

# Operational Risks

The following are major risks that have the potential to significantly influence the financial position or performance of the Mitsubishi Tanabe Pharma Group. In recognition of these risks, the Mitsubishi Tanabe Pharma Group works to prevent the occurrence of risk events and to implement responses in the event of their occurrence. Items in this document relating to the future are based on the judgment of the Mitsubishi Tanabe Pharma Group as of the end of fiscal 2018 (March 31, 2019).

## 1 Risks related to R&D

The R&D of drugs requires lengthy investment and the commitment of substantial resources. In addition, pharmaceuticals cannot be sold if approval is not obtained under the legal and regulatory system of each country. Accordingly, it is difficult to accurately predict whether or not products will be launched and the timing of those launches. Furthermore, if problems with effectiveness or safety are found, or if a drug candidate is not expected to have economic value, development could be halted. Due to these types of factors, it is possible that R&D investment will not lead to the launch of new drugs, or that the initially-projected level of sales will not be achievable.

## 2 Risks related to adverse drug reactions

In the event of the appearance of serious adverse drug reactions or safety problems with a pharmaceutical, there could be a sales suspension, recall, etc.

## 3 Risks related to insurance systems

The sale of pharmaceuticals is significantly influenced by various health insurance systems, such as medical fees, drug price standards, etc. In the event of revisions to the drug price standard that is the official price of pharmaceuticals or to the drug price system; revisions to medical fees or revisions to various health insurance systems that influence trends in the use of pharmaceuticals by medical institutions; or similar revisions to the standards and systems employed overseas, there could be an influence on the Mitsubishi Tanabe Pharma Group's business activities.

## 4 Risks related to changes in the market environment

Due to the launch of competing products or generic drugs, the launch of new methods of treatment or new technologies, the announcement of new evidence, etc., there could be a relative change in the position of the Company's pharmaceutical products in clinical use.

## 5 Risks related to intellectual property

If the Mitsubishi Tanabe Pharma Group's business activities conflict with the intellectual property rights of other parties, it is possible that there could be a legal dispute or that the activities could be suspended. Also, in the event that the Mitsubishi Tanabe Pharma Group believes that its intellectual property rights have been infringed upon by another party, it is possible that the Mitsubishi Tanabe Pharma Group might file lawsuits.

## 6 Risks related to alliances with other companies

The Mitsubishi Tanabe Pharma Group works with other companies in joint research and development, product in-licensing and out-licensing, joint promotion and marketing, and the performance of various operations on a contract basis. In the future, if contracts with alliance partners are changed or canceled, if the management environment of alliance partners worsens, if the management policies of alliance partners change, or if the supply of products from these companies is delayed or suspended, there could be an adverse influence on the Mitsubishi Tanabe Pharma Group's business activities.

## 7 Risks related to business acquisitions, etc.

The Mitsubishi Tanabe Pharma Group conducts business development activities for sustained growth, and business acquisitions, etc., are implemented as a means to that end. It is possible that the expected acquisition effects, etc., will not be achieved due to such factors as changes to laws or regulations of various countries, political instability, uncertainty of economic trends, differences in business practices, changes in the economic environment or businesses of acquired businesses, etc.

## 8 Risks related to stable supply

Due to the emergence of technical or legal/regulatory problems in the Mitsubishi Tanabe Pharma Group's internal or external production, distribution sales, etc., or to operational stoppages, etc., resulting from fires or other disasters, there could be a suspension of or substantial delay in the supply of products.

## 9 Risks related to financial market conditions and exchange rate fluctuations

The Mitsubishi Tanabe Pharma Group receives and delivers money related to exports and imports of certain pharmaceuticals and raw materials and also receives from overseas patent-right usage fees related to out-licensed pharmaceuticals. In addition, the Mitsubishi Tanabe Pharma Group has overseas assets, including overseas consolidated subsidiaries. Accordingly, substantial fluctuations in financial market conditions or exchange rates could lead to declines in revenue, increases in procurement costs, the generation of foreign exchange losses, etc., declines in the assets of overseas consolidated subsidiaries, and the recording of loss on sales or valuation loss due to declines in the market prices of stocks, bonds, etc.

## 10 Risks related to the environment

In the event that chemical substances, etc., used in business activities have a serious influence on the environment, expenses required for environmental improvement could arise, social trust could decline, or liability for damages, etc., could arise.

## 11 Risks related to lawsuits

(1) The Mitsubishi Tanabe Pharma Group could face lawsuits in regard to adverse drug reactions, product liability, labor problems, fair trade, etc.

(2) For "the Special Relief Law Concerning the Payment of Benefits to Relieve the Patients of Hepatitis C Infected through Specified Fibrinogen Preparations and Specified Blood-Coagulation Factor IX Preparations Contaminated by Hepatitis C Virus," which was put into effect in January 2008, the time limit for filing a claim for benefits was extended to January 2023. Accordingly, there could be an increase in the number of people who receive payment of benefits, etc.

## 12 Risks related to information

In the event of a leakage of the confidential information of the Mitsubishi Tanabe Pharma Group or of obstruction of business due to inappropriate handling of information, system deficiencies, cyberattacks, etc., the Mitsubishi Tanabe Pharma Group could experience a loss of its competitive strength, a decline in social trust, etc.

## 13 Risks related to overseas business development

Substantial investment is necessary to expand and advance overseas operations, and it is possible that, due to changes in the laws and systems of various countries, the worsening of diplomatic relations, or natural disaster, etc., operations under development might be affected and the opportunity to recover that investment might be lost.

## 14 Risks related to major disasters, etc.

Due to a major disaster, pandemic, terrorist incident, or secondary disaster, there could be a suspension or significant delay in the supply of products, a delay in R&D plans, etc.

## 15 Relationship with parent company and other group companies

In regard to transactions between the Company and its parent company, Mitsubishi Chemical Holdings (MCHC), or companies in the MCHC Group, in making decisions the highest priority is given to increasing the enterprise value of the Mitsubishi Tanabe Pharma Group in order to maximize the benefit to all of the Company's shareholders. Transactions with a high degree of importance are implemented after the Board of Directors conducts sufficient deliberations and gives its approval.

In the event that there is a change in the capital relationship with the MCHC Group, the Mitsubishi Tanabe Pharma Group's business activities could be affected.