Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

13-Aug-2014

English - Or. English

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

DAF/COMP/WD(2014)53
Unclassified

Cancels & replaces the same document of 05 June 2014

GENERIC PHARMACEUTICALS

-- Note by Japan --

18-19 June 2014

This document reproduces a written contribution from Japan submitted for Item VI of the 121st meeting of OECD Competition Committee on 18-19 June 2014.

More documents related to this discussion can be found at http://www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm.

JT03361169

English - Or. English

1. Introduction

1. Pharmaceutical products in Japan are roughly divided into two categories: prescription drugs[1] and over-the-counter drugs[2] (hereinafter "OTC drugs"). Prescription drugs are further divided into original drugs and generic drugs.

2. In Japan, a generic drug is defined as a pharmaceutical product that is approved by the Minister of Health, Labour and Welfare (hereinafter "MHLW") as the equivalent product in quality, efficacy, and safety to the original drug after the term of patent protection of the original drug expires.

3. In Japan, there has not yet been any case related to generic drugs where the competition law was enforced; however, in this contribution paper, the overview of generic drug market, patents in respect to pharmaceutical products, the process of entry into the prescription drugs market, and efforts toward dissemination of generic drugs by MHLW in Japan are described below.

2. The overview of generic drug market

2.1 Market size

4. The market size of prescription drugs[3] was 7,711.4 billion yen in fiscal year 2006 and 9,560.1 billion yen in fiscal year 2012, while that of generic drugs[4] was 350 billion yen in fiscal year 2006 and 989.6 billion yen in fiscal year 2012. In accordance with the expansion of the prescription drug market (in particular, generic drug market) in Japan, the proportion of generic drugs to prescription drugs has increased in value terms (from 4.5% in fiscal year 2006 to 10.3% in fiscal year 2012).

2.2 Main manufacturers of generic drugs

5. In fiscal year 2012, regarding the market share of the generic drugs based on the domestic sales value (drug price basis),[5] Sawai Pharmaceutical Co., Ltd. ranked first (8.1%), Nichi-Iko Pharmaceutical Co., Ltd. ranked second (7.6%), Teva Pharma Japan Inc. ranked third (6.5%), followed by Towa Pharmaceutical Co., Ltd. (5.6%) and Nipro Pharma Corporation (4.7%). In addition, there were approximately 200 manufacturers of generic drugs other than the above, and their total market share accounted to 67.5% in 2012. There is no ownership relationship between leading Japanese generic drug manufacturers and original drug manufacturers except for Teva Pharma Japan Inc., which is a subsidiary of the original drug manufacturer Teva Pharmaceutical Industries Ltd. (Israel).

---

1 Drugs intended for use by a physician or dentist or under the prescription or instructions of a physician or dentist (Notification No. 481 of Pharmaceutical and Medical Safety Bureau dated April 8, 1999)

2 Drugs other than prescription drugs (Notification No. 481 of Pharmaceutical and Medical Safety Bureau dated April 8, 1999)

3 Nikkei Market Share Research fiscal year 2008 and fiscal year 2014 (Market size in the prescription drug market)

4 Nikkei Market Share Research fiscal year 2008 and fiscal year 2014 (Market size in the generic drug market)

5 Nikkei Market Share Research fiscal year 2014 (Market share in the generic drug market)

2.3 Drug price

6. The retail selling price of prescription drugs (including generic drugs) that is covered by the medical insurance system is determined by the MHLW based on the

7. *National Health Insurance (NHI) Drug Price Standard*[6]. In general, the price of generic drugs is lower than that of original drugs because it is set as a discounted price from that of original drugs. In the determination of the discounted price, the following two cases are separated depending on the situations at the time of application for approval of the generic drug prices. The first case applies to a generic drug that is going to be listed on the NHI Drug Price Standard list for the first time. In this case, the price of the generic drug is calculated by multiplying the price of the original drug by 0.6[7]. The other case refers to when there are already other generic drugs manufactured by other companies on the NHI Drug Price Standard list. In this second case, the price of the generic drug is to be the same as the cheapest generic drug listed[8].Even after the drug prices were determined once, the market wholesale prices of pharmaceutical products continue to be surveyed and, based on the survey results, the retail price of generic drugs is revised every two years.

3. Patents in respect to pharmaceutical products

8. Patents in respect to pharmaceutical products are classified into four different types: (i) substance patent (patent protection for new chemical substances), (ii) use patent (patent protection for the use of new efficacy or effect and safety of specific substances), (iii) formulation patent (patent protection for the new device on formulation such as the stabilization of the quality of pharmaceutical products), and (iv) process patent (patent protection for new manufacturing methods).

9. Original drugs have patent terms during which original drug manufacturers can exclusively manufacture and sell the products based on their patent rights. Other manufacturers cannot manufacture or sell pharmaceutical products using those protected patent during this term. Patent rights will generally be protected for 20 years from the filing date of the patent application; however, the terms of patents for pharmaceutical products may be extended for up to five years as an exception. This is because, in the case of pharmaceutical products, the term during which manufacturers actually can utilize their patents effectively may become short due to the approval procedures for the manufacture and sales under the Pharmaceutical Affairs Law (see Item 4.1.iv below), which can require a long period of time.

4. The process of entry into the prescription drugs market

4.1 The process of entry into the original drugs market

10. The manufacture and sales of original and generic drugs require various licenses and approvals (under the Pharmaceutical Affairs Law) from the MHLW. In regards to these licenses and approvals,

---

6 The national standard price for each class of drugs that is considered appropriate for the medical service covered by health insurance. A standard price is set forth for individual brands or for each ingredient/dosage form/specification under the attached name (generic name). In principle, the former method has been adopted.

7 In cases where more than ten products of generic drugs for one original drug are going to be listed on the drug price standard list, the price will be calculated by multiplying the original price by 0.5 (limited to oral medicine).

8 In cases where more than 20 products of generic drugs (10 products for oral medicine), including new generic drugs whose application is under review, for one original drug is going to be listed on the drug price standard list, the price will be calculated by multiplying the price of the cheapest generic drug by 0.9.

original and generic drugs have many requirements in common as both are considered prescription drugs. Below is the description of the process of entry into the original drugs market.

1. Pharmaceutical research and development

   An original drug manufacturer usually develops its original drugs through basic, non-clinical, and clinical studies over a decade or more. The most important process in developing original drugs is the clinical trial (a study that is conducted by testing on actual human). Clinical trials are conducted according to the protocol described in the clinical trial plan notification[9].

2. Manufacturing license for prescription drugs

   A manufacturing site or factory of prescription drug manufacturer (for each manufacturing site or factory) needs to receive permission or certification as a manufacturer of general prescription drugs under the Pharmaceutical Affairs Law from the MHLW to prove its manufacturing capability for prescription drugs.

3. Manufacturing and sales license for prescription drugs

   An original drug manufacturer needs to receive a license for general manufacturing and distribution (shipping to the market) of prescription drugs under the Pharmaceutical Affairs Law from the MHLW so that products are manufactured and sold under the condition where requirements for quality and safety of such products are met.

4. Manufacturing and sales approval for prescription drugs

   A manufacturer receives approval for manufacture and sales (shipping to the market) of individual original drugs under the Pharmaceutical Affairs Law from the MHLW to prove that there is no concern in the efficacy and safety of the individual original drugs. In the process for the approval, a manufacturer receives confirmation by the MHLW under the Pharmaceutical Affairs Law for compliance of its manufacturing process of original drugs with Good Manufacturing Practice (GMP)[10].

5. Application for listing on the NHI drug price list

   A manufacturer submits an application to determine the drug price for the original drug that was approved for manufacturing and distribution.

6. Reexamination period

   A manufacturer who developed an original drug is obliged, under the Pharmaceutical Affairs Law, to monitor the efficacy and safety of such drug for a certain period of time (generally eight years) after its launch. This period is called the reexamination period.

---

9 The plan that original drug manufacturers submit to the MHLW to request permission for medical institutions to conduct a clinical trial.

10 An Ordinance of the Ministry of Health, Labour and Welfare in respect of the manufacturing and quality control criteria of medicines and quasi-drugs.

4.2 The process of entry into the generic drugs market

4.2.1 Main differences between original and generic drugs regarding market entry process

11. To manufacture and sell generic drugs, among processes listed in Section 4.1, the following processes are required: (i) Pharmaceutical research and development, (ii) Manufacturing license for prescription drugs, (iii) Manufacturing and sales license for prescription drugs, (iv) Manufacture and sales approval for prescription drugs, and (v) Application for listing on the NHI drug price list. For generic drugs, (vi) Reexamination period does not apply. There are differences, between original and generic drugs, in processes (i), (iv), and (v), but not in (ii) to (iii).

- Difference in pharmaceutical research and development

  The development of generic drugs can be completed at lower costs and in a shorter period of time than that of original drugs because research data on original drugs is available.

- Difference in manufacturing and sales

  - The application for approval of generic drugs can be made only after the reexamination period of the original drug has ended.
  - Although the approval of original drugs requires submission of data on many study results, as listed in Section 4.1 i), that of generic drugs requires relatively small amount of data because it is sufficient for generic drugs to just prove that their quality, efficacy, and safety are equivalent to the original drug based on study results.
  - Given that a manufacturer cannot sell generic drugs during the term of patent protection for the original drug as mentioned above in Section 3, in practice, a manufacturer receives approval for manufacture and sales (shipping to the market) of individual generic drugs under the Pharmaceutical Affairs Law from the MHLW after the term of patent for the original drug has ended.

4.2.2 Ex-ante coordination for the patent dispute

12. At the point of reviewing the application for approval for the generic drug (see in Section 4.2.1 mentioned above), the MHLW verifies whether the generic drug infringes the patent of the original drug. However, there are cases that are difficult even for patent specialists to judge; for example, when it is not clear whether the original drug manufacturer has established a patent or satisfied a criterion of non-obviousness or an inventive step, the patent dispute may arise in the future. In fact, the patent dispute between original and generic manufacturers regarding infringement of a patent (e.g., a lawsuit seeking for injunction) has arisen after the launch of generic drugs. Therefore, the MHLW set forth the policy that generic drug manufacturers are urged to make a prior consultation with original drug manufacturers. The details are as follows:

- (Generic drug manufacturers should make a prior consultation with original drug manufacturers before they apply to determine the list price for the products that may cause the contestation.
- Generic drug manufacturers should report to the MHLW when the stable supply of the drug may be hindered by the dispute over a patent regarding the product whose price has already been listed.
- The MHLW may request generic manufacturers to submit, when necessary, materials that can objectively prove the capability for stable supply; for example, a written consent from patentee (i.e. original drug manufacturer).

5. Efforts toward dissemination of generic drugs by the MHLW

13. Disseminating the use of generic drugs would contribute to reducing patient's financial burden and improving the finances of the national medical insurance system. For this reason, the MHLW established the "Action Programme for Promoting the Safe Use of Generic Drugs" in 2007 and set a goal to increase the market volume share of generic drugs (among all the prescription drugs) to 30% or more by fiscal year 2012. To reach such a goal, the MHLW tackled issues such as stable supplies, quality assurance and promotion of the provision of information for generic drugs to gain more trust from patients and healthcare professionals. As a result, the market volume share of generic drugs (among all the prescription drugs) increased from 16.8% in 2005 to 27.6% in 2013.

14. To further promote the use of generic drugs, the MHLW has developed the "Roadmap for further promotion of the use of generic drugs" in 2013. In this roadmap, the MHLW revised the indicator of the market volume share of generic drugs from "all the prescription drugs" basis to the "original drugs with generic alternatives and generic drugs" basis[11] and set a new goal to increase its share to 60% or more by March 2018. To achieve this goal, the MHLW has been working to ensure reliability to stable supply and quality, enhance provision of information, revise medical fees and promote other activities with monitoring of the state of achievement. As one of these activities during the revision of medical fees in 2014, the MHLW has amended the calculation system for the NHI drug price standard for generic drugs mentioned above in Section 2.3 to further reduce the price of generic drugs[12].

[11] Market volume share of generic drugs (%)＝ (number of generic drugs / number of the original drugs with generic alternatives and generic drugs) ×100.

[12] In case that a generic drug is listed for the first time, its price is currently calculated by multiplying the price of the original drug by 0.6, in principle, instead of 0.7, which was previously used.