

# Facing a Turning Point

Japan's postwar welfare policy of promoting public welfare spurred medical demand, and the government's protectionist stance towards domestic industry created stable high earnings for the pharmaceutical industry. Recent policy changes, however, have brought the industry's business climate to a turning point.

In 1981, as boosting national medical costs became a major financial problem, the government instituted price restraints on pharmaceutical products. Since then, prices for medicines have fallen. Nevertheless, the pharmaceutical industry has enjoyed a stability in profits unmatched by any other manufacturing industry and the difference in price between domestic and foreign pharmaceuticals has become an issue. These profits are due to the health insurance system which sets no limits on cumulative payments for medicines but instead reimburses for whatever medicine is used. Under this system, profits stem from the related shift in usage to higher priced medicines (with the same effect), and adjustments in the kinds and quantities of medicines used. In reaction to these trends, it is expected that there will be an increase in the imposition of spending ceilings and lump-sum payments, especially for the treatment of hospitalized elderly people.

In 1993 the Ministry of Health and Welfare began recommending expanded use of late-comer products, cheaper versions of previously developed products. These specially protected products will see a

rise in demand, especially for the treatment of the chronically ill. The MHW is also considering reducing the number of pharmaceuticals that are covered by health insurance, and requiring the insured to pay a greater portion of their medical bills. These policy trends will also affect the market for late-comer products.

Compared to the pharmaceutical research and development companies of Europe and the U.S., Japan's pharmaceutical companies do not measure up either in terms of added value or productivity. There are therefore two reasons for this difference in profitability. First, there are many competing companies in Japan, and the proportion of personnel, especially in sales, is not justified by the scale of the market. Second, because Japan is weak in R&D, Japanese companies can produce few products that would sell in a global market. The result of these two trends is the introduction and stock of products

that are inferior in terms of earnings.

Two other trends are in the offing. First, because of the difficulty of developing new pharmaceuticals in recent years, the cost of research and development may put pressure on earnings. Second, under the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, the international pharmaceutical industry is moving towards creating international standards for approval of pharmaceutical products. As barriers fall between the markets of the principal countries, Japan's testing and approval system for pharmaceutical products will likely become tougher. This is a big topic for the mid- to long-term future of Japan's pharmaceutical industry.

According to a survey by Nikkei Biotech, Japan's 1994 biotechnology market was ¥581 billion, down 4.8% from the previous year, the very first drop.

This decrease is due to the sudden shrinking of the market for Interferon as a treatment for hepatitis C. The ¥200 billion market for Interferon in 1993 dropped to ¥140 billion because of a cut in the pharmaceutical price effective April 1994, it already being administered to those in need of the medication, and because approval for use as a repeat treatment was withdrawn. The market for Interferon will likely drop to ¥100 billion in 1995, so even if other areas see growth, the market as a whole will at best stay level.

In 1994, guidelines for the use of genetic therapy and inspections were drawn up, and this spring clinical trials are expected to begin. Guidelines concerning the safety of direct applications of genetic recombination therapy are expected to be drawn up in the first half of fiscal 1995. The foundations for the future of these treatments is gradually being laid.

(Yokoo Hisaaki, senior economist)

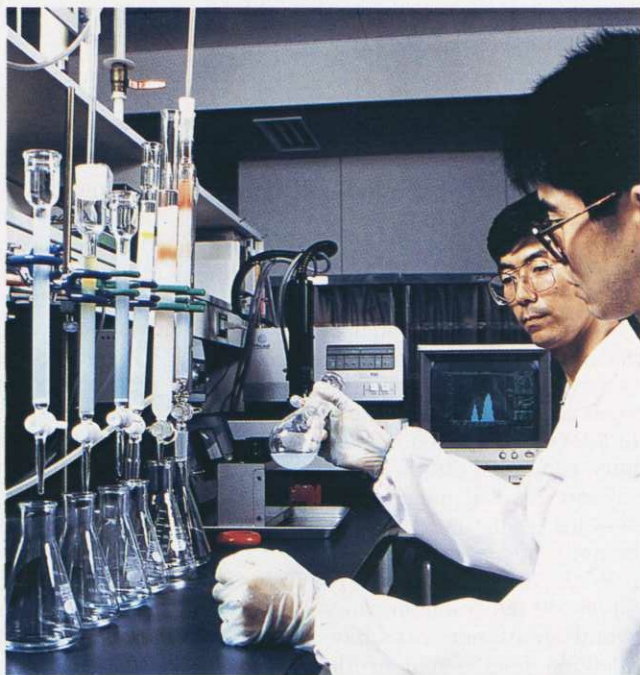


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New products under development are expected to be internationally competitive.