

Tie-in with Western Counterparts

Japanese pharmaceutical production declined 2.2% year-on-year in 1992, posting the biggest decrease ever. Manufacture of prescription drugs, which accounted for 84% of total production, declined 2.8%, with particularly sharp drops in antibiotics and vitamins and flat sales in cardiovascular, CNS and GI tract drugs.

It has been noted that the Japanese pharmaceutical market, which is the world's second largest after the U.S., has been slowing in growth in recent years, and there were no signs of this trend stabilizing in 1993. Ever growing national health care costs and efforts to contain them, also seen in Germany by the GSG and by the proposed health insurance system reform in the U.S., have been common problems among the industrialized countries. In major countries other than the U.K., competing interests of both the regulatory authorities and drug makers have come increasingly into conflict.

The impact of administrative policies on earnings are particularly serious for Japanese drug manufacturers, who, as a result of hindered entry into the international market, depend on the domestic market for 95% of their total sales. So far their earnings have remained generally strong, especially for the major companies, but some have recorded losses due to weaker sales of top-selling drugs as well as a sharp rise in research and development expenses, and the gap in earnings among companies is widening.

Japanese drug expenditures are relatively higher than in other countries: per capita expenditure on medicine in 1989 was \$245 in Japan, \$179 in the U.S. and \$98 in the EC, and as a percentage of GDP was 1.1% in Japan, 0.86% in the U.S. and 0.8% in the EC. Some challenge these figures, pointing out that there is a system of periodic price cuts



It appears likely that the pharmaceuticals industry will emphasize cooperation with U.S. and European firms for research and development and sales in the future.

by the government and so, considering actual buying power of the yen, Japanese drug prices are relatively cheap. On this, however, opinions are divided. Even if we consider the rapid aging of society, it is still fairly possible that domestic drug demand will slow even further.

Although earnings of Japanese drug manufacturers are exceptional, they are not as impressive when compared to those of foreign drug makers. Sales by Takeda, Japan's largest maker, are only about 30% of Glaxo and Merck & Co. Generally speaking, the gross value added ratio and productivity of Japanese companies are about 50% to 60%, and their operating ratio remains at around 30% to 50% of their Western peers.

Major Japanese drug makers generally carry a full line of products for marketing purposes, but many of these products are licensed from foreign producers or purchased from smaller domestic companies. Except for Yamanouchi and some other medium-standing companies, few makers fill more than 60% of their sales with their own products. Licensed or imported medicines are estimated to account for 62% of total

domestic sales. These drugs are marketed with a tremendous sales budget and sales force, trending toward less profitability for Japanese makers. However, the drug marketing system has been revised and reform measures have been underway since fiscal 1992; in line with this, marketing methods and associated systems of Japanese mak-

ers are showing signs of change. Also, the highly divided drug wholesalers have been gradually integrating.

On the other hand, in addition to the existing official drug price cuts based on the merit and market price of individual pharmaceuticals the Ministry of Health and Welfare is pursuing a new policy of regulating dosage. The new regulation is initially to be applied to those elderly patients with chronic diseases who are hospitalized for long periods of time, and then gradually expanded to those with chronic diseases or of old age but not hospitalized. Also, the excessive use of antibiotics, vitamins and nutrients, which is typical in Japanese medical treatment, is being curtailed, and markets for these products are shrinking further.

Another point to note is that utilization of generic drugs to restrain medical costs is being officially proposed for the first time. The Japanese generic drug market is estimated at about 6% of the total market, but as official prices are no different from brand name prices, their impact is limited marginally to doctors and corporations. Moreover, coordination of technical requirements for the

registration of drugs among Japan, the U.S. and the EC by the ICH will definitely affect the research and development activities of Japanese makers, as it means stricter examination of the efficacy of new drugs.

Traditional government policies tend to be protective of domestic makers and rather lenient toward questions of drug effectiveness, while encouraging drug demand by beefing up the health insurance system. Japan's anti-cancer drug market stands at \$1,531 million, exceeding the U.S.'s \$1,320 million on a simple currency translation basis. Among domestically developed anti-cancer medicines, with 50% of the Japanese market, only two products are approved for use by the FDA. Such a situation, however, cannot continue.

Like Western drug manufacturers, which are currently undergoing extensive internal restructuring and moving toward greater integration and strategic tie-ups with other companies, Japanese drug makers are henceforth likely to face unprecedented competition and restructuring. This challenge seems necessary for Japanese drug makers to develop themselves to become internationally accepted R&D companies, or to resume regional (including Eastern Asia and ASEAN countries) importance by focusing on cost-effectiveness and adapting to managed care systems.

Currently, R&D procedures for drugs are highly segmented and elaborated and advancing rapidly. As a consequence, there are fewer and fewer companies that can finance R&D with their own resources, even for the world's top players; securing R&D costs, which is being given first priority by drug makers, is becoming more difficult.

Although Japanese manufacturers traditionally have been considered somewhat inferior to their Western counterparts in their ability to develop innovative drugs or those with significant therapeutic gains, they are leading in quinoline development and recently have been increasing their expertise in various fields related to aging. Also, with the drug delivery system, Japanese makers are better equipped for differentiating between, and enhancing value-

added to, their products, as well as quickly delivering these products to the market. In the future, we believe that interdependence among major Japanese and Western drug companies will further diversify and become more strategic, and the drug industry network will rapidly develop.

Finally, we will discuss the market trend and R&D activities of Japanese bio-pharmaceuticals. In 1992, the domestic bio-pharmaceutical market grew strongly amid the weak overall drug market. It recorded ¥270 billion (\$2,163 million) on an official drug price basis, and is expected to reach ¥340 billion (\$3,063 million) in 1993. This is mainly because of the expanded application of interferon (IFN) to Hepatitis C, and consequently overall interferon sales rose 4.7 times in two years (1991 and 1992).

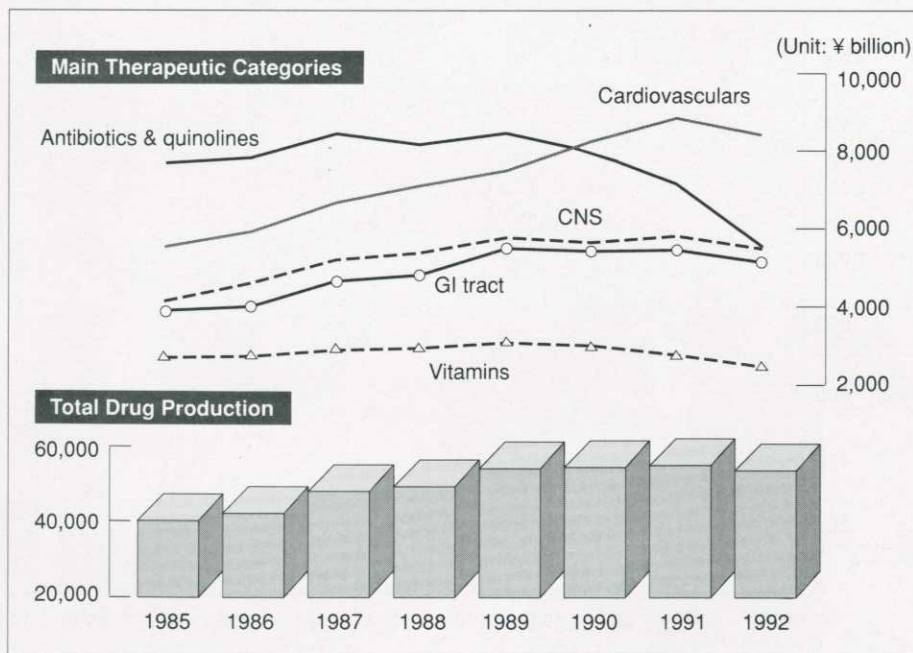
However, because of this phenomenal success, an awareness of the problem of large price gaps among different brands, due to their cost-based price settings, and of poor effectiveness arose. This

development will have a rather negative effect on the future market. A halt in TPA growth is explained by the inclination of doctors to take surgical approaches, and, in order to expand the market, it seems necessary to reexamine the question of appropriate drug dosages and the right of doctors to prescribe medicines. Also, although EPOs and G-CSFs have shown a steady growth of 14% to 16% annually, sales are largely limited to the domestic market due to patient concerns and growth is slowing.

Given that expensive drugs are likely to be avoided more in the future, the bio-pharmaceutical market appears to be at a turning point. New drugs currently under development include TNF, IL and DIC cares. They are expected to be marketed around the late 1990s, but by that time many companies, including those who entered the industry in the 1980s to diversify, are expected to have withdrawn their support.

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Growth of Main Therapeutic Categories and Total Drug Production



Source: Pharmaceutical industry production statistics, MHW