

Report on Distribution of Pharmaceuticals (Overview)

September 27, 2006
Japan Fair Trade Commission

I. Investigation Purpose and Method

Recently, national medical expense in Japan exceeds 32 trillion yen. Reducing these expenses is an urgent issue. It is also important to reduce pharmaceutical costs, which represent slightly more than 20% of medical costs.

The Japan Fair Trade Commission investigated distribution of pharmaceuticals (trade of generic drugs that are believed to contribute to reducing medical costs and joint purchasing by medical institutions collaborating for price negotiations taking advantage of scale) to provide proposals from the viewpoint of competition policies.

Specifically, the JFTC implemented questionnaires for pharmaceutical manufacturers, wholesalers and medical institutions and interviews with them.

II. Investigation

1. Structure of the pharmaceutical industry

Pharmaceutical market scale in Japan: ¥6,737.7billion (shipment amount in FY2004)
Generic drugs represent a lower share in pharmaceuticals as compared with their share in Europe and the U.S. (17% by quantity)
Manufacturers provide medical institutions with information about quality etc. through their medical representatives.

2. Business practices for pharmaceuticals

Many medical institutions feel "anxious about safety and stable supply of generic drugs and information provided about them" (84.6%).
In some examples, brand drug manufacturers provided inappropriate information about generic drugs to medical institutions.
If it is possible to select from some drugs, many consumers "always select the generic drug" or "may select the generic drug depending on the case." (96.7%)
Not many medical institutions are collaborating on joint purchasing because margins of the wholesaler are small and they cannot expect to procure at remarkably cheap prices by joint purchase (18.1% of medical institutions are involved in joint purchasing).
The main reason why medical institutions studying joint purchasing have difficulty in promoting joint purchases primarily is that the number of pharmaceutical items cannot be reduced.
Manufacturers request that wholesalers report resale prices using computer systems.

3. Evaluation and competition policies

The Ministry of Health, Labour and Welfare continuously should work for promoting generic drugs and generic drug manufacturers should eliminate concerns of medical institutions about stable supply, information provision and quality assurance.
Brand drug manufacturers' interference with generic drug trading is in violation of the Antimonopoly Act (Interference with transactions). Manufacturers should not provide medical institutions with inappropriate information about pharmaceuticals.
Prescribing or preparing generic drugs for patients, doctors and pharmacists should explain that the generic drugs are as safe and effective as brand drugs.
Wholesalers should make sales efforts such as negotiations for review of rebate or allowance payment standards with manufacturers when they purchase more through joint purchasing.
Medical institutions should have higher cost consciousness. For example, they should reduce the number of pharmaceutical items to be purchased to increase the purchase quantity per item and consider, depending on circumstance, direct purchase from manufacturers. Doctors should cooperate in reducing the number of pharmaceutical items as much as possible.
If a manufacturer restricts the resale price at the wholesaler based on information about resale prices from wholesalers, such restriction will be in violation of the Antimonopoly Act (Resale price restriction). The JFTC will continuously pay attention to the industry so that such action will not be taken.

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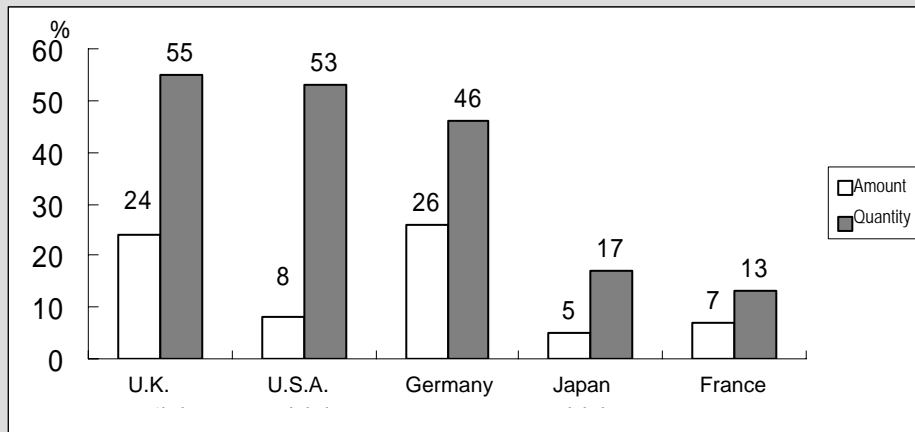
III. Overview of the Results

1. Structure of the Pharmaceutical Industry

(1) Market scale

- Pharmaceutical market in Japan: 6,737.7billion yen (shipment amount in FY2004)
- Generic drugs represent a lower share in the whole transaction amount of pharmaceuticals than their share in European countries and the U.S. (17% by quantity)

Comparison of Diffusion Rate of Generic Drugs

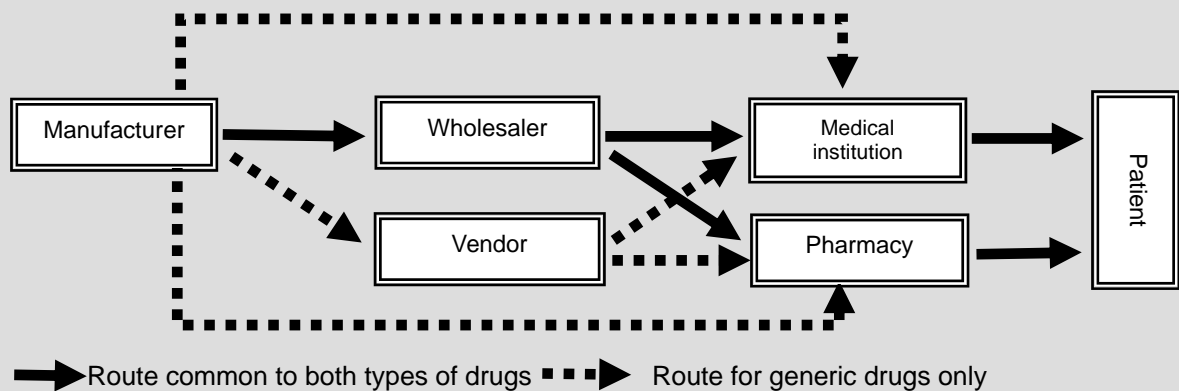


Prepared based on "On generic Pharmaceuticals" by Japan Generic Pharmaceutical Manufacturers Association
 Figures are for 2004, except the figure for the UK for 2003

(2) Distribution Route

- Brand drug manufacturers sell products to medical institutions via wholesalers. Generic drug manufacturers sometimes sell products through vendors specialized in generic drugs.

Distribution Route



- ##### (3) Manufacturers provide information about quality, effectiveness and safety of the drugs to medical institutions via their medical representatives.

2. Business Practices for Pharmaceuticals and Evaluation from Competition Policies

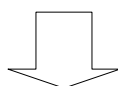
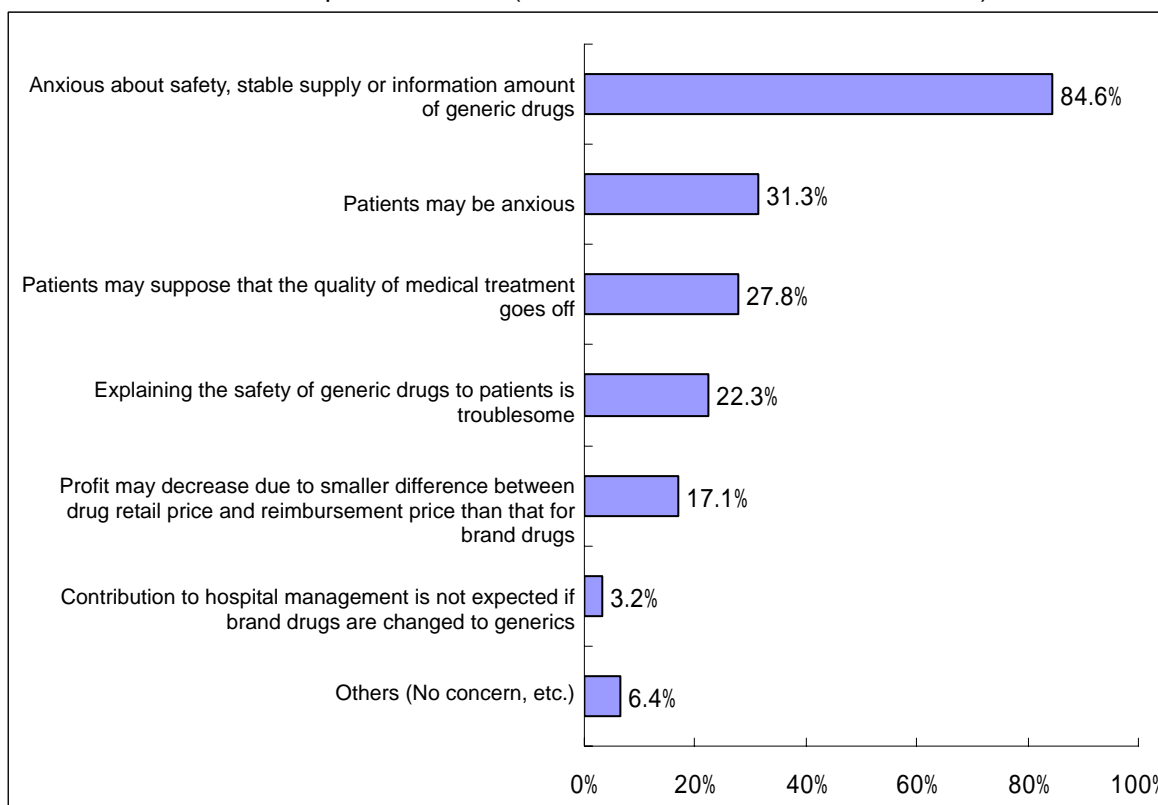
(1) Use of generic drugs

A. Medical institutions, Understanding about generic drugs

Almost all medical institutions use generic drugs. When the JFTC asked medical institutions about concerns they had before using generic drugs, medical institutions answered as shown in the table below.

Concerns before use of generic drugs (multiple answer)

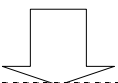
Number of valid responses 345 (Questionnaire for medical institutions)



- The Ministry of Health, Labour and Welfare continuously should work for promoting generic drugs and generic drug manufacturers should wipe away concerns of medical institutions about stable supply, information provision and quality assurance and take actions to obtain understanding about these matters.

B. Explanation about Generic Drugs by Brand Drug Manufacturers

- Provision of inaccurate information about prescription examples of generic drugs
- Information of manufacturing defects found in a particular generic drug is given to medical institutions as if it was about generic drugs in general



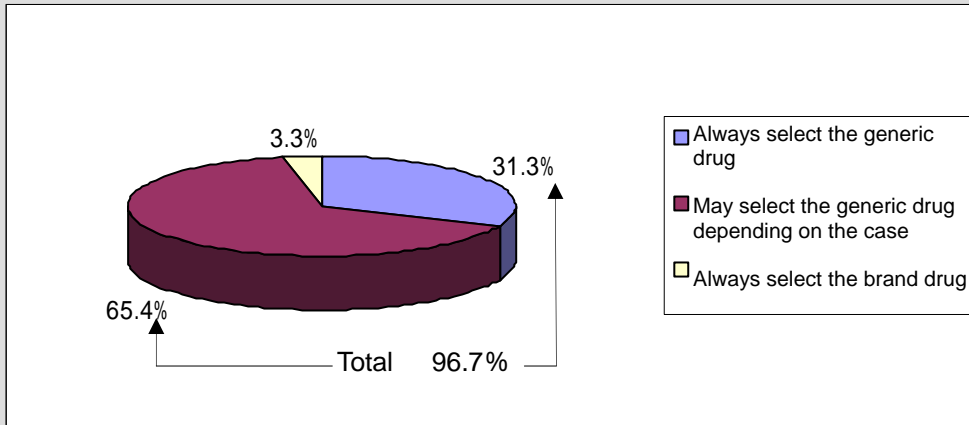
- In case, brand drug manufactures interfere with sales activities by generic drug manufacturers, it will be in violation of the Antimonopoly Act (Interference of transactions). Brand drug manufacturers should not, when providing information about pharmaceuticals to medical institutions, provide inaccurate information about prescription examples of generic drugs, or explain information about manufacturing defects of a particular generic drug as if it were about generic drugs in general, for example.

C. Consumers Selection of Pharmaceuticals

- When generic drugs or brand drugs are selectable, 31.3% of consumers always select the generic drug and 65.4% of consumers select the generic drug depending on the case.

Selection of generic drug

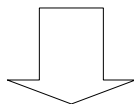
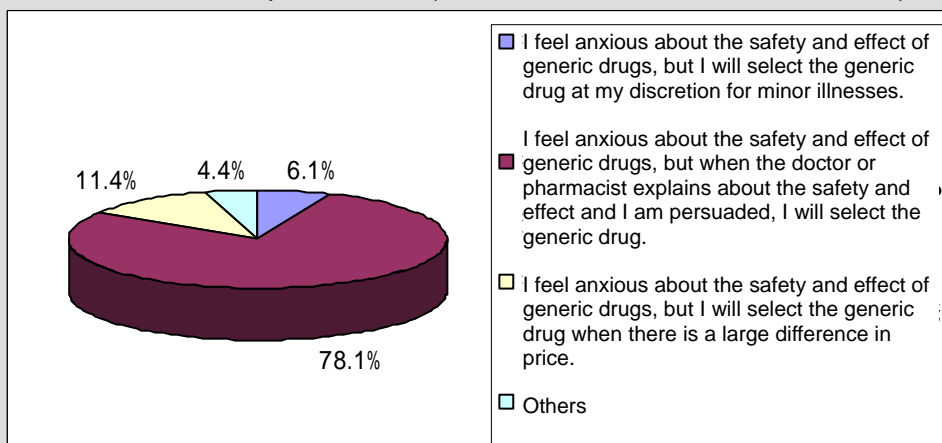
Number of valid responses: 1052 (Questionnaire for consumer monitors)



- Among the consumers who answered that they would select the generic drug depending on the case, 78.1% of consumers answered, "Though I feel anxious about the safety or effect of generic drugs, I will select the generic drug if I am persuaded by explanation about the safety and effect from the doctor or pharmacist."

When you select the generic drug

Number of valid responses: 686 (Questionnaire for consumer monitors)



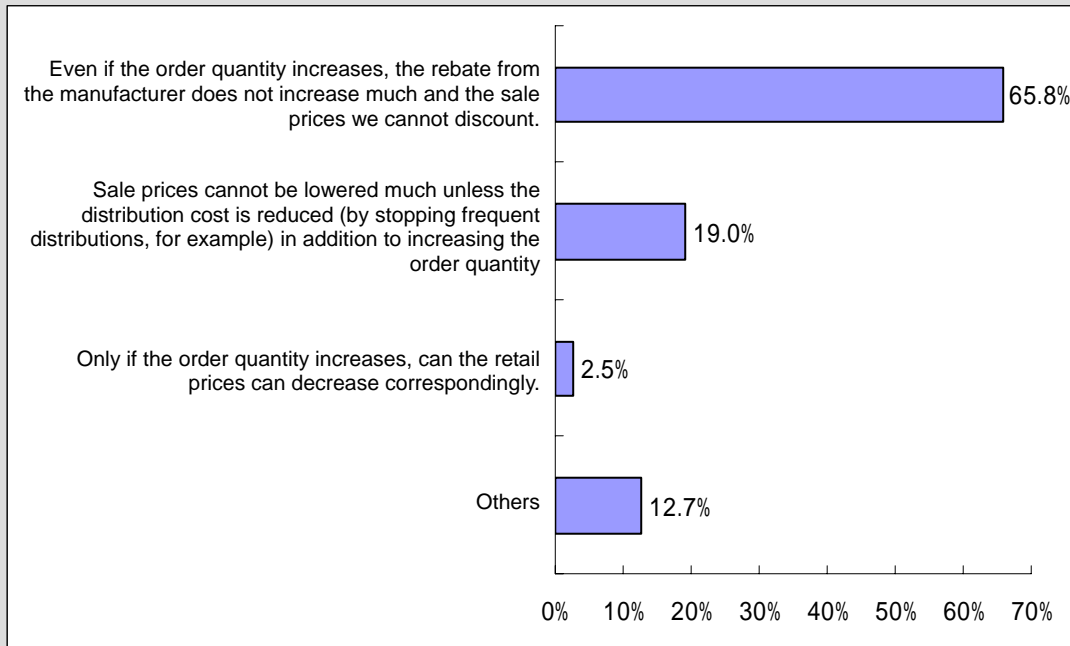
- The consumer should be able to select medications (brand drug or generic drug) as much as possible.
- Doctors or pharmacists should explain that the generic drugs are as safe and effective as brand drugs when prescribing or preparing generic drugs for patients.

(2) Joint purchase of pharmaceuticals

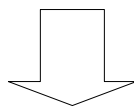
- Only a few medical institutions purchase pharmaceuticals jointly with other institutions (18.1% of medical institutions are involved in joint purchasing) (Questionnaire for medical institutions).
- 32.5% of medical institutions that do not jointly purchase pharmaceuticals answered the reason for avoiding such action as follows: "The profit of the wholesaler is said to be very little due to the invoice price system. We cannot expect procurement at significantly reduced price through joint purchase." (Same as above)
- Of wholesalers 65.8% answered as follows: "Even if the order quantity increases, rebate from the manufacturer does not increase so much and the resale prices we cannot discount."

Price setting corresponding to order quantity

number of valid responses: 79 (Questionnaire for wholesalers)



- The major reason for difficulty in promoting joint purchasing is that the number of pharmaceutical items is not reduced (indicated by responses from medical institutions)



- Wholesalers should make efforts such as negotiations for review of rebate or allowance payment standard with manufacturers when the purchased quantity increases through joint purchasing.
- Medical institutions should have higher cost consciousness by reducing the number of purchased pharmaceutical items to increase the purchase quantity per item and studying, in some cases, direct purchase from manufacturers, for example. In addition, Doctors cooperate in reducing the number of pharmaceutical items as much as possible.

(3) Trade practices between manufacturers and wholesalers

- Wholesalers obtain only a little profit.

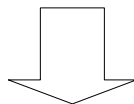
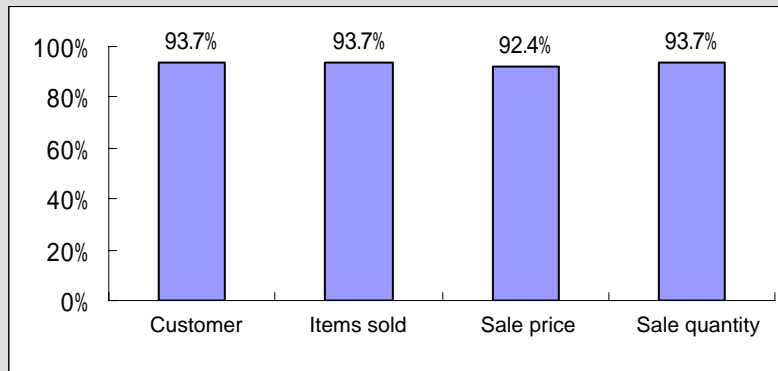
Comparison of total cost of sales and sale prices at wholesaler (example)

Mode of actual purchasing cost (a)	85 ~ 81
General and administrative expenses at wholesaler (b)	7.5
Total cost of sales (c) = (a) + (b)	92.5 ~ 88.5

Wholesalers obtain only a little profit (d) –(c)

Sale price (d)	94 ~ 87
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- 92.4% of wholesalers report sale price information to manufacturers .
Ratio of wholesalers reporting the sale prices and other information to manufacturers
Number of valid responses 79 (Questionnaire for manufacturers)



- If a manufacturer constrains the sale prices at the wholesaler based on information such as sale prices from the wholesaler, it is in violation of the Antimonopoly Act (Resale price restriction).
The JFTC will continuously pay attention to prevent such actions.