

**Five Recommendations  
Toward the Drastic Expansion of  
Foreign Direct Investment in Japan**

- *Japan evolves towards more open market* -

May 19, 2008

**Expert Committee on FDI Promotion**

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“Expert Committee on FDI Promotion” was established by Minister Hiroko Ota, the Minister of State for Economic and Fiscal Policy in January 2008. The committee discussed reasons of a low level of FDI into Japan, and measures to promote FDI further.

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# Five Recommendations

## **1. Enhancement of system toward the facilitation of M&As**

*In order to contribute to the facilitation of M&As, which are an important means of FDI in Japan, wide-ranging studies should be advanced, and the further improvement of Japan's M&A system should be accelerated.*

## **2. Comprehensive studies on Foreign Direct Investment regulations**

*While maintaining national security, public order, and so on, the regulations with appropriate predictability should be advanced. The scope and grounds of cases where Foreign Direct Investment regulations are necessary as exceptions to the principle of nondiscrimination between domestic and foreign investors should be clarified, and Japan's open investment policy should be shown to the rest of the world.*

## **3. Establishment of priority strategies by sector**

*In order to revitalize the Japanese economy and improve quality of life, priority sectors should be taken up and priority efforts should be formulated as action programs. First of all, in response to these recommendations, in the field of medical devices and pharmaceutical products, which will be especially important in terms of revitalizing the Japanese economy and improving quality of life, an action program should be formulated that puts the focus on the field of medical devices.*

## **4. Reduction of business costs and improvement of system transparency**

*Amid global competition, the reform of regulations and systems should be promoted, thereby reducing business costs in Japan and improving system transparency, so that foreign companies and investors can see the merits of FDI in Japan.*

## **5. Regional revitalization by foreign capital, strengthening of appeal that foreign capital is welcome, etc.**

*In order to realize regional revitalization through the attraction of foreign capital, regions should be built in which it is easy for foreign capital to be active, and the appeal that foreign capital is welcome should be strengthened.*

# Contents

I. Revitalization of the Japanese economy through the promotion of foreign direct investment in Japan	....3
II. Five Recommendations for the Promotion of FDI in Japan	....4
III. Promotional Structure for FDI in Japan	...12
Appendix	...13
Members	...15

# I. Revitalization of the Japanese economy through the promotion of foreign direct investment in Japan

## **(FDI in Japan is extremely important for the revitalization of the Japanese economy)**

FDI in Japan not only brings about new technology and management know-how but also exerts a major influence on and promotes the new development of Japan's existing technology, know-how, etc., and it is an extremely important factor in stimulating and revitalizing the Japanese economy and increasing job opportunities.

## **(The plan to double FDI in Japan is making progress, but the level is still low in international terms)**

Since the establishment of the Japan Investment Council in 1994, the government has twice announced targets for doubling the amount of FDI in Japan and has been making efforts to promote FDI in Japan. Compared with countries in the U.S. and Europe, however, the level remains low, and the gap with other countries is widening.

## **(As the competition to attract foreign capital intensifies, enhancement of the investment environment is necessary to overcome the global competition)**

In order to survive in the globalized world economy, countries are engaging in intense competition to attract foreign capital. However, it must be said that interest among foreign investors and companies in FDI in Japan is low compared with the BRICs (Brazil, Russia, India, and China), which are achieving tremendous growth, and countries in the U.S. and Europe, which are striving to improve their investment environments.

In these circumstances, in order to drastically expand FDI in Japan and connect this with the revitalization of Japan, it is necessary to actively build an investment environment that can overcome the global competition.

## **(Recommendation of measures to be implemented urgently)**

In order to dramatically increase FDI in Japan and to connect this with the growth of the Japanese economy, while bearing in mind the results of "the Program for Acceleration of Foreign Direct Investment in Japan", which is currently being implemented, we recommend the following measures that should be implemented urgently.

## II. Five Recommendations for the Promotion of FDI in Japan

### **1. Enhancement of system toward the facilitation of M&As**

*In order to contribute to the facilitation of M&As, which are an important means of FDI in Japan, wide-ranging studies should be advanced, including the following matters, and the further improvement of Japan's M&A system should be accelerated.*

#### **(1) Corporate M&A activities in Japan**

- M&A is one basic means of corporate investment activity, and like the companies of other countries, Japanese companies also use M&A as an important method of cross-border investment. In Japan, since the end of the 1990s, when reform of the economic system relating to M&A advanced, the number of cases of domestic M&As has increased rapidly, and M&As by foreign companies ("OUT-IN") are on an upward trend, too. The increased liveliness of M&A, which is showing diverse development, generally contributes to the revitalization of the Japanese economy and is also expected to have a desirable effect in terms of the promotion of FDI in Japan. Accordingly, it is necessary to boost the predictability of the M&A process through sort-out, clarification, etc. of the M&A system.

#### **(2) Sort-out and clarification of takeover rules without delay**

- As a consequence of the increased liveliness of M&A activities, on the corporate side the introduction of defensive measures against takeovers has been advancing, and regarding disputes involving takeover bids, there have been cases that have gone as far as judicial rulings. However, understanding of the rules concerning the introduction of defensive measures has yet to take root and confusion has been seen in the interpretation of judicial rulings, hindering the smooth development of M&As. There is a possibility that such factors may become obstructions to investment from overseas.
- Specifically, among other things, the following possibilities have been pointed out that (a) defensive measures, which essentially should ensure a process by which shareholders can properly assess of a takeover proposal, will function to obstruct investment; (b) through the appearance of defensive measures allowing the target company to compensate the potential acquirer with cash, etc., there will be an outflow of funds that originally should have been returned to shareholders in the form of dividends, etc., which would damage shareholder interests; and (c) there will be an increase of cross-shareholdings aimed at approving the

deployment of defensive measures at general meetings of shareholders.

- In order to solve these problems, basically the establishment of rules through the accumulation of judicial precedents is desirable, but this cannot be expected to be attained in a short time. Therefore, regarding the use and implementation of defensive measures that does not restrain appropriate takeover activities, with the cooperation of the Financial Services Agency, the Ministry of Justice, the Ministry of Economy, Trade and Industry, stock exchanges, and others, a conclusion should be reached by this summer that reflects the opinions of a wide range of related parties. In conducting these studies, consideration should be given to the fair assessment of acquisition of takeovers (the improvement of corporate governance through the threats of possible takeovers, etc.), and the following points should be taken into account:

---When introducing or deploying defensive measures, are the interests of shareholders and investors protected? (how to achieve shareholder interest protection, including economic burden)

---Has a direct dialogue between the potential acquirer and the existing management team been promoted, and have shareholders been ensured opportunities to make a comparative study of respective management reform plans and choose between them?

---If a special committee which gives its opinions to the board of directors is established when the board makes a decision concerning the deployment of defensive measures, what should the composition of the committee be?

### **(3) Promotion of studies for the facilitation of cross-boarder M&As**

- Since the enactment of the Company Law, there has been only one case of a triangular merger. With reference to an analysis of the reasons for this, studies should be made of the establishment of a system that is easy to use in practice. In order to facilitate cross-border M&As further, studies of system and taxation concerning M&A measures, including clarification of the application of the system and the tax treatment for reorganization, as well as the expansion of the range of options, should be made taking into account to the specific needs.
- In order to further announce the details of the system overseas, explanations of Japan's M&A system and tax system thereon should be made available to investors overseas in their languages.

### **(4) Elimination of allergy toward M&As by foreign companies**

- Not a few Japanese companies still have an allergy regarding the takeover of domestic companies by foreign companies ("OUT-IN"). In order to eliminate this foreign capital

allergy, the prime minister, cabinet ministers, heads of local governments, business leaders, and so on should send a clear message that investment from overseas is welcome in Japan.

- In addition, organizations that promote investment in Japan, such as the Japan External Trade Organization (JETRO), should implement a project from FY 2008 to collect and introduce cases in which M&As by foreign companies in particular have led to the business revival of the target Japanese company, the improvement of business performance, the securing of jobs for their employees, and so on.

## **2. Comprehensive studies on Foreign Direct Investment regulations**

***While maintaining national security, public order, and so on, the regulations with appropriate predictability should be advanced. The scope and grounds of cases where Foreign Direct Investment regulations are necessary as exceptions to the principle of nondiscrimination between domestic and foreign investors should be clarified, and Japan's open investment policy should be shown to the rest of the world.***

- Japan, faced with a population decline, needs to realize economic growth through the promotion of investment from other countries, and should make the regulations more predictable while maintaining national security, public order, and so on.
- For this purpose, Japan should promote studies on FDI regulations and clarify the scope and grounds of cases where FDI regulations are necessary as exceptions to the principle of nondiscrimination between domestic and foreign investors. In this regard, Japan should take into account, among other things, (a) harmony with international agreements and systems, and efforts in major developed countries; (b) ensuring that operation of regulations is more predictable to foreign investors; (c) the possibility of introduction of other mechanisms to maintain national security, public order, and so on (for example, restrictions on business activities, regulations on the possession of large-lot shares by domestic and foreign investors, etc.); and (d) relationship with the promotion of FDI in Japan; etc.
- In particular, if there is no other way than setting exceptions to the principle of nondiscrimination between domestic and foreign investors in cases that involve the perspective of ensuring public benefit, such as public infrastructure, clearer explanations are required.
- The government should reiterate Japan's open investment policy to FDI in Japan while advancing the comprehensive studies on these issues related to FDI regulations in FY2008.

### **3. Establishment of priority strategies by sector**

*In order also to revitalize the Japanese economy and improve quality of life, priority sectors should be taken up and priority efforts should be formulated as action programs. First of all, in response to these recommendations, in the field of medical devices and pharmaceutical products, which will be especially important in terms of revitalizing the Japanese economy and improving quality of life, an action program should be formulated that puts the focus on the field of medical devices.*

#### **(1) Bringing the world's most advanced medicine to Japan**

- In the “5-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices,” which was issued in April 2007, regarding pharmaceuticals, the goal was declared of shortening the period from new drug development to approval by 2.5 years and eliminating the “drug lag<sup>1</sup>.” However, there is no such target regarding medical devices, and efforts are still lagging. In the case of medical devices as well, a target should be stipulated to drastically shorten the period up to approval, place devices that can be used on the front-lines of medical care on a par with the U.S and Europe., and thereby eliminate the “device lag<sup>2</sup>”; as with drugs, specific target periods should be set; and comprehensive efforts should be commenced as soon as possible. Also, the state of progress of these efforts should be confirmed in “Government-Private Sector Dialogue for Discovery of Innovative Drugs and Medical Devices.<sup>3</sup>”, and efforts should be made toward further improvements. (For details, see Appendix 1.)
- The environment should be improved so that the development of pharmaceuticals and medical devices is promoted in Japan and medical device manufacturers, pharmaceutical companies, and so on do not turn their backs on Japan, and efforts should be made to raise medical standards in Japan and contribute to the relief of patients. (For details, see Appendix 2.)

#### **(2) Selection of sectors**

- From now on also, prioritized sectors should be selected, and action programs should be successively formulated. For example, target sectors could be such areas as tourism and travel,

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<sup>1</sup> The “drug lag” means situation that drugs that have approved in the U.S. and Europe have not approved in Japan and are not available to the Japanese people.

<sup>2</sup> The “device lag” means situation that medical devices that have approved in the U.S. and Europe have not approved in Japan and are not available to the Japanese people.

<sup>3</sup> The membership of this council for the creation of innovation and so on comprises related cabinet ministers (minister for science and technology policy, minister of education, culture, sports, science and technology, minister of health, labor and welfare, and minister of economy, trade and industry), the leaders of the pharmaceutical and medical device businesses, and experts.



which are very important for regional economies.

#### **4. Reduction of business costs and improvement of system transparency**

*Amid global competition, the reform of regulations and systems should be promoted, thereby reducing business costs in Japan and improving system transparency, so that foreign companies and investors can see the merits of FDI in Japan.*

##### **(1) Reduction of the corporate tax rate (nominal rate) in order to attract foreign capital**

- Whereas cross-border corporate activities have become increasingly lively with the globalization and corporate tax rates has been reduced in some other countries in recent years, the effective corporate tax rate<sup>4</sup> in Japan (calculated by the nominal rates) is one of the highest among the OECD member countries. Some views state that not only foreign but also Japanese companies are cautious about selecting Japan as their investment destination. In order to realize an investment environment that is attractive for all companies locating in Japan, studies regarding the reduction of the corporate tax rate should be made in light of the revision of the tax base and fundamental tax reform.

##### **(2) Drastic improvement of the “no-action letter” system and written reply procedures for taxes**

- Although the further utilization of the no-action letter system is taken up in “the Program for Acceleration of Foreign Direct Investment in Japan”, it remains inadequate. For example, the number of reply cases announced in FY 2006 was only 11 in the government as a whole. Moreover, it has been suggested that some companies have been urged not to make inquiries. Therefore, it is necessary for studies to be conducted during FY 2008 toward increasing the convenience of the system, including raising the transparency of the procedures and reviewing of the systems. In light of the conclusions of these studies, where necessary, such measures should be adopted as the disclosure of reasons and numbers for cases where no reply has been given and the introduction of third-party mediation procedures so that in cases where replies are

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<sup>4</sup> This is the nominal rate of corporate taxes, including both national and local taxes. In Japan’s case, taking into consideration that the corporate enterprise tax is deductible in the calculation of taxable income, the effective corporate tax rate is calculated from the corporate tax rate (national tax), the corporate enterprise tax rate (local tax, taxation on income basis), and the corporate inhabitant tax rate (tax rate for taxable income on corporate basis). The effective corporate tax = (corporate tax rate + corporate inhabitant tax rate + corporate enterprise tax rate)/(1 + corporate enterprise tax rate).

not made or are significantly delayed, the inquirer can petition the organization with surveillance functions.

- Regarding written responses to taxpayer advance inquiries about national taxes, since they improve the predictability of business transactions, companies, etc. have a great need for the reinforcement of functions. The National Tax Agency should make efforts to enhance the setup for promptly giving written responses and strengthen its functions, including the developing experts internally and the increase outside personnel with fixed-term appointments, etc.

### **(3) Evaluation of regulations and administrative burden survey**

- Regarding the ex-ante evaluation of regulations through the regulatory impact analysis (RIA) method, which was made obligatory for government ministries and agencies from October 2007, the evaluation process for newly introduced regulation should be strengthened. For this purpose, it is necessary to build a new mechanism for scrutinizing from a cross-ministerial perspective to judge whether or not the newly introduced regulations are appropriate, focusing on such points as ensuring the objectivity and transparency of evaluation, studying and analyzing costs arising from regulations through quantitative methods.
- The time required for administrative procedures and other administrative burden (Red Tape<sup>5</sup>) exert a major impact on corporate activity. From the perspective of further promoting regulatory reform, Japan should actively participate in efforts in the OECD to survey red tape.

### **(4) Revision of hearing procedures etc. under the Antimonopoly Act**

- Under the Antimonopoly Act, the Fair Trade Commission initially issues an administrative order, receives an objection from the company concerned, and conducts examinations itself through the hearing procedures. Because none of the other countries does not adopt this system, some have pointed out that it should be abolished. Therefore, a thorough review of the provisions relating to the hearing procedures should be conducted from the viewpoint of neutrality and fairness.
- It should also be examined what the due-process in the investigation procedures based on the Antimonopoly Act should be, from the viewpoint of enabling the company concerned to exercise an appropriate right of defense, taking into account such factors as harmonization with international standards, consistency with other systems in Japan, and differences in the judicial systems in Japan and other countries.

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<sup>5</sup> Here, Red Tape means the burden placed on companies and citizens by administrative procedures, such as the time required for permit/approval procedures and the submission of documents.

#### **(5) Promotion of utilization of private-sector dynamism in public service by government**

- Regarding public services provided by the national and local government, the Japanese Government will examine the measures such as the standardization of contracts and the clarification of service specifications for promotion of further utilization of private-sector dynamism including foreign capitals, and will materialize these measures during FY 2008.

### **5. Regional revitalization by foreign capital, strengthening of appeal that foreign capital is welcome, etc.**

*In order to realize regional revitalization through the attraction of foreign capital, regions should be built in which it is easy for foreign capital to be active, and the appeal that foreign capital is welcome should be strengthened.*

#### **(1) Strategic attraction of foreign capital in wide-area economic zones (“local to local”)**

- In order to effectively and efficiently convey the attractions of Japan’s regions to foreign companies, the capacity of prefectures and municipalities themselves is limited. Therefore, in enthusiastic local governments, through the leadership and coordination of their heads, efforts should be made to promote wide-area cooperation, as illustrated by the Greater Nagoya Initiative, utilizing the human resources and know-how of local business circles and with the support of JETRO and other related organizations.

#### **(2) Activities to attract foreign capital centered on former private-sector personnel**

- In order to utilize private-sector know-how relating to finance, sales, marketing, and so on, personnel with roots in the private sector should be actively used in FDI-promotion activities, including activities conducted through wide-area cooperation. In addition, schemes in which information about the needs of foreign companies obtained through FDI-promotion activities are transmitted back to related ministries and agencies, leading to the improvement of FDI-promotion activities should be strengthened.

#### **(3) Building of living environments suitable for foreigners**

- It has been pointed out that talented foreign businesspeople tend to shun appointments in Japan out of concern about the shortage of living services, such as healthcare and schools, that foreigners can use with ease. In order to improve this situation, a project should be implemented

to collect and introduce the efforts of municipalities toward the enhancement of living infrastructure for foreigners, such as medical service and education.

**(4) Facilitating continuation of business of small and medium-sized companies through foreign capital M&As**

- From the perspectives of business continuation and the ensuring of jobs for workers in the regions, the efforts of JETRO, local governments, and other related organizations to attract foreign capital that contributes to the facilitation of the business continuation of small and medium-sized companies through M&As should be strengthened.

**(5) Strengthening of appeal that FDI in Japan is welcome**

- The Cabinet Office, Ministry of Internal Affairs and Communications, Ministry of Economy, Trade and Industry, JETRO, and others should cooperate and study measures to show both domestically and internationally Japan's attitude of welcoming investment in Japan, such as the utilization of an award system, reaching a conclusion by the end of FY 2008 and implementing them at the earliest opportunity.

### III. Promotional Structure for FDI in Japan

From the perspective of continuing to encourage activities to promote FDI in Japan through the efforts of the government as a whole, “the Program for Acceleration of Foreign Direct Investment in Japan” should be revised based on the recommendations of this Expert Committee. The state of progress of the revised “ the Program for Acceleration of Foreign Direct Investment in Japan” should be checked regularly and revisions made where necessary. A structure should be newly established for that purpose.

## **Appendix:**

### **Some Measures on medical devices and pharmaceuticals**

#### **1. Efforts to Eliminate the “Device Lag”**

(Revision of review standards)

\* With regard to pre-marketing regulation for medical devices, expand the scope of products subject to third-party certification to all Class II products. Thereafter, further expansion to Class III and Class IV should be examined.

\*Further clarify the scope of the situation where an application for partial change of medical device specifications is required, such as by indicating specific examples in an easy-to-understand manner.

\*In conjunction with the speeding up of reviews for the approval of medical devices, strengthen the guarantee of safety after marketing, such as by enhancing post-marketing surveys.

\*Promote streamlining data requirements which are necessary for approval review, such as stability test data, with attention to ensuring the safety. Also, continue to tackle with the simplification of application dossier.

\* Enhance consistencies of regulations with internationally-recognised risk-based medical device classification and medical device nomenclature.

(Transparency of review process)

\*Standardize the process of review by, among other things, having the Pharmaceuticals and Medical Devices Agency (PMDA) acquire ISO certification.

\* Promote disclosure of the minutes, including the names of speakers, of the Pharmaceutical Affairs and Food Sanitation Council where discussions were held about the approvals of pharmaceuticals and medical devices.

(Strengthening of the medical devices review evaluation setup)

\*Triple the number of medical device reviewers in the PMDA in about five years, from the present 35 to about 100. Regarding financial sources needed, with reference to international situations, study a basic rebuilding of the commission system. In addition, establish a body of members from the government and manufacturers to check the improvement of approval review and the state of progress made in eliminating the device lag.

\*Make efforts to improve the quality of reviewers by, among other things, enhancement of training through cooperation with companies and exchange with universities, research institutes, etc. both in

Japan and abroad.

\*Improve both the quality and quantity of clinical trials consultations, including, for example, responding to detailed inquiries regarding development, clinical trials, etc.

\*Introduce a preliminary review system which substantive review is done during clinical trials and a three-track system for the parallel review of new medical devices, improved medical devices, and generic medical devices.

\*Drastically shorten the review period, set a standard review period, and increase the predictability of the time taken up to the completion of reviews.

(Revision of national health insurance reimbursement prices of pharmaceuticals and medical devices)

\*In deciding national health insurance reimbursement prices, implement studies to take account of the newness and innovation of pharmaceuticals and medical devices and the improvement of safety and convenience through reform and improvement.

## **2. Revitalization of research and development of pharmaceuticals and medical devices**

(“Super special zone”)

\*Regarding the idea of “a special zone for cutting-edge medical development (“super special zone”)”, which was proposed by expert members of the Council on Economic and Fiscal Policy at its meeting on March 18, this should be implemented as soon as possible and, among other things, the priority implementation of clinical trial consultations and reviews, and the promotion of use of medical device prototypes in clinical research.

(Promotion of international joint clinical research)

\*Increase the number of cases of the implementation of international joint clinical research by five times in five years by, among other things, selecting from a few to about 10 medical institutions to serve as centers of international research, establishing a setup whereby they each collaborate with cooperative medical institutions in Japan and overseas, and ensuring thorough international consistency with regard to good clinical practice (GCP) and so on.

\*Promote the mutual use of clinical test data in the countries of East Asia, such as China and South Korea, and endeavor to increase efficiency in the collection of cases of illness among the Japanese.

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