Last Updated: December 7, 2011

Rating Methodology by Sector

Pharmaceuticals

Pharmaceuticals are mainly categorized into ethical drugs, which are provided to patients by hospital pharmacies or by dispensing pharmacies outside hospitals in accordance with a doctor's prescription, and non-prescription drugs that are freely available at pharmacies and other stores without a doctor's prescription. Ethical drugs involve pharmaceutical companies who develop, manufacture, and sell pharmaceuticals, pharmaceutical wholesalers who are engaged in the distribution of the drugs, and dispensing pharmacies who directly provide the drugs to patients. This document will describe pharmaceutical companies, pharmaceutical wholesalers, and dispensing pharmacies. Pharmaceuticals in this document refer to ethical drugs.

1. Business base

Prices of pharmaceuticals (drug prices) are official prices that are set by the government and that are, in principle, revised once every two years. As a result, the pharmaceutical industry is noticeably influenced by the policy and fiscal situation of the government. As the government aims to cut drug costs, which account for approximately 30% of the nation's medical expenses, in its effort to contain the rise in these expenses resulting from the aging of society and the progress of medical technologies, the growth of the domestic pharmaceutical market has been sluggish. In response, pharmaceutical companies have been focusing on developing operations in overseas markets, where the medium-to long-term growth can be expected, particularly in recent times in emerging countries. In contrast, pharmaceutical wholesalers and dispensing pharmacies are businesses that mainly operate in Japan. The domestic market for pharmaceutical wholesalers and dispensing pharmacies is not subject to foreign competitions, but opportunities for domestic players to develop overseas operations are also limited. Pharmaceutical wholesalers have been facing declining margins for an extended period as they need to deal with pharmaceutical companies that want to keep drug prices high, and hospitals and dispensing pharmacies that want to maximize their profits from differences in drug prices. With a significant market reorganization since the late 1990s in a bid to offset falling margins with cost cutting, there are now just four pharmaceutical wholesalers. In the dispensing pharmacies segment, the market has been expanding, boosting the degree of separation of prescribing and dispensing. However, when the earnings environment becomes severe, after the effects of the separation have peaked and dispensing fees are reviewed in the future, a market reorganization similar to that which has occurred with pharmaceutical wholesalers is likely to be unavoidable.

(1) Characteristics of the industry

(i) Market overview

Japan's healthcare costs account for approximately 10% of GDP. Of these expenses, drug costs account for approximately 20%. The Japan's pharmaceutical market is the second-largest market in the world, after the United States, but growth has recently been sluggish, as it has been in Europe, the United States, and other developed countries. In contrast, the market in emerging countries, particularly in China, is growing rapidly, narrowing the gap with that in developed countries.

Globally, the growth of original drugs has been stagnant, given the expiration of a number of patents of blockbuster medicines, while the market for generic drugs has grown significantly. Compared with Western countries, Japan has been noticeably slow in expanding the use of generic drugs. However, with the introduction of policy incentives, generic drugs are likely to become more popular in the future.

(ii) Competition situation

Pharmaceutical companies, pharmaceutical wholesalers, and dispensing pharmacies face different competitive situations. The pharmaceutical companies are competing globally, as major foreign companies have been operating in the Japan for some time, and major Japanese pharmaceutical companies are also developing overseas businesses, although they have lagged their major overseas peers in this respect. Meanwhile, pharmaceutical wholesalers and dispensing pharmacies mainly operate in Japan, and there are almost no foreign companies operating in this market in Japan. As a result, the competition is limited to Japan only.

Pharmaceutical companies have to date relied mainly on original drugs for their growth. However, domestic pharmaceutical companies specializing in generic drugs are now starting to emerge, and a number of major generic drug specialists from overseas have also entered the market. As domestic companies focusing mainly on original drugs have also started to strengthen their generic drug business, the competitive landscape has become more complicated than before.

Competition among the four integrated groups of pharmaceutical wholesalers is severe. When pharmaceutical wholesalers were the group companies of pharmaceutical manufacturers, their product lineups were weighted in favor of certain products. Following industry reorganization, however, each group now handles almost a full range of products of pharmaceutical companies. These changes also meant that, because pharmaceutical wholesalers cannot differentiate themselves from their competitors in terms of their product lineups, they often engage in price competition.

Meanwhile, the market share of even major dispensing pharmacies is only a few percentage points, and there are still many small and midsize chain operators and individually managed dispensing pharmacies. However, dispensing fees are likely to be squeezed even further in the future, and as generic drugs become more popular, major dispensing pharmacies, with more influence in purchasing pharmaceuticals and a superior ability to secure and train pharmacists, develop automated dispensing operations, and control inventory are likely to increase their dominance in the market. As a result, small and midsize chain operators and other dispensing pharmacies are likely to be acquired by the major pharmacies.

(iii) Cost structure

Because the cost structures of companies that develop, manufacture, and sell pharmaceuticals are very different from those of pharmaceutical wholesalers and dispensing pharmacies that distribute pharmaceuticals, we must consider each sector separately.

Even among pharmaceutical companies, the cost structures of the companies who focus on original drugs and those that specialize in generic drugs are different. For companies focusing on original drugs, R&D expenses account for a large portion of business costs. It takes years of R&D and very large investments before a company can launch an original drug. It takes more than a decade for a pharmaceutical company to go through all the basic research, nonclinical trials, clinical trials (Phase I through III), approval applications, screening, and approvals needed to launch a new drug. Moreover, they face the risk of the suspension or termination of the development of most candidate chemical compounds, mainly for safety reasons, as well as the risk of failures in efficacy or profitability after launch. Including R&D expenses for chemical compounds whose development was terminated, R&D expenses for one new drug can be huge. For that reason, it is important for the pharmaceutical companies to streamline expenses and improve their success rates. Often, pharmaceutical companies will acquire candidate chemical compounds externally to strengthen their drug pipelines. In these cases, the companies usually make initial lump-sum payments and milestone payments in accordance with the stage of development. It is important to note that the amount of initial lump-sum payments may be high for candidate chemical compounds that are at the advanced development stage, and are considered to have a good chance of being approved as new drugs, or that are expected to become blockbuster drugs after they are launched. Meanwhile, generic drugs are developed based on experience in the clinical use of original drugs for an extended period. As a result, generic drugs can be launched after only bioequivalence trials and other small-scale clinical trials. This in turn means that the R&D expenses of pharmaceutical companies that specialize in generic drugs are low. However, the promotion of generic drugs is often hindered by a lack of trust in generic drugs in terms of the reliability of supply, product quality, and information provision. As a result, companies that specialize in generic drugs have been boosting their production capabilities and the number of medical representatives (MRs), resulting in an increase in fixed costs.

Pharmaceutical wholesalers report operating income that is calculated by subtracting expenses from the difference between the prices of products delivered to medical institutions, such as hospitals and dispensing pharmacies, and the effective prices of products purchased from pharmaceutical companies (including rebates and other incomes). The prices of products delivered to medical institutions vary depending on the degree of competition. The logistics costs of managing sales offices, distribution centers, and other facilities and labor costs for marketing specialists (MSs) and other staff are considerable for pharmaceutical wholesalers. To deal with these issues, pharmaceutical wholesalers consolidated distribution bases and cut the number of laborers through the industrial reorganization. The pharmaceutical wholesalers have been eliminating long-standing inappropriate business practices, such as (i) long-term non-conclusion of agreements and shipments with provisional invoice prices (transactions involving the delivery of products to medical institutions even before product prices are finalized, in light of the nature of the emergency of pharmaceuticals), (ii) aggregated transactions (transactions whose prices are determined based on overall product prices, not on the prices of each product), and (iii) minus primary sales differentials. However, it is still necessary to pay attention to the aspect that, while improving the practices as mentioned above, pharmaceutical wholesalers often escalate the price competition.

Revenue for dispensing pharmacies consists of income from pharmaceuticals and technical fees. The operating income of each store is calculated by subtracting the costs of products purchased from pharmaceutical wholesalers and expenses related to the store from revenue. Major dispensing operators who can wield purchasing power tend to be able to achieve somewhat lower purchasing prices of pharmaceuticals (higher profits from pharmaceuticals). In addition, introducing equipment to streamline dispensing operations, strengthening the system of training for pharmacists and improvement in quality of pharmacists, and adopting a range of sophisticated systems for managing a drug history and inventories, are the key issues to increasing technical fees and streamlining store expenses.

(2) Important factors in market position and competitiveness

(i) Market position

Pharmaceutical companies became larger with the extensive industry reorganization that took place in the 2000s. However, even Japan’s top companies are still much smaller than major pharmaceutical companies in the United States and Europe, which went through a series of large-scale reorganizations starting in the 1990s. As a result, we focus on how strong pharmaceutical companies are in specific business sectors, and the extent of the progress they have made in developing overseas operations.

After pharmaceutical wholesalers were integrated into four business groups, each of the groups has offered an almost full lineup of products nationwide. To secure rebate allowances and bolster information provision fees, it is important to maintain reasonable market shares by establishing certain business foundations in each sales area.

Although the market share of major dispensing pharmacies is still low, the chain operators who manage large-scale operations across larger areas (nationwide) actually have an edge in negotiating the purchase of pharmaceuticals and recruiting pharmacists. Because universities with pharmaceutical faculties tend to be concentrated on major cities, small and midsize chain operators who operate in local regions are finding it difficult to secure pharmacists. If these operators, however, operate across larger areas, they can transfer pharmacists who are recruited in cities to local regions.

(ii) Earnings strength of core businesses

As for pharmaceutical companies, we value the sales trends of existing drugs, the status of the development of new drugs, and overseas development. We evaluate the sales trends of existing drugs by analyzing the medium-term profitability of each product, as we take into account the competitive status in relation to other drugs, as well as the status of the development of drugs by competitors that are expected to be launched in the near future, patent periods, the possibility of the launch of generic drugs after the expiration of the patent periods, and measures to secure market share. The basic strategies for companies mainly specializing in original drugs to compete with generic drugs are to provide information to medical institutions about the appropriate use of drugs and their safety based on accumulated clinical data, and to carry out appropriate lifecycle management (the extension of product lives mainly by adding new efficacy and improving dosage forms). With respect to R&D expenses, it is important for pharmaceutical companies to achieve the efficient use of limited management resources as far as possible by focusing on research areas that are suitable for their operations. We also pay attention to whether or not pharmaceutical companies have new drugs in the pipeline that are at different development stages of Phase I through III in a well balanced manner, so that the companies are able to continually launch new drugs, and whether or not they plan to carry out overseas development or cooperate with other companies to increase the speed of development. Overseas sales of major pharmaceutical companies account for more than 50% of their total sales, while second-tier and smaller pharmaceutical companies generally lag major companies in developing foreign operations. As little growth can be expected in the domestic market, it has become increasingly important to develop businesses overseas, where a large potential market awaits. Unless a company is well funded and possesses a full pipeline, however, it is difficult for the pharmaceutical companies to manage by themselves all processes of overseas operations from development to sales. Overseas development has so far been centered on Western countries, but it will be increasingly important in the future to develop overseas operations in emerging countries.

With pharmaceutical wholesalers, we look at factors in a comprehensive manner, including the characteristics of the areas where sales bases are established, the progress of management streamlining, the size of rebate allowances, ability to negotiate with medical institutions, price management capabilities, and information provision fees. As for the distribution of generic drugs, there are many cases where the drugs are distributed directly by companies specializing in generic drugs or by sales companies owned by such companies. However, when generic drugs come into widespread use, the role played by pharmaceutical wholesalers is expected to grow more important. As a result of an increase in the market share of generic drugs, there are concerns that the average unit prices of pharmaceuticals will fall in the future. (Prices of generic drugs are roughly 30% and 70% of those of original drugs.) As the ratio of drug-price margins of generic drugs is generally larger than original drugs, it will be important for pharmaceutical wholesalers to take the initiative in securing profits by increasing the overall sales volume.

In dispensing pharmacies, we believe that the earnings environment is likely to become more severe, mainly reflecting the revision of dispensing fees. Amid static growth in earnings from the existing stores, it is necessary to continually secure earnings by expanding the store network and increasing the prescriptions accepted in the whole store network. To open new stores, it is essential to establish a system to collect information about the commencement of the separation of the operations of medical institutions and potential properties for new stores, and to improve systems of recruiting and training pharmacists. In addition, when judging the earnings strength of new stores, we focus on standards for opening stores and investment collection plans. New stores in the past were mostly opened near hospitals and clinics. But as the separation rate increases, the potential for opening new drug stores near hospitals has been declining. As a result, major chain operators have been striving to open new stores in medical malls, facilities in which a number of clinics are operating, which have been actively developed in recent years. They are also striving to strengthen the development of drug stores that can deal with prescriptions from a wide range of unspecified hospitals and clinics. Major chain operators are also actively engaged in the purchase of stores and in M&A. In such cases, it is necessary to confirm if purchasing prices are reasonable.

(iii) Earnings strength of the diversified business

Many pharmaceutical companies were once handling drugs sold without prescriptions, nutriceutical products, agricultural chemicals, animal drugs, and chemical products, in addition to ethical drugs. However, given a more refined business focus, pharmaceutical companies are now categorized into those specializing in original drugs, those that also handle generic drugs, and those that continue to deal with OTC drugs that are sold without prescriptions, in addition to ethical drugs. With respect to companies that manage diversified businesses of generic drugs and OTC drugs, we focus not only on the profitability of these diversified businesses as individual businesses, but also on the position of such businesses in groups of relevant companies, and the present and future synergies of the diversified businesses with ethical drugs.

Pharmaceutical wholesaler groups are expanding into the pharmaceutical manufacturing business and dispensing pharmacies operations. As a result of a peaking of the recent industry reorganization, the growth potential of the core businesses has, in fact, been falling. Consequently, pharmaceutical wholesalers have been actively acquiring dispensing or establishing capital alliances with pharmacies, the final link in the pharmaceutical supply chain. When entering the dispensing pharmacies business, pharmaceutical wholesalers need to carefully maintain a sound relationship with non-group dispensing pharmacies chains, which are their customers. Still, such initiatives are likely to generate synergies with the core businesses. In addition, when management integration or business alliances are initiated with wholesalers in other industries, such as medical equipment, daily commodities, and foods, it is necessary to carefully examine synergies with the core businesses.

Dispensing pharmacies manage businesses related to generic drugs, drug stores, the dispatch and the referral of pharmacists, help doctors change jobs and provide support in opening new clinics, and offer nursing care services, among other businesses. Dispensing pharmacies are entering into businesses related to generic drugs, aiming to generate earnings that will compensate for a decline in earnings from their core businesses, due to a rising popularity in the use of generic drugs in the future. The risks involved differ depending on whether they are actually engaged in manufacturing drugs or whether they are only engaged in wholesale specializing in generic drugs. In any case, because the main customers of subsidiaries that handle business related to generic drugs are the dispensing pharmacies of the relevant dispensing pharmacy group, customers are safely secured. On the other hand, entering the manufacturing business requires investments in production facilities, and the initial costs suppress earnings, often resulting in a weaker financial situation. Meanwhile, managing drug stores can generate a certain level of synergy with the core businesses, by establishing dispensing pharmacies along with drug stores and taking other initiatives. The issue, however, is considered to be achieving differentiation with major drug store specialty operators. The business of helping doctors change jobs and open clinics is unlikely to grow in the future. However, this support is expected to generate synergies with the core business as it can strengthen ties with hospitals and clinics that issue prescriptions.

2. Financial base

(1) Earnings strength

The operating income of pharmaceutical companies is very susceptible to fluctuations in R&D expenses. Therefore, we check not only operating income, but also operating income before R&D expenses. We also strive to understand trends in earnings from major products and trends in earnings by region as far as possible. With pharmaceutical wholesalers, we monitor real operating income that takes into account purchase discounts, information provision fees, and other items that are recorded in non-operating income. We also confirm the actual status of unprofitable transactions as some medical institutions are facing management problems. In the dispensing pharmacies, we check operating income after analyzing items such as the details of dispensing fees, drug-price margins, store expenses, and profits and losses by store. We also analyze the earnings strength of the diversified business of all three sectors based on operating income by segment.

Key financial indicators:

- ■ Operating income and ordinary income
- ■ Operating income by segment
- ■ ROA

(2) Cash flow

It is important to secure cash flows to finance ordinary investments and loans. Pharmaceutical companies require funds to acquire chemical compounds for potential new drugs, and pharmaceutical wholesalers require them to invest in distribution facilities, while dispensing pharmacies use funds to open their own new stores and to acquire competitors. In addition, when heavy investment is required on a temporary basis by pharmaceutical companies to carry out M&A to develop overseas operations, or by pharmaceutical wholesalers or dispensing pharmacies to carry out M&A to develop diversified businesses, we focus on whether or not the companies have the ability to generate cash flow sufficient to rectify a temporary setback in their financial situation after such activities, and to rebuild a sound financial situation in a relatively short period.

Key financial indicators:

- ■ Operating cash flows
- ■ Investment cash flows
- ■ Ratio of interest-bearing debt to EBITDA

(3) Safety

All three sectors have a number of companies with relatively sound financial situations. In contrast, some companies that have made large acquisitions and sizable investments in new businesses have been left with weaker finances. Because pharmaceutical companies are likely to aggressively develop overseas operations and undertake large-scale M&A to secure new drugs, while dispensing pharmacies will be engaged in comprehensive industry reorganization in the future, the financial strength of individual companies will produce differences in their medium- to long-term growth.

Key financial indicators:

- ■ Interest-bearing debt
- ■ Shareholders' equity and Equity ratio
- ■ Debt equity ratio

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