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**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE**

GENERIC PHARMACEUTICALS

-- Note by Chinese Taipei --

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

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1. This paper will outline the development of generic pharmaceuticals in Chinese Taipei, and address the competition issues and cases of generic pharmaceuticals that have been investigated by the Fair Trade Commission (FTC), as well as court rulings. In preparing this paper, the FTC has consulted the central competent authority of health, the Ministry of Health and Welfare (MOHW), and the patent office, the Intellectual Property Office (IPO) of the Ministry of Economic Affairs (MOEA), to obtain relevant information, and has referred to rulings of the Intellectual Property Court.

1. Overview of Generic Pharmaceuticals in Chinese Taipei

2. In Chinese Taipei, pharmaceuticals should go through the process of Drug Review and Registration, and can only be manufactured, imported or distributed after being granted a permit. The review process emphasizes safety, efficacy and quality: the safety review includes a discussion of pharmaceutical toxicity and its adverse effects; the efficacy review involves the evaluation of the therapeutic effect; and the quality review seeks sustainable and stable manufacturing and management. Generic drugs should be consistent with the original patented drugs in terms of ingredients, drug form, therapeutic effect and dosage. They should be considered as the formula and product, to which modifications are made for developing new drugs. Hence, documents regarding their safety and efficacy are not required while applying for the Drug Review and Registration. With respect to quality, applicants are required to submit the standard operational handbook for chemical manufacturing and control (the content should include controls over the physical and chemical properties of raw materials, testing specifications and methods, manufacturing processes and stability tests, etc.). A common practice in many countries is that, for generic drugs, it is not necessary to repeat all the clinical trials regarding the safety and efficacy of their active ingredients. According to international regulations, after development and production generic drugs are subject to bioequivalence tests by taking the original patented drugs as the standard control. The generic drugs and standard control are administered to the same group of subjects under the same conditions. The results should show no statistically significant differences between generic drugs and the standard control in terms of the pharmacological effects or the amount and speed of active ingredients in blood circulation or on the functioning site. The results serve as a major reference for proving the safety and efficacy of generic drugs. Such a procedure is considered adequate for clarifying consumers' concerns about generic drugs.

3. According to the statistics for pharmaceutical permits in 2012, permits for generic drugs in Chinese Taipei accounted for 82.4% of the total, of which permits for domestically made generic drugs made up 89.6% and those for imported ones the remaining 10.4%. As revealed by the data in past years, about 70% of NHI drugs are domestically-made generic drugs. Pharmaceutical supply in Chinese Taipei relies mainly on domestic pharmaceutical manufacturers. There are no trading and import barriers, or restrictions on the acquisition of generic drugs.

4. The National Health Insurance (NHI) implemented in Chinese Taipei in 1995 is a single-payer compulsory social insurance plan. The National Health Insurance Administration (NHIA) is the only insurer, and is responsible for providing medical services to all citizens. The NHI neither imposes any restrictions on the use of generic pharmaceuticals nor does it limit daily pharmaceutical expenditure. It also does not offer any financial incentives to the physicians, pharmacists, or consumers who prescribe or use the generic drugs. However, in the event where the physician does not specify that an alternative may not be used, the pharmacist shall use the lower cost pharmaceutical (including generic pharmaceuticals) to reasonably control pharmaceutical expenditure¹.

¹ Article 25, Regulations Governing the NHI Medical Care: "Where a physician does not specify that the prescribed drug or medical device cannot be substituted in a prescription, a pharmacist (assistant pharmacist) may replace the drug with a drug of another brand with the same ingredients, dosage and

1. As the separation of medicine and pharmacy has not yet been popularized in Chinese Taipei's medical market, most major hospitals provide pharmaceutical dispensing services, and directly apply for the reimbursement of pharmaceutical expenditure from the NHIA. Due to the quantity and conditions under which medical institutes procure pharmaceuticals, the actual price of pharmaceuticals will naturally vary and form a gap between the price and NHI payments. This creates the issue of whether medical institutions are making unreasonable profits from pharmaceuticals.²

2. Competition between Originator and Generic Drugs

5. As a small economy, there are many domestic pharmaceutical manufacturers in the pharmaceutical market of Chinese Taipei. Exporting pharmaceuticals has proven to be difficult and the manufacturers have relatively small scales of operation with weak research and development capability. Therefore, domestic pharmaceutical manufacturers mainly manufacture generic drugs. According to Paragraph 2, Article 31 of the National Health Insurance Pharmaceutical Benefits and Reimbursement Schedule, which states that the reimbursement price of a generic drug may not be higher than 80% of the reimbursement price of the originator, unfair competition might arise from different reimbursement prices for originators and domestic pharmaceutical manufacturers. In the light of growing expenditure on NHI drugs, the NHIA implemented the “*National Health Insurance Drug Pricing Principles*” and announced the “*Guidelines for the National Health Insurance Drug List and Payment Schemes*,” which showed the list of NHI drugs and the prices that would be reimbursed. The NHI drugs and amount of NHI reimbursements are disclosed on the NHIA website. To avoid unnecessary waste and the irrational use of drugs, the NHIA carefully reviews pharmaceutical expenditure, and utilizes cloud computing technology to integrate medical records, which are provided as reference to physicians. All these measures have been intended to improve the quality of medical care and ensure that resources are used rationally. Hence, transparent drug pricing has created intense competition between originator drugs and generic drugs in the medical system.

6. The Biotechnology and Pharmaceutical Industries Promotion Office under the MOEA, which is convened by the Industrial Development Bureau, MOEA, consists of the MOHW (the agency that issues pharmaceutical permits), the Intellectual Property Office (IP agency), and the Bureau of Standards, Meteorology & Inspection (standard-setting agency). The office carries out coordination and discussions regarding legal issues of pharmaceutical manufacturing and marketing, including permits, patents, copyright, or standards. However, the office does not engage in discussions on competition issues.

7. With regard to compulsory licensing, in the event of a national emergency or other major emergencies, the competent authority of the Patent Act, the Intellectual Property Office, should compulsorily license the required patent in accordance with the emergency order or notification of the central competent authority of the target business, and shall notify the patent owner as soon as possible. The Office may apply for compulsory licensing³ when it determines that compulsory licensing is necessary due to one of the following three conditions:

contents at the same or lower price, or replace the medical device with specialty material of another brand of the same functional category, and inform the beneficiary.”

² See DAF/COMP/GF/WD(2014)31, page 3-4.

³ Article 87 of the Patent Act.

1. where a patented invention is to be exploited non-commercially for the enhancement of public interest;
2. where a later invention or utility model patent cannot be exploited without infringing upon a prior invention or utility model patent, and where the later invention or utility model patent involves an important technical advancement of considerable economic significance in relation to the prior invention or utility model patent; or
3. where a patentee has committed acts restricting competition or has committed unfair competition acts, for which a judgment has been made by a court of law or a decision has been rendered by the FTC.

8. Furthermore, the Office may approve an application for compulsory licensing in the event that it is in order to aid a country without or with insufficient pharmaceutical manufacturing ability to acquire pharmaceuticals for treating AIDS, pulmonary tuberculosis, malaria, or other infectious diseases. However, this must be under the premise that the applicant could not negotiate licensing within a considerable time period using reasonable business conditions.

3. Pharmaceutical Competition Cases Handled in Accordance with the Fair Trade Act

9. Regarding the possible involvement of originators in restrictive or unfair competition, e.g., issuing patent infringement warnings without proper cause/procedure or using unreasonably low price bids to deter generics from entering the market, the FTC mainly investigates individual cases and does not get involved with the overall industry's pharmaceutical prices or permit policy.

10. The FTC investigated a case in which an originator distributor tendered to supply pharmaceuticals at a price far below its purchasing cost to drive out competitors. This act of restrictive competition and preventing fair competition was a violation of the FTA, and the distributor was fined NT\$ 3 million.⁴ The FTC also investigated several complaints filed by generic drug companies alleging that the originator drug manufacturer issued patent infringement warning letters to their trade counterparts that might violate the FTA. These cases involved the proper exercise of patent rights and the FTC did not find any originator drug companies in violation of the FTA after carefully reviewing these cases.

11. The FTC also investigated some complaints filed by originator drug companies alleging that generic drug companies violated the FTA by imitating the appearance and the package insert (prescribing information or patient information leaflet) of their products. For example, Pfizer Inc. reported to the FTC that the generic drug "Nova" manufactured by Yuanchou Chemical & Pharmaceutical Co. had the same ingredients as their patent drug "Norvasc," and used the same text format and color as well as the oval-shaped word "fine" with similar size and shape. The originator claimed that this would cause confusion among consumers and was in violation of Article 20⁵ and Article 24⁶ of the FTA. After investigating the

⁴ See DAF/COMP/GF/WD(2014)31, page 6-7.

⁵ Paragraph 1, Article 20 of the Fair Trade Act: No enterprise shall have any of the following acts with respect to the goods or services it supplies:

(1) using in the same or similar manner, the personal name, business or corporate name, or trademark of another, or container, packaging, or appearance of another's goods, or any other symbol that represents such person's goods, commonly known to relevant enterprises or consumers, so as to cause confusion with such person's goods; or selling, transporting, exporting, or importing goods bearing such representation;

(2) using in the same or similar manner, the personal name, business or corporate name, or service mark of another, or any other symbol that represents such person's business or service, commonly known to

case, the FTC decided that the two products would not cause confusion to consumers and the generic drug company did not violate the FTA.

4. Civil Cases Related to Competition between Originator Drugs and Generic Drugs

12. The number of civil cases between originators and generics has shown an upward trend in recent years. After an originator drug company's patent expires, the company often files infringement lawsuits against generic drug companies, claiming to protect their "pharmaceutical patent" and "package insert copyright," but actually intending to maintain their monopoly in the market. Generic drug companies have also filed civil lawsuits for damages to their rights.

Case 1: Genovate Biotechnology Co., Ltd. vs. Takeda Pharmaceutical Industry Ltd.

13. Genovate Biotechnology Co. filed a lawsuit with the intellectual property court. The company had applied to the MOHW for a pharmaceutical permit and to conduct clinical trials for their product Vippar (oral diabetes medication), which contains "pioglitazone," a prescription drug that they developed. Takeda Pharmaceutical Industry Ltd. knew that it does not own the patent to "pioglitazone," but falsely claimed that it did to Taichung District Court in 2004, and requested a provisional injunction against Vippar for infringing its invention patent No.135500 "pharmaceutical compositions for preventing and treating diabetes." The provisional injunction was approved and executed by the court. This led to the MOHW delaying the issuance of Vippar's pharmaceutical permit and prevented its legal sales, pushing back the time when the product entered the market and causing Genovate to sustain damages. Genovate Biotechnology claimed that Takeda Pharmaceutical engaged in unfair competition via the court's securitization proceedings to maintain the monopoly of Actos, the patent drug manufactured by Takeda Pharmaceutical, because clinical trials of Vippar would severely threaten the market share and price of Actos. This is a violation of the FTA and Genovate Biotechnology thus sought civil compensation in accordance with the law.

14. The case was tried in the Intellectual Property Court for the first instance, and the court ruled in favor of the defendant, finding that Takeda Pharmaceutical followed the proper procedure of the Patent Act and did not engage in unfair competition. Genovate Biotechnology appealed and in the second instance Takeda Pharmaceutical admitted that Vippar had the same ingredients as Actos, and that it claimed that the clinical trials and application for a pharmaceutical permit for Vippar infringed its patent, even though it was aware that invention patent No.135500 "pharmaceutical compositions for preventing and treating diabetes" did not include patent rights over the ingredient of the drug, "pioglitazone." The provisional injunction filed by Takeda Pharmaceutical was granted and prevented Vippar from entering the market for several years, allowing Takeda Pharmaceutical to gain additional profit without any competition with Actos. The legal action taken by Takeda Pharmaceutical was a means to preventing a competitor's product from entering the market, and the abuse of this right affected fair trade, which was a violation of Article 24 of the FTA. Takeda Pharmaceutical was thus liable for any damages in accordance with Articles 31 and 32 of the FTA⁷. The court of second instance ruled in December 2010 that Takeda Pharmaceutical should

relevant enterprises or consumers, so as to cause confusion with the facilities or activities of the business or service of such person; or

(3) using on the same or similar goods the mark that is identical or similar to a well-known foreign trademark that has not been registered in this country; or selling, transporting, exporting, or importing goods bearing such trademark.

⁶ Article 24 of the Fair Trade Act: In addition to what is provided for in this Law, no enterprise shall otherwise have any deceptive or obviously unfair conduct that is able to affect trading order.

⁷ Article 31 of the Fair Trade Act: Any enterprise that violates any of the provisions of this Law and thereby infringes upon the rights and interests of another shall be liable the damages arising therefrom.

compensate Genovate Biotechnology NT\$50 million in accordance with the FTA and Code of Civil Procedure, and should pay annual interest of 5% starting on April 22nd, 2009 until the debt was paid off. Although Takeda Pharmaceutical appealed to the Supreme Court, its appeal was dismissed on February 23rd, 2012 and the ruling was made final.

Article 32 of the Fair Trade Act: In response to the request of the person being injured as referred to in the preceding article, a court may, taking into consideration of the nature of the infringement, award damages more than actual damages if the violation is intentional; provided that no award shall exceed three times of the amount of damages that is proven.

Where the infringing person gains from its act of infringement, the injured may request to assess the damages exclusively based on the monetary gain to such infringing person.