

June 16, 2010

Mitsubishi Tanabe Pharma Corporation

Business Improvement Plan (Summary)

In response to the business improvement order issued by the Ministry of Health, Labour and Welfare (MHLW) to Mitsubishi Tanabe Pharma Corporation and its subsidiary Bipla Corporation, the two companies submitted a business improvement plan to the MHLW, respectively. This plan was compiled on the basis of the recommendations presented by the Medway Problem Outside Investigation Committee and recent domestic and international stream in drug quality and safety issues.

Mitsubishi Tanabe Pharma has already taken direct measures to correct these issues and recurrence counter measures. In addition to those measures, the Company will promptly implement necessary measures to improve manufacturing control and quality control at all manufacturing sites of the Company, its Group companies, as well as consigned manufacturing sites outside the Group.

Fully aware of the gravity of being charged with a violation of the Pharmaceutical Affairs Act, everyone at Mitsubishi Tanabe Pharma Group will promote the prevention of recurrence as the highest priority management issue. To ensure that the information on this incident is shared among all employees and that each employee takes a responsible approach toward preventing recurrence, the Company enhances its personnel training and education, establish a Compliance Day and take other necessary measures. The Company will exert steady and continuing efforts to promote the corporate culture of giving priority to safety and quality.

As to progress control of the business improvement plan, a committee comprising outside experts will review the progress and present suggestions. These review and suggestions will be made public from time to time, to ensure transparency in the improvement activities.

The summary of the business improvement plan submitted to the MHLW is as shown below.

Note: This document is an English translation of "Summary of Business Improvement Plan" made in Japanese.

Business Improvement Plan (Summary)

1. Groupwide actions to regain trust

All appropriate measures will be taken to reinforce corporate governance on a groupwide basis and to reduce risks associated with business activities, organizational structure, personnel, and other areas in all Group companies including the subsidiaries.

1) Management system

- Change of management [June 22, 2010]

Some directors are changed to clarifying social responsibility.

- Return of executive compensation [May 2010]

Some executive compensation will be returned as a means of clarifying social responsibility (10% to 50% of monthly compensation).

- Appointment of independent outside directors [from fiscal 2011 onward]

To ensure management transparency and objectivity, appointment of independent outside directors will be considered.

2) Reinforcing corporate governance, extending the scope to operate Group subsidiaries

- Establishment of Medway Issue Management Office [June 2010]

To ensure execution of the business improvement plan, Medway Issue Management Office will be established under the president's direct control. This office will keep all employees informed about the Medway issue, and will monitor and control the progress of the business improvement plan across Group companies.

- Inspection by outside experts and disclosure of business improvement status
[from July 2010 onward]

An independent committee comprising outside experts will be established to objectively inspect and assess implementation of the business improvement plan and to make suggestions to the management regarding actions to be taken. The activities of the committee, results of inspections and suggestions presented will be made public on the Company's website appropriately to ensure transparency.

- Establishing Group Management Promotion Office [June 2010]

Taking seriously the fact that the Company, as a parent company, failed to prevent the inappropriate activity that subsidiary had long committed, the Company will establish Group Management Promotion Office to reinforce groupwide corporate governance.

- Reinforcing coordination with Group subsidiaries [June 2010 onward]

The Company will develop a structure for facilitating coordination among Group subsidiaries, the overall supervision department and functional supervision departments by designating departments in charge of supervising overall operations as well as individual functions, such as manufacturing, technology or quality, of Group subsidiaries.

- Promoting personnel exchange and correcting imbalance in personnel

[from June 2010 onward]

The Company will work to rectify, as mid- and long-term Group-wide priority issues, the longstanding problems of stagnant and unbalanced personnel assignment (some employees have been in the same workplace for many years, and employees from a certain company at which they had worked before the merger have been disproportionately positioned in some organizations).

3) Enhancing compliance

- Meetings with executive participation [from July 2010 onward]

To enhance and share awareness of compliance among all officers and employees, the Company will organize, in each workplace, meetings in which executives shall also participate.

- Enhancing compliance training [from December 2010 onward]

To enhance professional ethics and normative consciousness, the Company will improve general training (training on general topics common to all employees), and will increase the effectiveness of departmental training by selecting practical and concrete themes developed according to the characteristics of each department, and by adopting group discussion, role-playing and other effective methods. In addition, retraining of managers will be promptly implemented.

- **Pharmaceutical Affairs Act training** [from October 2010 onward]
 Training on the Pharmaceutical Affairs Act and other relevant laws and regulations will be provided to all officers and employees. This training will also be implemented as part of the training programs for newly recruited employees and managers, including newly appointed managers.

- **Continuing education on drug-induced suffering** [Continued since fiscal 2008]
 To raise awareness of drug safety, the Company continues to implement drug safety training as education on drug-induced suffering.

- **Revising managers eligibility criteria** [To be implemented in fiscal 2011]
 The criteria for appointing managerial personnel will include awareness of compliance issues and level of compliance.

- **Appropriate imposition of disciplinary actions**
 [To be implemented in July 2010]
 As a means of preventing fraudulent acts, the Company will take strict disciplinary measures. To facilitate early detection of fraudulent acts, the Company will introduce a system that reduces punishment of wrongdoers who voluntarily reported their misconduct.

- **Establishment of “4.13 Compliance Day” (tentative name)**
 [To be approved in July 2010]
 Compliance Day will be established to keep our memory of this incident from fading away. With the president delivering a message and all officers and employees signing a compliance declaration, the day will provide a regular occasion for reaffirming the importance of compliance.

- 4) **Improving and expanding the internal hotline system for greater ease of access by employees, for early detection of fraudulent acts**
 - **Reaffirming and publicizing the hotline function** [from July 2010 onward]
 Through compliance training for all employees, the Company will make it fully understood among employees that whistleblowers shall not receive any disadvantageous treatment, and that high confidentiality of whistleblowers shall be maintained.

- Enhancing convenience of the hotline [June 2010]

To enhance the convenience of the hotline, the Company will extend its service hours, make the hotline toll-free and take other improvement measures.

- Making the hotline available to more users [To be considered in and after September 2010]

To ensure early detection of fraudulent acts, the Company will make the hotline more widely known to employees of non-Group companies to which the Company consigns manufacturing or other operations.

2. Actions to address manufacturing control and quality control issues

As a manufacturer and marketer (Mitsubishi Tanabe Pharma Corporation), the Company will enhance supervision and guidance of Bipha to prevent recurrence of the incidents, and will take stricter preventive measures at manufacturing sites of the Company and its Group companies. In addition, these measures will be taken, as much as possible at manufacturing sites, of non-Group companies to which manufacturing is consigned.

Listed below are actions that the Company has already implemented or plans to implement.

1) Actions targeting Bipha

- Enhancing GMP¹⁾ training and increasing knowledge [from July 2009 onward]
- Improving the meeting system on GMP and structure for operating GMP [from July 2009 onward]
- Enhancing measures to increase reliability of quality tests [from June 2010 onward]
- Establishing a technical management division for compiling technical information [September 2010]
- Sending appropriate personnel for manufacturing and quality control from the Company [May 2009]
- Promoting personnel exchange and introducing the Groupwide personnel system, to foster a sense of solidarity [April 2009]
- Reinforcing coordination with Mitsubishi Tanabe Pharma (Designating

- departments in charge of each function, such as quality assurance, technical supervision or manufacturing supervision) [June 2009]
- System under which GQP²⁾ personnel are dispatched from Mitsubishi Tanabe Pharma to local manufacturing sites to perform their duties [October 2010]
- Mutual check and balance function by quality test personnel (Introduction of two-man system) [from December 2009 onward]
- Reassessing meetings and improving communication [from June 2009 onward]
- Improving a personnel training system [April 2009]

2) Actions targeting manufacturing sites of the Company and its Group companies

- Developing a system for ensuring reliability of NDA data [April 2008]
- Developing a system for ensuring reliability of IND data [April 2008]
- Establishing a CMC³⁾ Biotechnology Development Office (technical supervision department for activities relating to bio-based products, established within CMC Research Center) [April 2010]
- Creating a system for technology transfer to be implemented under supervision of the Company's quality assurance division [October 2009]
- Enhancing GMP auditing by GQP division [from October 2010 onward]
- Reinforcing activities to reduce risk in quality tests [from April 2009 onward]
- Implementing Quality Review Meetings and Annual Product Reviews to evaluate appropriateness of quality and manufacturing process [from October 2010 onward]

- 1) GMP (Good Manufacturing Practice): Standards for manufacturing control and quality control of drugs etc.
- 2) GQP (Good Quality Practice): Standards for quality assurance of drugs etc. to be manufactured and marketed
- 3) CMC (Chemistry, Manufacturing and Control): Chemistry, manufacturing and quality control in the processes from drug development to manufacturing