

Prescription Drug Market in Japan: Forecast to 2016

➤ **Research Outline**

Yano Research Institute has conducted a study on the prescription drug market in Japan with following conditions.

1. Research period: April 2008 to May 2009
2. Research targets: Pharmaceutical companies, pharmaceutical wholesalers, hospitals and clinics, pharmacies, governmental agencies, academic experts, etc.
3. Research methodologies:
Face-to-face interviews with relevant personnel were primarily employed, being supplemented by literature research.

➤ **Key Findings**

◆ **Production size for 2016 is projected at 9,162.1 billion yen (Scenario II)**

Scenario I is developed for the case of medical system reform having a large influence on pharmaceutical demands. The market size is estimated at 7,291.7 billion yen in 2008, 6,913.0 billion yen in 2012 and 7,239.3 billion yen in 2016. In this scenario the year 2012 will have the smallest production size in value. Scenario II is developed for the case of medical system reform having a loose influence on pharmaceutical demands and pharmaceutical companies having solid strength. The market size is estimated at 7,442.1 billion yen in 2008, 7,941.0 billion yen in 2012 and 9,162.1 billion yen in 2016.

◆ **Anticancer Agents Drive Market**

It is expected that patients will increase in the categories of cancer, cardiovascular diseases, mental disorder and depression, menopause and allergy considering aging society, natural and social environments and eating habit. Future expansion is anticipated in the categories of digestive organ agents, metabolism agents, antineoplastic agents, central nervous system agents, urinary organ agents, hormone agents and diagnostic reagents.

➤ **Report format:**

Published report: "Pharmaceutical Market: 10 Year Forecast 2009"

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Format: 184 pages in A4 format

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➤ Research Summary

1. Market overview

According to Pharmaceutical Production Statistics Yearbook by the Ministry of Health, Labour and Welfare, the overall market of prescription drugs increased by 2.7 percent from 1998 to 2007. By pharmacologic effect, anticancer agents largely grew by 10.1 percent. Antiallergics also increased by 6.2 percent.

The Japanese pharmaceutical market is attractive to pharmaceutical companies to a certain degree. Under the universal public insurance system, however, not every aspect is satisfactory to pharmaceutical companies.

Advantages of the Japanese pharmaceutical market include: 1) drug price revision cycle is regular; 2) covered by insurance if it is a national health insurance price listing drug; 3) placebo drugs are not many in the market as much as they are overseas; 4) parallel imports from overseas are not many; 5) high-cost medical care benefit system is implemented; 6) generic drugs are not very much popular as much as they are overseas; and 7) there are popular patent-expired brand drugs.

Disadvantages of the Japanese pharmaceutical market include: 1) high pricing is difficult; 2) review period before approval is longer than that in the US; 3) drug price reduction is applied even to new drugs in the patent period; 4) pressure to use generic drugs is increasing; 5) clinical trial cost is higher than that in the overseas markets and collecting target patients is difficult; and 6) drug lag is marked.

Although the market environments are becoming severer, the needs for excellent pharmaceuticals have not dropped, if anything, demands are expected to increase in the globalization process.

2. Notable trends

The Federation of Pharmaceutical Manufacturers' Association of Japan (FPMAJ) is proposing new National Health Insurance price system for establishing a "new drug of price revision grace" category excluding on-patent blockbuster drugs from the targets to revise drug price in return for their accepting immediate replacement with generic drugs after patent expiration. If such system is implemented, patent-expired brand drugs will face the difficulty in maintaining the current revenue level. Therefore, the pharmaceutical companies whose main revenues are from patent-expired brand drugs would be forced to merge with other companies or withdraw from the market unless they are able to launch new promising drugs if the new system is introduced in 2012 as FPMAJ suggests.

However, it is doubtful if the framework to replace patent-expired brand drugs with generic drugs can prevail easily in a short period in Japan. At least five to ten years or even longer period may be required. This is because the Japanese market needs a certain time to adjust in terms of the responses of physicians and pharmacists to generic drugs and the maturity of generic drug manufacturers. In addition, the prices of patent-expired brand drugs fall as price revisions are repeated in the current system and thus it offers reliable drugs developed by new drug manufacturers at reasonable prices although they are not as low as those of generic drugs.

Considering these factors, Yano Research Institute has proposed three-layer structure of pharmaceutical category. The first layer is of on-patent new drugs; the second layer is of off-patent new drugs or patent-expired brand drugs; and the third layer is of generic drugs. This method is for moratorium period to be reviewed in ten years, which would give time for pharmaceutical companies that depend on patent-expired brand drugs to decide future directions and strategies. Furthermore, physicians and pharmacists are prepared to reduce reluctance toward generic drugs and the quality of generic drugs will improve in the meantime. The Ministry of Health, Labour and Welfare would also be able to achieve an increase in quantity by more than 30 percent by 2012.

3. Future prospects

Patients are expected to increase in the categories of cancer, cardiovascular diseases, mental disorder and depression, menopause and allergy considering aging society, natural and social environments and eating habit. Under this situation future expansion is anticipated in the categories of digestive organ agents, metabolism agents, antineoplastic agents, central nervous system agents, urinary organ agents, hormone agents and diagnostic reagents. The total cardiovascular agents market is expected to show a gradual

growth as generic drugs will increase although blockbuster products may appear among newly launched pharmaceuticals.

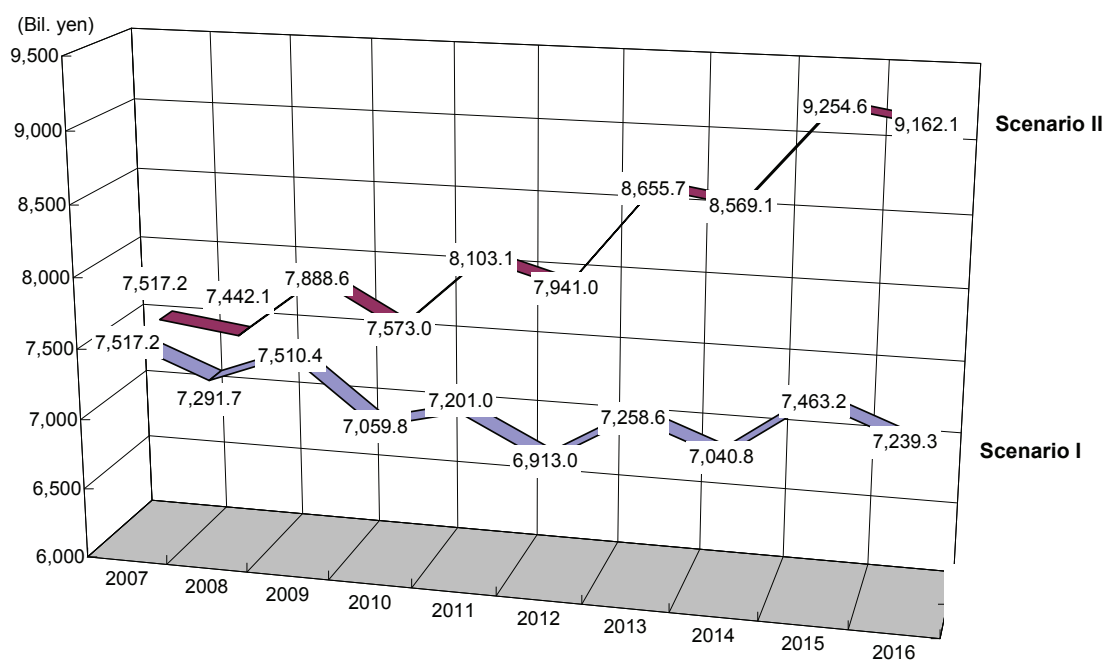
The Japanese pharmaceutical market does not experience year-on-year steady growth as it undergoes drug price revision once in two years, however, it is easy to make future market projection unlike the US market where severe competition for obtaining market share occurs among generic drugs and drug prices are lowered once exclusive sales is over upon patent expiration. But it is difficult to forecast the rate of reduction in 2010 when next drug price revision is made as the difference between list price and actual price is largely increasing. The reduction may go up to double-digit rate, which has a large influence on future projection.

Moreover, the new drug price system that has been proposed by FPMAJ is now discussed at the drug price study group of Central Social Insurance Medical Council. The discussion results may largely affect the future pharmaceutical market situation.

Yano Research Institute forecast 2008 to 2016 production sizes of prescription drugs, including import products, based on definite figures in 2007 in two scenarios. Presuppositions for the forecast are: 1) drug price revision is conducted once in two years; 2) governmental policy to reduce medical cost continues; 3) drug price system will be reviewed; and 4) adjustment margin will be maintained.

Scenario I is developed for the case of medical system reform having a large influence on pharmaceutical demands. The market size is estimated at 7,291.7 billion yen in 2008, 6,913.0 billion yen in 2012 and 7,239.3 billion yen in 2016. In this scenario the year 2012 will have the smallest production size in value. Scenario II is developed for the case of medical system reform having a loose influence on pharmaceutical demands and pharmaceutical companies having solid strength. The market size is estimated at 7,442.1 billion yen in 2008, 7,941.0 billion yen in 2012 and 9,162.1 billion yen in 2016.

[Prescription Drug Production Forecast]



Scenario I: The case of medical system reform having a large influence on pharmaceutical demands

Scenario II: The case of medical system reform having a loose influence on pharmaceutical demands and pharmaceutical companies having solid strength.

Estimated by Yano Research Institute Ltd.

* The scenarios are projected based on the production value in Pharmaceutical Production Statistics Yearbook by the Ministry of Health, Labour and Welfare.

* The figures for 2008 and after are forecast.

* Incl. imports.