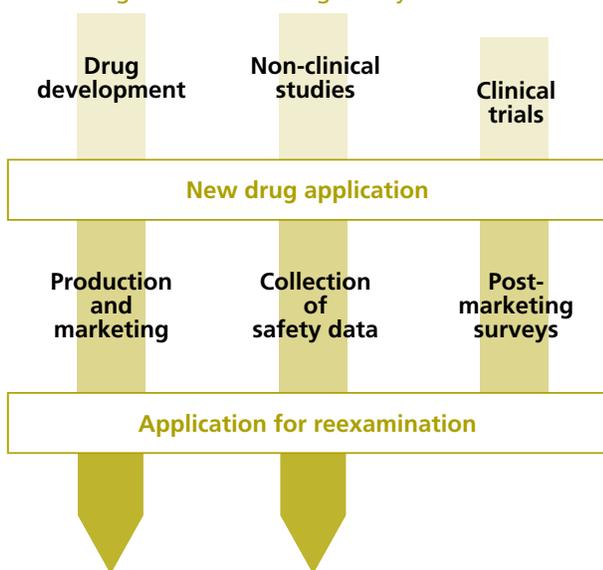


## Post-Marketing Surveys

The marketing of pharmaceuticals in Japan begins only after obtaining manufacturing and marketing approval from the Ministry of Health, Labour and Welfare based on the results of rigorous clinical trials concerning efficacy and safety. However, the process through manufacturing and marketing approval yields limited data, since clinical trials are conducted with only a small number of cases, the ages and conditions of patients are restricted, and the drugs being investigated are not used on children, expectant and nursing women or people with serious medical problems, such as diseases of the liver or kidney.

Accordingly, Mitsubishi Tanabe Pharma conducts post-marketing surveys, collecting data on thousands of cases, which it uses to precisely clarify the safety and efficacy profiles of its pharmaceuticals and to encourage their effective and safe use, thereby helping to prevent the onset of adverse reactions.

### Positioning of Post-marketing Surveys



## Quality Assurance for Pharmaceuticals

Mitsubishi Tanabe Pharma maintains product quality in accordance with government regulations on GMP for regulating drug manufacturing and on GQP for regulating the quality of drugs. In accordance with its Quality Policy—the highest priority of which is patient safety—the Company rigorously supervises, audits, and directs its factories in Japan and overseas and handles any quality issues that may arise, in an effort to ensure the quality of its products. For

example, the Company strives to increase quality through the establishment of quality targets and the implementation of quality assurance plans. In addition, aiming to unify its quality assurance standards on a global basis, the Group has established quality assurance standards for Mitsubishi Tanabe Pharma and all manufacturing bases in the Group.

Mitsubishi Tanabe Pharma is sensitive to feedback from the front lines, and the Company calls on nurses and pharmacists to hear how its products are being used and under what conditions. It then works to reflect that feedback in its quality improvement initiatives.

Mitsubishi Tanabe Pharma will continue to implement measures to prevent a recurrence of past problems and related quality control issues, as well as business improvement measures. Moving forward, the Company will make every effort to manufacture high-quality pharmaceuticals that can be used with complete reassurance and peace of mind.

## Top Management Seminars

As a measure to prevent recurrence of problems similar to an incident in Japan involving HIV-tainted blood products and quality control problems, the Group holds top management seminars for all Mitsubishi Tanabe Pharma directors and executive officers, as well as the presidents and management teams at Group companies engaged in the pharmaceutical business.

In the 2011 fiscal year, the Group held a training session on “Drug Safety Measures—Current Issues and the Role Companies are Expected to Play” with an invited expert in regulatory science. The guest speaker presented a look back at past pharmaceutical safety problems and examined current issues through a reconsideration of safety problems in companies, including the relationship between pharmaceuticals and society and the healthcare environment.



Top management seminar



## Community Involvement and Development



**Yoko Takahashi**  
President, Japan Philanthropic Association

### Helping individuals enjoy life and live their dreams

In setting up its Tenohira Partnership Program, Mitsubishi Tanabe Pharma commissioned the Japan Philanthropic Association to handle program administration and screen organizations considered for support. The Tenohira Partnership Program embodies the guiding values of the Mitsubishi Tanabe Pharma Corporate Behavior Charter—Pride and Sense of Mission, Challenge and Innovation, Trust and Teamwork, and Harmonious Coexistence with Society. At the Japan Philanthropic Association, we share Mitsubishi Tanabe Pharma's goal of helping improve the quality of life of individuals struggling with disease. We are looking to broaden our impact, and hope, with your help, to develop this program into one that brings warmth and lends strength to these patients and their families.

The screening process for the Tenohira Partnership Program has shown me just how many people are battling disease, while hoping for the development of new methods of treatment and the discovery of new drugs. A patient's life is not solely defined by his or her battle with disease. His or her life is filled with the same irreplaceable moments as anyone else. I hope this program will bring support to both these individuals, and to their friends and family members, to help them enjoy their lives and live their dreams and realize their hopes for the future.



# Social Contribution Activities

## Establishment of the Declaration on Corporate Citizenship

The Mitsubishi Tanabe Pharma Group aims to contribute to the healthier lives of people around the world through creation of pharmaceuticals as a global, research-driven pharmaceutical company that is trusted by communities. In its Corporate Behavior Charter, the Group declares its commitment to achieving harmonious coexistence with society by acting with consideration for local communities and the environment. The Mitsubishi Tanabe Pharma Group Declaration on Corporate Citizenship was formulated to further clarify the Group's philosophy in these respects. The Group will continue to proactively develop corporate citizenship activities that contribute to the attainment of a society that is sustainable, healthy, and comfortable.

### Mitsubishi Tanabe Pharma Group Declaration on Corporate Citizenship

The Mitsubishi Tanabe Pharma Group will strive to contribute to society through its pharmaceutical operations in accordance with its Philosophy, Vision, and Corporate Behavior Charter. In addition, as a good corporate citizen, the Mitsubishi Tanabe Pharma Group will proactively implement the following activities to contribute to the resolution of problems related to health and living environments in the countries and regions where the Group conducts business.

#### Activities to Contribute to the Resolution of Problems Related to Health and Living Environments

1. Activities to promote medical research and nurture human resources
2. Activities to help patients and families find more joy and satisfaction in their lives
3. Activities to improve health and welfare in developing countries
4. Activities to energize communities and develop more comfortable living environments
5. Other activities

## Overview of New Programs

Supporting Fun Activities for Patients and Families

### Support for CP Soccer (soccer played by seven people with cerebral palsy)

Played by teams of seven people with physical disabilities caused by cerebral palsy, head trauma or other conditions, CP soccer is an official event in the Paralympics. The Mitsubishi Tanabe Pharma Group donates funds to the Yodogawa Ward Social Welfare Council of Osaka City to help support the passion these athletes have for playing on Osaka PAZ, the CP soccer team in Osaka, as well as to promote interaction among local residents irrespective of their physical abilities and disabilities.



Mitsubishi Tanabe Pharma made available the soccer pitch at Kashima Office and also provided monetary support for the Oba Cup, a CP soccer tournament.

## Establishing the Mitsubishi Tanabe Pharma Tenohira Partnership Program

Despite the enormous efforts of pharmaceutical companies throughout the world to develop needed drugs, a large number of serious diseases remain incurable. As a pharmaceutical company, Mitsubishi Tanabe Pharma works to discover new drugs that will treat these diseases. At the same time, the Company also views providing support for patients struggling with disease and their families as an important mission. To mark its fifth anniversary in 2012, Mitsubishi Tanabe Pharma established the Tenohira Partnership Program, under which the Company provides support for the activities of associations of patients with incurable diseases. The Company has begun to fund selected patient associations and support groups for patients with incurable diseases that seek to improve quality of life for patients with these diseases through improvements in medical treatment and working conditions.

In order to ensure transparency and fairness, a Screening Committee made up of outside experts has been established outside of the company to handle the screening and selection of organizations to receive funds, with administrative support provided by the Japan Philanthropic Association, a non-profit organization.



# Community Involvement and Development

## Social Contribution Activities

### Online Seminars for Patients

In January 2013, Mitsubishi Tanabe Pharma co-sponsored a Radio Nikkei online patient seminar on psoriasis entitled "I want to know! Psoriasis—Proper treatment for a better life." This live online broadcast from Radio Nikkei featured three dermatologists. The Company worked with the Psoriasis Patients Association in Tokyo (P-PAT) to attract audience participants. On the day of the live broadcast, the seminar attracted approximately 500 website hits.

One P-PAT member in the audience that day expressed satisfaction, saying, "It's a wonderful time we live in when we are able to listen to experts speak from the comfort of our own homes. This was a very valuable experience for our patient association."

Radio Nikkei broadcast excerpts of the seminar over the radio in February 2013 and made on-demand streaming of the seminar available on the official Radio Nikkei website, as well.



Psoriasis online seminar

### Supporting Research through Foundations

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

#### Grants of the Mitsubishi Pharma Research Foundation in Fiscal 2012

Grants for pharmacotherapy research	Basic research	24 projects	24 million yen
	Aid for young researchers	10 projects	10 million yen
	Financial aid for education abroad	3 projects	6 million yen
Grants for hematology research	Basic research	24 projects	24 million yen
	Aid for young researchers	10 projects	10 million yen
	Financial aid for education abroad	3 projects	6 million yen
Grants for cardiovascular medicine research	Basic research	24 projects	24 million yen
	Aid for young researchers	10 projects	10 million yen
	Financial aid for education abroad	3 projects	6 million yen
Special projects		1 project	10 million yen
Grants for research that supports disaster-stricken areas	Pharmacotherapy	2 projects	3 million yen
	Cardiovascular medicine	2 projects	3 million yen
<b>Total</b>		<b>116 projects</b>	<b>136 million yen</b>

#### Grants of the Japan Foundation for Applied Enzymology in Fiscal 2012

Grants for enzyme research	Applied research on enzymes and enzyme research related to life science	30 projects	22.5 million yen
	The Japanese Society of Applied Glycoscience	1 project	300,000 yen
Grants for specific groups and activities	Research groups focused on determining causes and conditions of adult onset diseases	45 projects	14.95 million yen
	Vascular Biology Innovation Conference	22 projects	10.5 million yen
	Research groups focused on determining causes and conditions of systemic inflammation	7 projects	7 million yen
	Front Runner of Future Diabetes Research Conference	16 projects	8 million yen
<b>Total</b>		<b>121 projects</b>	<b>63.25 million yen</b>



## MSC Volunteer Salon

Mitsubishi Tanabe Pharma holds the MSC Volunteer Salon to offer those interested in volunteer activities an opportunity to interact with others of a similar mind. An acronym for "makers, sellers, and consumers," MSC focuses primarily on bimonthly Volunteer Salons in which participants have a chance to talk directly with guest speakers. These salons include presentations and discussions of the activities conducted by various volunteer groups, talks on useful topics for daily life, music, and health campaigns.

The MSC Volunteer Salon also collects donations of



Audience listens to a speaker at a Volunteer Salon.

used postal stamps and telephone cards. The salon administrative office presents them to welfare groups and other organizations in Japan to support the administration of these facilities.

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

As part of its social contribution activities, Mitsubishi Tanabe Pharma has been donating over-the-counter (OTC) medicines to Kodomo-no-kuni (Children's Land) for 41 years. This park in Yokohama City, Kanagawa Prefecture is operated by the Association of Kodomo-no-kuni. The Company made its latest donation in June 2012.

On the day the donation was made, Park Director Katsuhide Yasuzawa expressed his appreciation, saying, "Many children visited the park in the spring for school trips and other outings. As we move toward summer and open



Donating OTC drugs

the park pool, we will receive visitors of all ages, not only children. I know these donated medicines will be extremely helpful to children who need them."

## Local Events Held by Mitsubishi Tanabe Pharma Plants

Mitsubishi Tanabe Pharma Group plants and offices hold local events to encourage positive interaction and communication with local communities.

In August 2012, the Mitsubishi Tanabe Pharma plant in Yoshitomi Town sponsored the 39<sup>th</sup> Yoshitomi Summer Festival, an event that takes place in August each year. The more than 2,000 people in attendance included local residents, employees, and their family members. The day was filled with stage performances of summer Obon dances by neighborhood children's associations, Shinto music and dances, and popular songs by local singers. The event's grand finale, a massive fireworks display, was greeted by fervent cheers and applause from festival goers.

The Mitsubishi Tanabe Pharma plant in Ashikaga held the 6<sup>th</sup> Ashikaga Festival on the plant premises in August 2012. The venue was packed with more than 1,000 festival-goers, including many local residents. Many office employees worked the food and drink booths, giving them a great opportunity to interact more closely with neighborhood residents. Performing on a stage set up just for the occasion, local drum groups and employee bands were greeted by thunderous applause from the audience.



Yoshitomi Summer Festival



Ashikaga Festival

# Independent Verification Report

## Independent Verification Report

To: Mitsubishi Tanabe Pharma Corporation



BUREAU  
VERITAS

July 19, 2013

Bureau Veritas Japan Co., Ltd.  
System Certification Services Headquarters



### Objective of verification

Bureau Veritas Japan Co., Ltd. (Bureau Veritas) has evaluated the environmental performance data for the Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe Pharma) CSR Report 2013, (the Report), covering the Fiscal Year 2012. The Report is issued under the responsibility of Mitsubishi Tanabe Pharma. Bureau Veritas' responsibility is to provide independent verification of environmental performance data, based on objective evidence.

### Scope of work

Bureau Veritas verified the environmental performance data for the reporting period April 2012 to March 2013.

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

Mitsubishi Tanabe Pharma Corporation Head Office:	Administration
Mitsubishi Tanabe Pharma Corporation Kazusa Site	Research of pharmaceuticals
Mitsubishi Tanabe Pharma Factory Ltd. Kashima Site	Manufacture of pharmaceuticals
Mitsubishi Tanabe Pharma Factory Ltd. Onoda Site	Manufacture of pharmaceuticals

### Verification Methodology

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

#### Head Office

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

#### Research and manufacturing sites

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

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

### Verification findings

Key findings:

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

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



# Third-Party Opinion

## Evaluation of the Mitsubishi Tanabe Pharma CSR Report 2013

### Overall Approach

In a departure from the usual format, Mitsubishi Tanabe Pharma has organized its CSR Report 2013 according to the ISO26000 seven core subjects of social responsibility for businesses and organizations: organizational governance, human rights, labor practices, the environment, fair operating practices, consumer issues, and community involvement and development. Developed through a multi-stakeholder process, ISO26000 is considered the international standard that most broadly reflects the demands of global stakeholders. This format suggests a sincere and earnest approach to addressing stakeholder needs and demands, and I commend Mitsubishi Tanabe Pharma for introducing this new approach.

It is also important that Mitsubishi Tanabe Pharma distinguishes its own CSR approach from that of other companies and that the Company focus on areas that have the greatest impact. In its Annual Report 2013, the Company emphasizes its view that it does "not need to compete through the same means [as other companies]... the principles of selection and concentration are [more] important." While I may be asking too much of the CSR Report 2013, which provides detailed explanations for each core subject, I would like to see Mitsubishi Tanabe Pharma reconcile the conflicting demands of diverse stakeholder needs and selection/concentration practices, and to find a way of conveying these choices. I suggest this because I believe that CSR is an important means of remaining true to one's own corporate values while navigating the complicated interplay of values in the global community. This is an extremely difficult, but important, task.

### Core Subjects

Mitsubishi Tanabe Pharma has been an industry leader in the area of the environment, adopting environmental measures early on. This early adoption has generated a great deal of environmental awareness among employees, as well as successful efforts to reduce waste. The Company has for all intents and purposes achieved its waste reduction target of zero emissions. The data in this report should, therefore, be read with the understanding that, having so significantly reduced waste already, it will be difficult for the Company to achieve further reductions. The Company's bold Medium-Term Environmental Action Plan (2011-2015) calling for a 30% reduction in CO<sub>2</sub> emissions over fiscal 2005 by fiscal 2015 was admirable enough, but it is even more astonishing that Mitsubishi Tanabe Pharma has already achieved a 36.3% reduction by the year under review, fiscal 2012. In addition, in view of the Company's disclosure of environment-related trouble, the sincerity of its approach to information disclosure cannot be called into question.

In terms of promoting diversity, particularly with regard to the proportion of women in senior management, Japanese companies consistently rank at the bottom of developed countries in international surveys. This is clearly an area of weakness for the Japanese business community. Although Mitsubishi Tanabe Pharma's initiatives are among the best in Japan, the Company's commitment to diversity would appear to fall short in comparison with non-Japanese corporations. Diversity in the workplace is the first step toward a multi-faceted understanding of the larger society, as well as a useful tool for building a corporate culture

that maximizes the value of each individual's work.

With regard to community involvement and development, Mitsubishi Tanabe Pharma pledges to contribute to the health of people around the world as a global, research-driven pharmaceutical company. This, however, is something that a single company cannot possibly accomplish on its own. It is incumbent on Mitsubishi Tanabe Pharma to utilize the expertise and skills of international organizations, NGOs, and patient groups by working in coordination with a broad spectrum of stakeholders. The CSR Report 2013 details the programs based on its Corporate Citizenship Charter and support for associations of patients with incurable diseases that the Company has begun implementing and indicates just how extensive these activities are.

### CSR Research

Last year, I analyzed information disclosure in the CSR reports of Japanese companies with regard to the seven core subjects and 37 secondary issues addressed by ISO26000. Although Japanese companies generally disclosed an extensive amount of information related to the environment, only about half of these companies disclosed information related to fair operating practices and community involvement and development. In my research, however, Mitsubishi Tanabe Pharma averaged more than 10 points better on the 37 topics for both the proportional and the quantitative disclosure surveys. With its new ISO26000-oriented format, the CSR Report 2013 is even more outstanding, providing more comprehensive disclosure and a greater quantity of information regarding human rights, fair operating practices, and community involvement and development.

In my research to date, I have found that, while corporate value falls as the risk of CO<sub>2</sub> emissions and soil pollution rises, the value of a company increases with the implementation of risk reduction activities and improvements in the transparency of information disclosure. "Value" is a key word highlighted throughout Mitsubishi Tanabe Pharma reports, which incorporate phrases such as "new value creation," "continuous value creation," and "maximizing corporate value." I would hope that Mitsubishi Tanabe Pharma initiatives, with their emphasis on the concept of value, would in fact lead to greater corporate value.

My latest research indicates that companies with long histories of successful sustainability generate stable profits, consistently contribute to society by distributing added value, and operate under management systems that have achieved symbiosis with stakeholders. As the global pharmaceutical market continues to expand, the Japanese pharmaceutical market will account for an accordingly smaller percentage of the global market, an issue addressed by Mitsubishi Tanabe Pharma addresses in its Annual Report. The Company has consistently contributed to society throughout its history and will undoubtedly draw on its established conscientious approach to CSR moving forward. I look forward to seeing how the Company's next move plays out and the next dynamic step the Company takes.

### Chika Saka, D.C.S.

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#### profile

Currently a member of the Science Council of Japan and The Environment Council of Osaka Prefectural Government and director of The Japan Corporate Social Accounting and Reporting Association. Author of *Theory of Environmental Accounting* (published by Tokyo Economic Information Publishing).



# Explanation of Terms

## Appropriate use of pharmaceuticals

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

## Clinical trials

Tests in which pharmaceuticals believed to have medical value are administered to patients as well as healthy subjects in order to determine their efficacy and side effects.

## E learning

A learning system conducted by means of electronic media including the PC and Internet.

## Generic drugs

Drugs that are marketed after the new drug patent expires. They have the same active ingredients in the same amounts as the new drug and have the same clinical efficacy.

## Good Clinical Practice (GCP)

Standards that govern how clinical trials for drugs should be conducted.

## Good Laboratory Practice (GLP)

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

## Good Manufacturing Practice (GMP)

Standards governing the production and quality of pharmaceutical and quasi-drug products.

## Good Post-marketing Study Practice (GPSP)

Standards for conducting post-marketing surveys and tests for pharmaceuticals.

## Good Quality Practice (GQP)

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

## Good Vigilance Practice (GVP)

Standards governing safety vigilance of pharmaceuticals after production and marketing.

## Good X Practice (GXP)

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

## ICH GCP

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

## Informed consent

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

## Market launch

Introducing a new product into the market.

## Medical representative (MR)

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

## Over-the-counter (OTC) drug

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

## Proof of concept (POC)

Confirmation of efficacy and safety of a candidate substance for a new drug based on trials made on humans during the research stage.

## Quality of Life (QOL)

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

## Self-medication

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

## Unmet medical needs

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

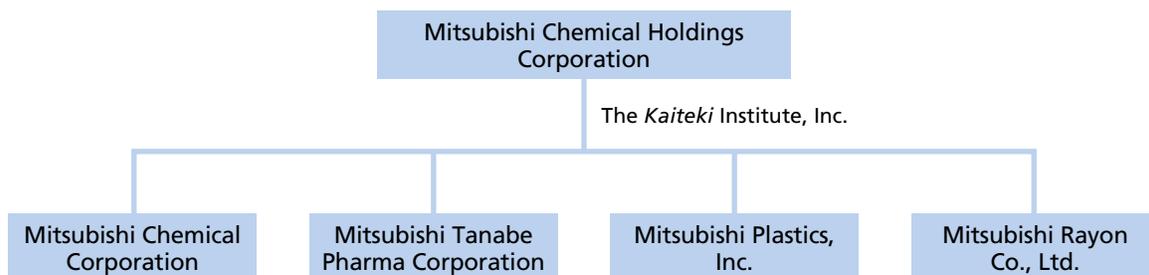
Mitsubishi Chemical Holdings Group's  
basic approach to social responsibility

Drawing on the three decision criteria of  
**Sustainability (Green),  
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* values widely across society.  
We will accomplish this through our corporate activities based on  
the three decision criteria of Sustainability (Green), Health, and Comfort.

To achieve that, we will commit to maintaining and reinforcing basic corporate activities  
in areas that are essential to enhancing *KAITEKI* values, 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





Mitsubishi Tanabe Pharma



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