

July 19, 2011

Press Release

[Mitsubishi Tanabe Pharma Corporation](#)

## Notice Regarding a Business Suspension Order for the Ashikaga Plant of Mitsubishi Tanabe Pharma Factory Ltd. and a Business Improvement Order for Mitsubishi Tanabe Pharma Corporation

Today, the Ashikaga Plant (Ashikaga, Tochigi) of Mitsubishi Tanabe Pharma Factory Ltd. (Head Office: Osaka; President and Representative Director: Kouji Nakamura), a consolidated subsidiary of Mitsubishi Tanabe Pharma Corporation, received a 10-day suspension of its pharmaceutical manufacturing operations order from Tochigi Prefecture in accordance with the Pharmaceutical Affairs Law 75-1 on account of a violation of the Good Manufacturing Practice (GMP) ministerial ordinance. In accordance with the order, operations at the plant will be suspended from July 20, 2011, to July 29, 2011. Furthermore, today Mitsubishi Tanabe Pharma Corporation received a business improvement order from the Minister of Health, Labour and Welfare in accordance with the Pharmaceutical Affairs Law 72-4-1 on account of a violation of the Good Quality Practice (GQP) ministerial ordinance related to operations that failed to follow GQP.

The Company and Mitsubishi Tanabe Pharma Factory Ltd. are taking the administrative actions very seriously, and we offer our sincere apologies to patients, medical professionals, and the rest of society.

The business suspension order for the Ashikaga Plant is related to the failure by the Ashikaga Plant, which is a manufacturer of ethical drugs, to appropriately perform certain quality tests to determine if products were suitable for shipping. As previously disclosed by the Company in January 2011, some aspects of testing for certain products—including Liple®, Limethason® Intravenous Injection, and Pazucross® Injection—were inadequate. In April 2010, Mitsubishi Tanabe Pharma Corporation received a business improvement order from the Minister of Health, Labour and Welfare in regard to a problem with Medway at Bipha Corporation, one of the Company's subsidiaries. In June 2010, the Company submitted a business improvement plan and since that time has worked to implement recurrence countermeasures. However, in consideration of the Company's response to the quality control problem at the Ashikaga Plant, the Company's initiatives in the area of recurrence countermeasures have been determined to be inadequate. The

Company has been ordered to revise the business improvement plan's recurrence countermeasures in order to further increase their effectiveness, and to report the results of that revision to the Ministry of Health, Labour and Welfare.

After the discovery that the plant had failed to appropriately perform certain quality tests, Mitsubishi Tanabe Pharma Corporation and the Mitsubishi Tanabe Pharma Group rapidly conducted comprehensive inspections of quality testing for the purpose of reconfirming the quality of products manufactured by all members of the Group. For all products currently being manufactured by the Group, the quality has been confirmed.

The Company formed "Crisis-management Committee" comprised eminent persons outside the Company, and obtained proposals for investigation of the cause and measures for preventing recurrence. In April, 2011, the Company released the Comprehensive Report on the Quality Control Problem, which was based on the results on the inspections on successive improvement measures, and on advice from the Committee.

The business suspension will not have an effect on the stable supply of the Company's products that are manufactured at the Ashikaga Plant.

The Group will renew its commitment to implementing strict observance of GQP, GMP, and all other pharmaceutical regulations. As employees and managers at a life-related company, everyone at the Group will work earnestly to prevent a recurrence, and moving forward we will do our utmost to regain the trust of society.

In regard to the influence of this incident on the Company's results, in the event that there are any items that need to be disclosed, the Company will provide notice in a timely manner.