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**Competition in the Healthcare Sector – Contribution from Japan**

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More documentation related to this discussion can be found at: [oe.cd/chthc](https://oe.cd/chthc).

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## *Competition in the Healthcare Sector*

### *– Contribution from Japan –*

#### **1. Introduction**

1. In Japan, to ensure the stable supply of generic drugs, the need for industrial structural reform has been pointed out. Initiatives to advance the reform would include: 1) joint initiatives by enterprises such as collaborative research and development, joint procurement, joint delivery, and joint production; 2) business combinations for industry reorganization; and 3) prior information exchange related to these activities.

2. In February 2025, in relation to these initiatives, the Japan Fair Trade Commission (JFTC), in collaboration with the Ministry of Health, Labour and Welfare (MHLW), compiled and published examples of actions that would not violate the Antimonopoly Act.

#### **2. Generic Drugs**

3. Prescription drugs prescribed by doctors following medical consultations are classified into innovator drugs and generic drugs. Innovator drugs have patent periods during which the patent holders can exclusively manufacture and market the drugs. However, once these patent periods expire, the active ingredients become public assets, and with the approval of the MHLW, other pharmaceutical companies can manufacture and market them. Drugs sold after the expiration of the patent period of innovator drugs are called generic drugs.

#### **3. The Importance of Promoting the Use of Generic Drugs**

4. Since Japan established the universal health insurance system that allows people to access necessary medical services with a certain amount of out-of-pocket payments in 1961, Japan has achieved the longest average life expectancy in the world and a high standard of insured medical care. However, more than half a century later, the environment surrounding healthcare has significantly changed due to rapid population aging and other factors. Amid continuing financial constraints on health insurance, it is necessary to build a sustainable system that can secure necessary medical care while responding to changes in the population structure.

5. To maintain the universal health insurance system, it is important to promote efficiency wherever possible while ensuring necessary medical care, as medical expenses expected to rise further due to factors, including medical technology advancement and aging.

6. Generic drugs are approved for manufacturing and marketing as therapeutically equivalent to innovator drugs. Therefore, generic drugs can be positioned as cheaper alternatives to innovator drugs.<sup>1</sup>
7. Consequently, by promoting the use of generic drugs, it becomes possible to:
- Reduce out-of-pocket-payment for medicine, and
  - Improve healthcare efficiency (reduce medical expenses) without compromising the quality of medical care.
8. For this reason, the Government of Japan is actively committed to promoting the use of generic drugs.

#### 4. Background and Objectives of Compiling the Collection of Examples

9. Generic drugs account for approximately half of all pharmaceutical transactions by volume and around 80% in terms of usage<sup>2</sup> in Japan. They have become a vital component in supporting public healthcare. However, there has been prolonged instability in the supply of generic drugs, triggered by administrative actions taken in 2021 related to the quality issues of generic drugs and other factors such as the spread of infectious diseases.
10. It has been pointed out that the factors behind this prolonged supply instability are not limited to specific or temporary problems at individual companies, but rather stem from structural issues within the industry, including the following:
- The repeated introduction of new products has led to the expansion of low-volume, multi-product manufacturing, which brings the risk of quality defects and reduces production efficiency and profitability.
  - Many of the companies are relatively small to medium-sized, with limited production capacity and output. Consequently, their manufacturing lines have little flexibility to respond to increases in demand.
11. To address these issues, it has been proposed that overlapping products across companies be consolidated and redundant items in each company be streamlined.<sup>3</sup> This would help optimize the current low-volume, multi-product manufacturing structure, increase production capacity and scale for individual products, and establish a more sustainable and profitable production system.
12. The MHLW envisions the ideal structure of the generic drug industry as follows:
- Companies with many products and large volume shares should undertake restructuring, consolidation, and appropriate product reduction to expand their market share as well as improve productivity and profitability. By doing so, they can develop their business similar to general trading companies.

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<sup>1</sup> Innovator drugs are said to require a long development period of about 9 to 17 years, as well as tens of billions of JPY in investment. In contrast, the development of generic drugs takes less time and costs, which is why their prices are lower.

<sup>2</sup> This means the proportion of generic drug usage volume compared to the volume of all drugs that have generic equivalents.

<sup>3</sup> Study Group on the Industrial Structure for Ensuring Stable Supply of Generic Drugs, “Report of the Study Group on the Industrial Structure for Ensuring Stable Supply of Generic Drugs”, (2024)

- Domain specific companies should consolidate their products in areas of their strength and ensure stable supply at an appropriate scale that maintains productivity.
- From the perspective of optimizing excessive competition for each ingredient and ensuring stable supply, the ideal number of suppliers for each active ingredient would be approximately five. A situation where many companies enter the market and each company holds only small shares does not contribute to stable supply or productivity improvement.

13. Based on the above proposals and the systems<sup>4</sup> in the generic drug industry, it is necessary to maintain a market which has several strong competitors with sufficient supply capacity. This structure ensures alternative supply from other companies in the event one company faces supply suspension or reduction. At the same time, it is also essential to maintain fair and free competition among enterprises in the market and to protect the interests of consumers. Collaborative efforts and business restructuring aimed at achieving the stable supply of generic drugs can be compatible with maintaining fair and free competition among enterprises and protecting the consumer interests.

14. In February 2025, the JFTC and the MHLW compiled and publicized the "Collection of Examples on the Antimonopoly Act for Industrial Structural Reform to Achieve Stable Supply of Generic Drugs", based on the JFTC's views regarding the Antimonopoly Act. Building on their ongoing efforts, this publication aims to further promote initiatives by enterprises to ensure the stable supply of generic drugs, by enhancing the transparency of the application and enforcement of the Antimonopoly Act and improving the predictability for enterprises. An overview of the Collection of Examples is introduced in section 5 below.

## 5. Collection of Examples

15. This provides examples and explanations regarding enterprise initiatives in the generic drug industry for industrial structural reform, which are not considered problematic under the Antimonopoly Act. These examples include initiatives regarding business combination, information exchange, product consolidation, joint production and manufacturing outsourcing, joint procurement, joint delivery, and other forms of inter-company collaboration. This paper introduces three initiatives from the Collection of Examples: 1) business combination for industry reorganization, 2) joint production and manufacturing outsourcing (as an example of joint initiatives), and 3) prior information exchange related to these initiatives.

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<sup>4</sup> Regarding the stable supply of generic drugs, generic drugs manufactures are expected to make efforts to comply with the following: "Except in cases of justifiable reasons, they should continuously manufacture and market the products for at least five years, always maintain necessary inventory to promptly respond to orders from insurance medical institutions and insurance pharmacies, and pay attention to the stable and continuous procurement of pharmaceutical raw materials."

## 5.1. Business Combination

16. Business combinations can contribute to the stable supply of generic drugs by increasing production scale and improving production efficiency. However, any business combination that may substantially restrains competition in a particular field of trade is prohibited under the Antimonopoly Act.

17. In defining a particular field of trade, the product scope and the geographic scope must be defined based on entire business activities of the company groups participating in the business combination plan. In principle, these definitions are determined based on the substitutability of demand.

18. In the field of prescription drug, a product scope is defined from the perspective of purchasers (such as medical institutions). When purchasers consider an innovator drug and a generic drug to have the same function and efficacy, those drugs are considered to be within the same product scope. In past business combination review cases, product scopes have often been defined based on Level 3 of the ATC (Anatomical Therapeutic Chemical) Classification System.<sup>5</sup>

19. Once the particular field of trade is defined, then it is assessed whether competition may be substantially restrained within the market. Specifically, in accordance with the JFTC's Business Combination Guidelines, a comprehensive assessment is made based on not only market share but also the overall competitive conditions.

20. Generally, business combinations between generic pharmaceutical companies are often not considered problematic under the Antimonopoly Act. This is due to factors such as: 1) the market share to be considered includes that of innovator drugs; and 2) the presence of strong competitors among generic drug companies and the possibility of new market entry.

### 5.1.1. (Example) Definition of a Particular Field of Trade

21. For the generic drug A, an antihypertensive drug containing the active ingredient P, three companies X, Y, and Z manufacture and market the products  $\alpha$ ,  $\beta$ , and  $\gamma$  respectively. Company X has decided to acquire the manufacturing and marketing businesses of products  $\beta$  and  $\gamma$  from its competitors Y and Z. As a result, X's market share in the antihypertensive drugs containing the active ingredient P alone will be 20%.

22. However, purchasers (such as medical institutions) also consider other antihypertensive drugs containing active ingredients Q or R to have the same functions and efficacy. Therefore, the product scope is defined as "antihypertensive drugs containing active ingredient P, Q or R." In this broader defined product scope, X's market share will be 10%.

- [Explanation]

23. When defining a particular field of trade for prescription drugs, it is generally defined based on categories of drugs that have the same function and efficacy from the perspective of purchasers (such as medical institutions.) In this context, the distinction between an innovator drug and a generic drug is not considered relevant. In many cases, product scopes are defined based on Level 3 of the ATC Classification System. This is because, drugs under the same Level 3 category are generally considered to share common

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<sup>5</sup> Classification of drugs based on anatomical area of action, indications and purpose, chemical composition, and mechanism of action.

features in terms of area of action, therapeutic effects, mechanism of action, and purpose. Furthermore, they are deemed by purchasers to have the same functions and efficacy.

24. Prescription drug manufacturers in Japan generally possess the systems and capability to supply products nationwide. Additionally, there are no circumstances such as difficulty in transportation due to product characteristics or differences in transportation costs that would lead to price disparities. Consequently, purchasers across Japan can procure products from any manufacturers at a comparable price. Therefore, the geographic scope for prescription drug is usually defined as "the whole of Japan."

## 5.2. Joint Production and Manufacturing Outsourcing

25. For multiple products containing the same active ingredient, there are cases where pharmaceutical companies consider improving manufacturing efficiency and reducing costs not by suspending supply or delisting from the price list, but by integrating manufacturing methods or facilities. This may involve consolidating manufacturing facilities within a company or its company group. Alternatively, a company may outsource manufacturing process for the product to another company, while continuing to hold its manufacturing and marketing authorization.

26. (Example) Integration of Manufacturing through Manufacturing Outsourcing

27. Company X, which manufactures and markets product  $\alpha$  of the generic drug A, expects it will need to downscale its business for product  $\alpha$ . Consequently, X decided to discontinue in-house manufacturing of product  $\alpha$ , and outsource the entire production of product  $\alpha$  to Company Y, a competitor that manufactures and markets product  $\beta$  of generic drug A. X will retain exclusive sales responsibility for product  $\alpha$ .

28. To ensure compliance during this arrangement, X and Y have agreed to limit information sharing to the extent reasonably necessary for the outsourcing. When information concerning significant competitive measures, such as the outsourced quantity of product  $\alpha$ , is involved, the companies will establish appropriate information barriers, such as restricting information sharing solely to relevant personnel involved in the arrangement and prohibiting the use of information for purposes other than those intended. Furthermore, both X and Y will continue to conduct their sales activities independently. This arrangement is taking place in the market with competitive pressure from other strong competitors producing therapeutically equivalent generic drugs, including generic drug A.

## 5.3. Information Exchange

29. In promoting joint initiatives among companies in the generic drugs industry, the initial step will involve various types of information exchange. In the case that this information exchange leads agreement among the companies on prices, quantities, customers and distribution channels or facilities, and they mutually constrain each other's business activities in a way that substantially restricts competition in the market, it constitutes a violation against "Unreasonable Restraints of Trade."<sup>6</sup> On the other hand, there are cases where even information exchange related to important competitive factors,

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<sup>6</sup> Under Article 3 of the Antimonopoly Act, "unreasonable restraint of trade" is prohibited. This refers to cases where "such business activities, by which any enterprise in concert with other enterprises, mutually restrict or conduct their business activities in such a manner as to fix, maintain or increase prices, or to limit production, technology, products, facilities or counterparties, thereby causing, contrary to the public interest, a substantial restraint of competition in any particular field of trade."

such as production volumes or manufacturing costs, is not usually considered problematic under the Antimonopoly Act. Such cases are permissible when the information exchange is reasonably necessary for considering and implementing joint initiatives, and appropriate information barrier measures are in place to ensure that enterprises do not mutually constrain each other's business activities. Information barrier measures typically involve the limiting the scope of information exchange to personnel involved in the joint initiatives, and prohibiting the use of that information for unintended purposes.

### ***5.3.1. (Example) Information Exchange for Joint Manufacturing***

30. X, Y, Z, and other companies manufacture and market generic drug A. Among them, X, Y, and Z are considering joint manufacturing for ensuring a stable supply of pharmaceutical drugs. In the course of the discussions, the three companies have agreed to share information only to the extent reasonably necessary. Specifically, it is necessary to consider the results of analyzing information related to important competitive factors, such as the future production volumes of generic drug A for determining the scale of joint production and manufacturing costs for considering which production methods to adopt.

31. To this end, the three companies have agreed to establish a special team, either jointly among the three or within one designated lead company, which does not include personnel from the sales departments of the three companies. This special team is tasked with collecting and analyzing information related to important competitive factors from the three companies and conducting necessary evaluations.

32. The three companies prohibit the team from sharing the collected information outside the team. Furthermore, where the sharing of such information is unavoidable and necessary for internal decision making regarding the joint production framework, the information should be processed so that the identity of the source company could not be identified. The processed information is shared only with companies necessary for the relevant decision-making, without being used in the manufacturing or marketing for generic drug A.

33. In addition, to prevent the use of the collected information for concerted actions in the manufacturing and marketing of generic drug A, the three companies also have adopted sufficient measures. These measures include prohibiting the individuals involved in the decision-making process from using information received via the special team for any purpose other than the intended purpose.

## **6. Further Efforts**

34. The JFTC and the MHLW compiled the Collection of Examples with the aim of supporting efforts by enterprises to ensure a stable supply of generic drugs. This is intended to further enhance transparency regarding the application and enforcement of the Antimonopoly Act, as well as to improve the predictability for enterprises. On the other hand, whether each initiative raises problems under the Antimonopoly Act must be examined on a case-by-case basis, depending on its specific nature. The JFTC and the MHLW will encourage enterprises to proactively consult on each initiative to those authorities. Furthermore, the JFTC and the MHLW plan to review and revise the Collection of Examples as necessary, taking into account the progress of enterprises efforts, changes in the market and business activities, and the accumulation of relevant cases.