April 13, 2010

Press Release

Mitsubishi Tanabe Pharma Corporation

Notice Regarding Administrative Action Related to Violation of Pharmaceutical Affairs Law

Today, Mitsubishi Tanabe Pharma Corporation and its subsidiary Bipha Corporation (Izumisawa 1007-124, Chitose, Hokkaido; hereafter, Bipha) received an administrative action, suspension of business and an order for improvement, from the Ministry of Health, Labour and Welfare in regard to a violation of the Pharmaceutical Affairs Act.

The reasons for the action included (1) the fact that the company, a manufacturer and marketer, manufactured and sold the ethical drugs "Medway Injection 5%" and "Medway Injection 25%" without ensuring that Bipha, the manufacturer, appropriately implemented manufacturing control and quality control, and (2) the fact that the NDA materials for those products that were submitted by the two companies contained materials that were based on fraudulent acts by Bipha. The details of the action are that the Company must suspend its first-class pharmaceutical manufacturing and sales operations for 25 days, from April 17, 2010 to May 11, 2010 and Bipha must suspend its pharmaceutical manufacturing operations for 30 days, from April 14, 2010 to May 13, 2010. The Company and Bipha have also been ordered to submit business improvement plans.

The Company and Bipha are taking this administrative action very seriously, and we offer our sincere apologies to patients, medical professionals, and the rest of society.

On March 24, 2009, the Company announced its decision to withdraw the marketing authorization for "Medway Injection 5%" and to voluntarily recall "Medway Injection 5%" and "Medway Injection 25%" from the market. Currently, all of the products that were shipped have been recalled. In addition, we have not received any reports of health problems resulting from this incident.

The Company has established the in-house Medway Issue Countermeasures Committee. This committee has thoroughly investigated the facts and the cause of the incident and has considered how to prevent a recurrence of such an incident. Furthermore, to ensure objectivity and independence, the Company has asked outside experts to establish the Medway Issue Outside Investigation Committee. This committee has worked toward the goal of investigating recurrence countermeasures and offering advice. Currently, the Company received the final report from the committee.

The Group will work to prevent a recurrence by reemphasizing the importance of strictly observing GMP, ensuring the reliability of materials used in support of applications, and ensuring rigorous compliance with other pharmaceutical related regulations throughout the Group. As employees and managers of a pharmaceutical enterprise in a life-related industry, everyone at the Company will work earnestly to prevent a recurrence, and we will do our utmost to regain the trust of society.

The influence of this incident on results is currently being considered and will be disclosed as soon as it is confirmed.

〈〈For Details, Contact the Following Section〉〉
Corporate Communications Dept., Mitsubishi Tanabe Pharma Corporation
Tel +81-6-6205-5211