

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 over-the-counter (OTC) 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 (National Health Insurance (NHI) drug prices) in Japan are official prices that are set by the government and are revised every year. 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 in its effort to contain the rise in the nation's medical 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. In contrast, pharmaceutical wholesalers and dispensing pharmacies are businesses that mainly operated in Japan. While there is almost no entry of foreign companies into the domestic market, overseas expansion of domestic companies is also limited to a few. Pharmaceutical wholesalers are caught between pharmaceutical companies that want to maintain the drug prices and hospitals and dispensing pharmacies that want to earn larger gains from differences between the selling prices and purchase prices, and their margins tend to decline. With a significant market reorganization since the late 1990s in a bid to offset falling margins with cost cutting, there are now roughly four pharmaceutical wholesaler groups. The dispensing pharmacy market has matured, as the separation of prescribing and dispensing drugs has been widely spread. The profit environment has become more difficult due to the revision of dispensing fees.

(1) Characteristics of the industry

(i) Market overview

The size of the global pharmaceutical market exceeds 200 trillion yen and is expanding. The size of the Japanese market is about 11 trillion yen and is growing slowly. In recent years, drug discovery methods have been diversifying, and in addition to small molecule drugs and antibody drugs, gene therapy and cell therapy have been put to practical use, and their presence is increasing. Generic drugs are becoming increasingly

popular around the world, including Japan, and original drugs that have reached the end of their sales exclusivity period are to be basically replaced by generic drugs.

(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 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 the Japanese markets. As a result, their competition is limited to Japan only.

In the pharmaceutical companies, rather than competition among companies, there is competition among drugs for the same indications, and drugs with better evidence are more competitive. Therefore, it is important to be the first to launch a drug among candidate chemical compounds with the same mechanism of action, or to launch a drug with higher efficacy. Generic drugs are difficult to be differentiated by evidence, and the larger the sales scale of an original drug, the more likely they are to be launched by many companies, so competition is more intense.

Competition exists among the four integrated groups of pharmaceutical wholesalers. 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. As pharmaceutical wholesalers cannot differentiate themselves from their competitors in terms of their product lineups, they often engage in price competition. Although the "Guidelines for the Improvement of Commercial Transaction Practices of Ethical Drugs for Manufacturers, Wholesalers, and Medical Institutions/Pharmacies" issued by the government have been used to ensure appropriate price formation, it is necessary to keep an eye on this trend. In addition, in recent years, an increasing number of products are being handled by pharmaceutical companies with limited wholesalers. These are drugs that require special management, and the accepting these products requires comprehensive capabilities, including logistics and price management functions.

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 mom and pop dispensing pharmacies. However, dispensing fees are likely to be squeezed even further in the future, and major dispensing pharmacies, with more buying power of 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

Since the cost structures of pharmaceutical companies that develop, manufacture, and sell pharmaceuticals are very different from those of pharmaceutical wholesalers and dispensing pharmacies that distribute

pharmaceuticals, let's take a look at each sector.

Even among pharmaceutical companies, the cost structures of the companies who focus on original drugs and those that specialize in generic drugs are different. Generally, the manufacturing cost of original drugs is small relative to the drug price, making it easy to secure gross profits. However, companies focusing on original drugs need to spend a large amount on R&D expenses. 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, the majority of candidate chemical compounds have had to be discontinued or suspended due to safety, efficacy, and post-launch economics. 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 in-license candidate chemical compounds from externally to strengthen their drug pipelines. In these cases, the companies usually make contractual upfront payments and milestone payments in accordance with the stage of development. The amount of contractual upfront payments tends to be large for candidate chemical compounds that are at the advanced development stage, i.e., are considered to have a good chance of being approved as new drugs, or that are expected to become large successful drugs after they are launched. Meanwhile, as generic drugs are developed based on experience in the clinical use of original drugs for an extended period, the R&D expenses of pharmaceutical companies that specialize in generic drugs are low. However, generic drug prices are low and the weight of manufacturing costs is high, making it difficult to secure gross profits. The fixed cost burden for stable supply and other purposes is also heavy, so accurate cost management is important.

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 others). The prices of products delivered to medical institutions vary depending on the degree of competition among peers. Based on the Guidelines for the Improvement of Commercial Transaction Practices of Ethical Drugs for Manufacturers, Wholesalers, and Medical Institutions/Pharmacies, issues including the following have been improved: (i) continual delivery without price agreements (transactions involving the delivery of products to medical institutions even before product prices are decided, in light of the nature of the emergency of pharmaceuticals); (ii) bundled transactions (transactions whose prices are determined based on the overall transactions, not on the prices of each product); and (iii) negative margin (wholesalers' selling price to medical institutions and pharmacies are lower than their purchase prices from manufacturers), and price competition has become more moderate than in the past. The logistics costs at sales offices, distribution centers, and other facilities and personnel costs for marketing specialists (MS) and other staff account for large portion of expenses for pharmaceutical wholesalers. Through the industry reorganization to date, streamlining have been promoted and there is less room for cost reduction.

Revenue for dispensing pharmacies consists of drug fee and technical fee. 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 this revenue. Major dispensing chains who can exert buying power are able to relatively lower their purchase prices (expansion of gains from differences between the selling prices and purchase prices). In addition, introducing equipment to streamline dispensing operations, strengthening the system of training for pharmacists and improvement in their quality, and sophistication of various systems such as those for managing a drug history and inventories, are important to increase technical fees and streamline store expenses.

(2) Important factors in market position and competitiveness

(i) Market position

JCR focuses on how strong pharmaceutical companies are in specific areas, and the extent of the progress they have made in developing overseas operations. Pharmaceutical companies with a large presence in a specific area are more likely to be able to secure excellent human resources in that area, and also have an advantage in in-licensing and co-development of candidate chemical compounds. Companies with global sales channels and development sites are more likely to maximize profits from a single product.

Although the four integrated groups of pharmaceutical wholesalers now operate nationwide with almost full lineup of products, it is important to build a certain business base in each operating region and secure a reasonable market share from the perspectives of securing rebates and allowances and expanding fees from information provision.

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. As 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

For pharmaceutical companies, it is important to consider whether they produce good drugs, maximize profits from the drugs they produce, have a large number of good drugs, and have candidate chemical compounds that could become their future mainstays. From these perspectives, JCR confirms sales trends of existing drugs, overseas expansion, and new drug development status. In terms of sales trends of existing drugs, JCR analyzes the medium-term earnings strength of each product. JCR also pays attention to the degree of diversification of revenue sources. Viewing the overseas development as the foundation for maximizing product value, JCR pays attention to global sales and development systems, as well as sales trends by region. In R&D, JCR confirms factors such as the number of late-stage candidate chemical compounds that have obtained PoC (confirmation of efficacy in humans), the expected level of contribution to performance, and the schedule until launch.

For pharmaceutical wholesalers, JCR looks at factors in a comprehensive manner, including the characteristics of the areas where sales bases are established, progress of management streamlining, size of

rebates and allowances, ability to negotiate with medical institutions, price management capabilities, and information provision fees. While the reduction of drug prices and the spread of generic drugs are putting downward pressure on the unit price of pharmaceuticals, the increase in the volume of pharmaceuticals due to the expansion of medical needs is increasing the burden of management costs.

In dispensing pharmacies, experiencing sluggish earnings growth from the existing stores, it is necessary to expand the store network and increase the prescriptions filled in the whole store network to continually secure earnings. In determining store development capabilities, JCR confirms the dispensing pharmacies' information collection system for potential properties for new stores, pharmacist recruitment and training system, store opening criteria, and investment recovery plan. JCR also pays attention to the store formats such as "pharmacies right outside hospitals or clinics," which are opened in the vicinity of hospitals or clinics, "pharmacies accepting prescriptions from an unspecified number of hospitals or clinics," and "pharmacies within the premises of hospitals or clinics," which were deregulated in 2016. When engaging in purchase of stores and M&A, it is necessary to pay attention to whether the acquisition price is appropriate.

(iii) Earnings strength of diversified business

Many pharmaceutical companies were once handling over-the-counter (OTC) drugs, nutritional supplements, agricultural chemicals, animal drugs, in addition to ethical drugs. However, as a result of selection and concentration of business, companies can be divided into those that specialize in original drugs, those that are also involved in generic drugs, and those that continue to engage in OTC drugs in addition to ethical drugs. With respect to companies that are also engaged in generic drugs and OTC drugs, JCR focuses not only on the earnings strength of these individual businesses, but also on their positions in the group and the synergies with other businesses.

Pharmaceutical wholesalers are developing pharmaceutical manufacturing, dispensing pharmacy, digital services, etc. as a group. As the industry reorganization has reached a stage of resting place and the market has matured, the room for growth in the core business has narrowed, and securing earnings in peripheral businesses is important. Since many of these businesses in general utilize the operating base of core business, JCR believes that synergies are expected to be easily achieved. However, when they enter into the dispensing pharmacies, it is necessary to pay attention to the maintaining relationships with the dispensing pharmacy chains outside the group, which are their customers. In addition, the movement toward business integrations and business alliances across industries, such as those with medical equipment wholesaling, daily necessities wholesaling, and food wholesaling, should be carefully evaluated for synergies with the core business.

Dispensing pharmacies are also engaged in generic drug related businesses, retailing of cosmetics, etc. In cases of generic drug related businesses, there is a difference in business risk between those that have expanded into the manufacturing field and those that remain as wholesalers specializing in generic drugs. In both cases, however, the generic drug related subsidiary's main customers are their own group's dispensing pharmacies, and sales are likely to be stable. In the cosmetics and other retail business, it is important to differentiate their product lineups from those of major drugstores.

2. Financial base

(1) Earnings strength

The operating income of pharmaceutical companies is very susceptible to fluctuations in R&D expenses. Therefore, JCR looks at not only operating income, but also operating income before R&D expenses. JCR also tries to understand trends in earnings from major products and trends in earnings by region as much as possible. For pharmaceutical wholesalers, JCR looks at operating income after understanding fee revenue and others. In the dispensing pharmacies, JCR looks at operating income after understanding items such as the details of dispensing fees, gains from differences between the selling prices and purchase prices, store expenses, and profits and losses by store in the core business. JCR also analyzes 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 generation capacity

It is important to secure enough cash flows to finance investments and loans on a normal basis, such as in-licensing of candidate chemical compounds for pharmaceutical companies, investments in distribution facilities for pharmaceutical wholesalers, and opening of their own new stores and acquisitions of competitors for dispensing pharmacies. In addition, when heavy investment is required on a temporary basis by pharmaceutical companies to conduct M&A to develop overseas operations, or by pharmaceutical wholesalers or dispensing pharmacies to conduct M&A to develop diversified businesses, JCR focuses on whether or not the companies have sufficient cash flow generation capacity to restore its financial structure in a relatively short period of time, even if their financial structure is temporarily deteriorated.

Key financial indicators:

- Operating cash flow
- Investment cash flow
- Ratio of interest-bearing debt to EBITDA

(3) Safety

All three sectors have a number of companies with relatively sound financial situations. However, some companies that have made large M&A deals or large investments in new businesses have been left with weaker finances relative to past years. Goodwill and intangible assets tend to become large for pharmaceutical companies due to their large-scale M&A to expand overseas operations or to secure new drugs, and for dispensing pharmacies due to the full-scale industry reorganization. JCR also pays attention to the risk of impairment of these assets and their balance with their equity capital.

Key financial indicators:

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

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