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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Japan

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Japan --

1. Introduction

1. Pharmaceuticals in Japan are largely divided into prescription drugs[1] and over-the-counter drugs[2] (hereinafter OTC drugs). The former are available by prescription of doctors or dentists, and end consumers purchase them at medical institutions or pharmacies (hereafter, "pharmacies, etc.") based on prescriptions from doctors or dentists. OTC drugs may be purchased directly at pharmacies, etc. and do not require prescriptions from doctors or dentists. In 2011, prescription drugs accounted for approx. 93% of the overall pharmaceutical market (in terms of shipment values in Japan), while OTC drugs constituted approx. 7%. Thus, prescription drugs comprise the majority in the market.

2. In Japan, the majority of prescription drugs are covered by the national health insurance system which is operated with insurance premiums collected from citizens. Under this system, end consumers are charged only 30%[3] of the price of each prescription drug they purchase, in principle, the rest being covered by the health insurance. To ensure the quality, efficacy, and safety of pharmaceuticals, the government imposes necessary regulations on the respective phases of the development, approval, manufacture, distribution, and use of drugs.

3. This contribution paper focuses on the wholesale and retail of prescription drugs among the distribution of pharmaceuticals. The paper outlines the regulations, the current situation of the market, the measures taken by the Japan Fair Trade Commission (JFTC), and regulatory reform trends in the field of pharmaceutical distribution. Finally, the paper refers to generic drugs.

2. Regulations in the field of prescription drug distribution

4. In relation to the distribution of prescription drugs, there are numerous regulations on the retail of the drugs, while there are only a few regulations on their wholesale.

2.1 Regulations on the retail of prescription drugs

2.1.1 Regulations on the establishment of business

5. The establishment of a pharmacy (i.e., a retail store for pharmaceuticals) requires the approval of the governor of the prefecture where it is located, and this approval needs to be renewed every six years

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1 Defined as the pharmaceuticals that are supplied for use by doctors or dentists or for use on the basis of prescriptions or instructions issued by these health care professionals (Notification No. 481 of the Director-General of the Pharmaceutical Safety Bureau, Ministry of Health and Welfare dated April 8, 1999)

2 Defined as the pharmaceuticals other than those treated as prescription drugs (Notification No. 481 of the Director-General of the Pharmaceutical Safety Bureau, Ministry of Health and Welfare dated April 8, 1999)

3 The rate is 20% for children under the starting age of compulsory education, 20% for people aged 70 to 74 (30% for those in this age group whose income level is the same as that of active workers), 10% for people aged 75 or older (30% for those in this age group whose income level is the same as that of active workers). However, currently the rate for people aged 70 to 74 has remained 10% since April 1, 2008.

after its establishment. Currently, there is no regulation that imposes restrictions on the locations where pharmacies are established[4].

6. No special permission is required for the provision of prescription drugs by medical institutions. As with pharmacies, there is currently no regulation that imposes restrictions on the locations where medical institutions are established.

2.1.2 Regulations on sales methods

7. When pharmacies sell prescription drugs on the basis of prescriptions from doctors, etc., they must be sold face to face by pharmacists.

8. For medical institutions, there is no specific legal restriction on sales methods. Prescription drugs are to be provided directly to patients within each medical institution on the basis of prescriptions.

2.1.3 Price regulations

9. The sale prices of prescription drugs covered by the health insurance system (the prices of drugs delivered from medical institutions or pharmacies to end consumers) are specified by the State (the Minister of Health, Labour and Welfare) in accordance with the National Health Insurance Drug Price Standard (hereinafter "drug price standard")[5].

10. The Ministry of Health, Labour and Welfare sets the drug price standard based on the principle of compensating the average purchase cost of drugs by medical institutions. The ministry revises the drug prices about every other year after conducting a survey of the market wholesale prices of drugs (drug price survey) to reflect them in the drug price standard accurately.

2.2 Regulations on the wholesale of prescription drugs

2.2.1 Regulations on the establishment of business and sales

11. A wholesale license is required to sell prescription drugs to pharmacies, etc. Wholesalers must not sell prescription drugs to parties other than pharmacies, etc.

2.2.2 Price regulations

12. There is no specific regulation on the wholesale prices of prescription drugs. Price formation in prescription drug distribution will be discussed in section 3.3.4 below.

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4 In the past, the Pharmaceutical Affairs Act used to impose a certain degree of distance restriction concerning the locations for establishing pharmacies, with the aim of reducing the number of areas with no or extremely small numbers of pharmacies. In 1975, however, the Supreme Court ruled that imposing restrictions on the establishment of pharmacies in areas with a high density of pharmacies went against the constitution, because the method is not compatible with the purpose (i.e., eliminating no-pharmacy area).

5 This price standard shows the standard prices of each type of drugs appropriate for treatments covered by health insurance. The standard prices are set by the State. There are two methods for setting a drug price standard. One is to set the standard for each brand of drugs, and the other is to set standards by giving names to drugs based on their ingredients, formulations, and standards (generic names). The former method is applied as a general rule.

2.3 Drug price margin

13. Since the drug price standard is set by the Ministry of Health, Labour and Welfare based on the principle of compensating the average purchase prices of drugs by pharmacies, etc., it is not assumed that pharmacies, etc. gain profits from the sale of prescription drugs. In actual trades of the drugs, however, trade terms such as the purchase volume differ among pharmacies, etc. so that the purchase prices (wholesale prices) are not uniform but may vary. For pharmacies, etc., this results in a difference between a selling price (retail price) and the purchasing price (wholesale price). This difference is called the drug price difference. Because the drug price difference results in the profit for pharmacies, etc., it is also called the drug price margin.

3. Current situations of the pharmaceutical distribution market

3.1 Separation of dispensing and prescribing functions

14. The separation of dispensing and prescribing functions means that doctors or dentists give prescriptions to patients, and pharmacists dispense drugs according to the prescriptions. The separation is aimed at dividing work between doctors or dentists and pharmacists in an attempt to improve the quality of the healthcare services provided to citizens.

3.2 Progress in the separation of dispensing and prescribing functions

15. In 1956, the Act on Partial Amendment of the Medical Practitioners Act, Dentist Act, and Pharmaceutical Affairs Act (the so-called law for the separation of dispensing and prescribing functions) came into effect, making it mandatory for prescriptions to be issued by doctors, etc. However, the separation of the dispensing and prescribing functions did not make much progress after this law came into effect. It was pointed out that one cause of this problem was medical institutions' intention to profit from the drug price margin, which was substantial in amount. In response, the medical fee reimbursement system was revised repeatedly, as well as the revisions of the drug price standard setting method, to reduce the drug price margin.

16. These measures led to the progress in the separation of dispensing and prescribing functions. The rate of the separation of dispensing and prescribing functions[6], which was 11.3% in fiscal year 1989 when the drug price difference was greater than 20%, increased to 65.1% in fiscal year 2011 when the drug price difference had been reduced to less than 10%.

3.3 Market Structure of the field of prescription drug distribution

3.3.1 Market size and degree of concentration

17. The turnover of prescription drugs in the overall prescription drug wholesale industry was 7656.8 billion yen in fiscal year 2006 and 8678.2 billion yen in fiscal year 2011. As for the degree of concentration of sales, 5-firm concentration ratio was 73.3% as of fiscal year 2011. This high concentration is attributed to a series of mergers and acquisitions that had been undertaken in the expectation of improved economic efficiency and other benefits created by economies of scale, to respond to changing institutional factors such as the progress in the separation of the dispensing and prescribing functions and the drug price reduction. In fact, the degree of concentration in the prescription drug wholesale market has been increasing, as shown in the table below.

[6] Rate of separation of dispensing and prescribing functions (%) = $\frac{\text{Number of prescriptions to pharmacies}}{\text{Number of prescriptions issued to outpatients (total)}} \times 100$

Category	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011
5-firm concentration/ ratio	59.8%	64.0%	65.3%	68.2%	73.4%	73.3%
10-firm concentration/ ratio	71.3%	79.2%	79.6%	79.0%	83.9%	83.1%
30-firm concentration / ratio	90.5%	93.6%	94.4%	95.3%	97.4%	96.8%
50-firm concentration / ratio	98.2%	99.1%	99.3%	99.6%	99.6%	99.5%
100-firm concentration / ratio	99.9%	100.0%	100.0%	100.0%	100.0%	100.0%
Total number of surveyed companies	133	121	121	89	118	123

Source: Statistics on the Pharmaceutical and Medical Device Industry for Fiscal year 2011, Ministry of Health, Labour and Welfare

3.3.2 Distribution channel

18. Prescription drugs are sold by pharmaceutical companies to pharmacies, etc. via wholesalers or sales companies specialized in distributing generic drugs.

3.3.3 Wholesalers

19. Wholesalers of prescription drugs are diverse in terms of their form. In terms of sales territory, some wholesalers cover the entire country, while others operate only in specific areas. Some companies distribute generic drugs only. There are also cooperatives established by medical institutions for the joint purchase of prescription drugs.

3.3.4 Price formation in the distribution

20. The retail prices of prescription drugs covered by the health insurance system are set as official prices based on the drug price standard. Accordingly, the official drug prices function as the maximum wholesale prices of prescription drugs.

21. Pharmaceutical companies sell prescription drugs to wholesalers at wholesale prices and provide wholesalers with separate rebates or allowances depending on the volume of drug sales made by the wholesalers. Accordingly, the actual sale prices offered by pharmaceutical companies are lower than the wholesale prices.

22. Wholesalers negotiate the wholesale prices with pharmacies, etc. in consideration of the rebates from pharmaceutical companies and their own costs and profits.

23. Recently, it is taking a longer time to determine the prices as a result of complication of negotiations because wholesalers aim to secure a minimum profit while pharmacies, etc. attempt to secure drug price margins.

4. Measures taken by the JFTC in the field of pharmaceutical distribution

4.1 Cartels related to the wholesale of drugs (Recommendation on December 3, 2001)

24. In this case, a group of nine drug wholesalers located in Miyagi Prefecture made the following decisions concerning sales of prescription drugs to pharmacies, etc. located in the same prefecture: 1) they shall not take existing trades of individual prescription drugs with pharmacies, etc. away from each other within the group, and; 2) concerning existing trades of individual prescription drugs delivered by the respective companies to pharmacies, etc., the target rate of discounts from the drug price standard shall be around 6.6%. The wholesalers were in fact found to be selling prescription drugs to pharmacies, etc. in accordance with these decisions. Accordingly, the JFTC took a legal action against the nine drug wholesalers on December 3, 2001.

5. Recent trends in regulatory reform on the distribution of OTC drugs

25. There is no regulation on prices of OTC drugs. In terms of sales methods, sales on the internet of OTC drugs (excluding low-risk items) had been prohibited under a ministerial ordinance. In response, there was a dispute over whether or not online sales of OTC drugs should be regulated, and the Supreme Court ruled that the regulation under the ministerial ordinance was illegal (Supreme Court Decision on January 11, 2013).

26. Given this ruling, discussions were held on how to sell drugs on the internet, etc. Based partly on the results of these discussions, the Pharmaceutical Affairs Act was amended, permitting internet sales of all OTC drugs (The amendment law is scheduled to come into effect in the spring of 2014.).

27. The amendment also led to the establishment of a new category of drugs called "drugs requiring instructions". These drugs include powerful drugs and "items soon after switching", that is, those items that have just been switched from prescription drugs to OTC drugs, and therefore whose risks as OTC drugs have yet to be identified. All of these drugs must be sold face to face by pharmacists.

28. Internet sales of drugs that come under "items soon after switching" will be permitted once three years have passed after they are switched to OTC drugs and their risks have been identified, in principle.

6. Generic drugs

6.1 Regulations on generic drugs

29. As in the case of original drugs, parties intending to manufacture and sell generic drugs must obtain an approval from the Minister of Health, Labour and Welfare under the Pharmaceutical Drugs Act. To obtain the approval, the party must prove that the generic drug it intends to manufacture and sell is equal to the original drug in terms of quality, efficacy, and safety.

6.2 Distribution channels of generic drugs

30. Manufacturers sell generic drugs to pharmacies, etc. either via wholesalers, as in the case of original drugs, or via sales companies, which only distribute generic drugs. One reason for using such sales companies is that those manufacturers needed to develop distribution routes on their own in the early days after they entered the business when existing wholesalers did not accept generic drugs.

6.3 Changes in the quantity share of generic drugs

31. The proportion of the quantity of generic drugs to that of all prescription drugs traded in Japan was 16.8% in 2005. One reason for the low share of generic drugs is that medical service providers, etc. are concerned about the quality, information, stability of supply, and other elements of generic drugs.

32. The share later increased to 27.6% in 2013, due in part to government measures to promote the use of generic drugs. However, although the proportion of generic drugs has been increasing, it remains low compared internationally. Possible reasons for this difference include the fact that the abovementioned concern still remains among medical service providers, and the differences in the Japanese health insurance system compared to those of other countries.

33. The Ministry of Health, Labour and Welfare drew up a "Roadmap for further promotion of the use of generic drugs" in 2013, in which it set a new goal. Specifically, the goal is to increase the share of generic drugs (among the original drugs with generic alternatives and generic drugs) to not less than 60% by the end of March 31, 2018.