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Excessive Pricing in Pharmaceutical Markets - Note by Chinese Taipei

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More documents related to this discussion can be found at

www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm

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This paper presents an overview of the pharmaceutical industry in Chinese Taipei and the enforcement activities of the Fair Trade Commission (hereinafter referred to as the “FTC”) in relation to pharmaceutical pricing.

1. The FTC’s stance on pricing issues

1. The rise and fall, or fluctuation, of prices is generally a reflection of overall economic activity. After considering operational costs, supply and demand of commodities as well as marketing strategies, prices set by individual enterprises at their own discretion in a relevant market can be attributed to the consequence of the market operating freely. In other words, the Fair Trade Act (hereinafter referred to as the “FTA”) does not apply to pricing issues that do not involve any abuse of monopoly power, concerted action, resale price maintenance and other anticompetitive conduct. There is generally no room for the FTC to intervene in market price setting under the FTA if prices are determined by the effective operation of market forces.

2. The FTC only conducts investigations into anticompetitive price decisions in relevant markets¹. Where anticompetitive practices are found through its investigations, the FTC may impose appropriate administrative penalties on the enterprises in breach of the FTA depending on the gravity of the violations. Furthermore, the FTC usually communicates with those market players that may be involved in excessive pricing or abnormal high prices. The FTC also outlines its views to the public on price changes in the form of press releases or seminar discussions prior to events that may result in significant price increases. In doing so, the FTC seeks to proactively prevent enterprises from contravening the FTA while initiating investigations where necessary.

3. For example, prices of daily necessities often increase before three traditional holidays² and the typhoon season (from summer to autumn) in Chinese Taipei. This phenomenon can be ascribed to various factors, including public expectation for future price rises, a temporary imbalance of supply and demand as well as widely reported price

¹ In March 2017, the FTC initiated an investigation into two infant formula companies for price increases in nine types of infant formula. The FTC’s investigation found that these two companies were not monopolists as defined under the FTA. While product features of infant formula showed a stronger brand preference for individual consumers, which might lead to consumer’s dependency on specific brand to some extent, there was no evidence to prove the existence of abuse of a dominant market position in consideration of the availability of substitutes in the relevant market. Furthermore, when dealing with excessive pricing cases, the FTC needs to take various factors into account to determine whether the alleged price is “excessive” or “unfair”. In this case, the FTC was of the opinion that the prices of infant formula were affected by a number of considerations rather than by a single factor, i.e. import costs. It concluded that the price increases were an outcome due to interactions between different reasons, including marketing costs, operational costs and market acceptance, and did not satisfy the criteria of excessive pricing.

² Three traditional holidays include Lunar New Year (usually during the end of January to mid-February), Dragon Boat Festival (mid-June) and Mid-Autumn Festival (late September).

changes in the media. With these factors, the general public tends to buy more daily necessities than necessary and the resultant demand boost may exacerbate the perceived price gouging. Therefore, Congressmen are likely to require governmental agencies to intervene in the market and take action to stabilize prices for the wellbeing of the society and their expense on necessities. Accordingly the government has established a “special task force of stabilizing commodity prices” comprising relevant governmental agencies (including the FTC), in order to carry out inspections of supply and demand conditions in markets in relation to daily necessities in exceptional circumstances.

2. The pharmaceutical³ industry in Chinese Taipei⁴

4. With rapid growth of an aging population in Chinese Taipei, the demand for healthcare goods and services continues to expand. The Business Monitor International (BMI) statistics showed that pharmaceutical spending per capita had increased from USD 223.1 in 2012 to USD 240.6 in 2016. To reduce healthcare costs, the government uses a variety of tools to control health expenditure, for example adjustment of National Health Insurance (hereinafter referred to as the “NHI”) premium rates, a new co-payment policy and price control of drugs under the NHI scheme. In particular, a biennial price adjustment of drugs covered by the NHI is working to decelerate the growth rate of the pharmaceutical industry, which has experienced modest growth since the inception of the NHI system.

5. BMI statistics further indicated that the domestic pharmaceutical industry reached NTD 181.57 billion in 2016. Brand name drugs manufactured by foreign pharmaceutical companies made major contributions to pharmaceutical sales while domestic pharmaceutical firms mainly produced and sold generic drugs. In 2016, pharmaceutical sales income from brand name drugs amounted to NTD 117.37 billion, which represented 64.6% of total sales of pharmaceutical products. Sales income from generic drugs and non-prescription medicines (over-the-counter drugs) in 2016 were NTD 50.44 billion and NTD 13.76 billion respectively, which accounted for 27.8% and 7.6% of pharmaceutical sales.

6. The pharmaceutical industry in Chinese Taipei includes “Active Pharmaceutical Ingredients”, “Western medicine preparations”, “Biologics” and “Chinese medicines”, among which western medicine makes up the most important part for the industry. Overall, there are approximately 320 pharmaceutical manufacturing companies in recent years, of which 125 firms producing western medicine preparations passed audits with standards of Pharmaceutical Good Manufacturing Practice (GMP) under the Pharmaceutical Inspection

³ Article 6 of the Pharmaceutical Affairs Act provides that “ The term “drugs” as used in this Act shall refer to any of the following raw materials and preparations:

- 1) Drugs which are listed in the Chinese Pharmacopoeia, or in the Pharmacopoeia of other countries, the official National Formularies or any of their supplements recognized by the central competent health authority;
- 2) Drugs which are not included in the preceding Subparagraph but are used in diagnosing, curing, alleviating or preventing the diseases of human beings;
- 3) Other drugs which are sufficient to affect the body structure and physiological functions of human beings; or
- 4) Drugs which are used in preparing such drugs set forth in the preceding three Subparagraphs.”

⁴ 2017 Yearbook of Pharmaceutical Industry

Co-operation Scheme (PIC/S). In any event, production and manufacturing as well as marketing for every type of medicine in Chinese Taipei are governed by relevant regulations issued by health-related governmental agencies.

7. Regarding the international trade of pharmaceuticals in Chinese Taipei, total medicines exports reached NTD 17.32 billion in 2016 while total imports were much higher, at NTD 94.98 billion. The top five countries that received Chinese Taipei exports were the United States, Australia, China, Japan and India, and the top five countries from which imports were received were Germany, the United States, France, Switzerland and Japan.

3. National Health Insurance System

8. Since 1995, Chinese Taipei has implemented the NHI system, a compulsory social insurance program. Under the NHI the dedicated insurer is obligated to pay medical bills for any disease, injury or incidents in relation to pregnancy and birth within an insurance policy period except the insured' deductible (as applicable). The purpose of NHI system is to help ease the financial burden of medical costs in the case of illness, injury or incidents during maternity. Current medicine covered by the NHI totals 16,000 items, which enable most people to receive comprehensive medical care services. As mentioned above, the demand for healthcare continues to grow with a larger aging population. The recent 10 years healthcare statistics show that the total NHI expenditure on medicines had increased from NTD 123.6 billion in 2008 to 183.5 billion in 2017, with an average annual growth rate of around 4.5%. Of the total expenditure, nearly 50% related to chronic illness, and 30% related to catastrophic illness.

9. For a prescription drug granted a permit by the competent authority through a process of review and registration, any pharmaceutical firm or medical care institution with the permit, complying with the principle of listing NHI drugs, can submit an application to the National Health Insurance Administration (NHIA) to propose to list the drug into NHI system. However, over-the-counter drugs, medicines designated by physicians, pharmacists and/or assistant pharmacists, preventative vaccines, non-essential pharmaceutical products (including contraceptive pills, hair tonic, dark spots remover, patches for quitting smoking and shampoo) or any other pharmaceutical products without cost-effectiveness may not be included in the NHI system.

10. The current medicine prices are specified in the "NHI Pharmaceutical Benefits and Reimbursement Schedule", which is subject to the "NHI Act". Thus contracted medical care institutions can follow the listed price in the Schedule to apply for reimbursement of costs incurred from medical treatments. The NHIA will regularly conduct a survey to collect actual transaction prices paid by each medical care institution so as to calculate national average prices for individual pharmaceutical products. On the basis of survey results, the NHIA may reflect bargain prices reported by the contracted medical service institutions on price decreases in medicines where appropriate and applicable.

11. To provide more choices in pharmaceutical markets, enhance the competitiveness of generic drugs and ultimately promote market competition, the NHI system intends to develop policies to accelerate the NHI review process of generic drugs and diminish the price caps between generic drugs and brand name drugs. For example, benchmark prices of generic drugs will be equal to 80% or 90% of corresponding brand name drugs. In addition, for those brand name drugs covered by the NHI for over 15 years, their prices will

be adjusted to be the same as the prices charged for generic drugs in compliance with PIC/S GMP. Through these policies, the NHI system can offer more options for hospitals and clinics, and to some extent provide contracted medical care institution incentives to purchase and prescribe generic drugs.

12. For the health of citizens and residents in Chinese Taipei, the NHI Act is enacted to develop the NHI system, thereby ensuring availability of and access to health services. In this regard, the NHI reimbursement scheme can be treated as a government action carried out by the NHIA under the NHI Act, which is exempt from the FTA. Nevertheless, competition among pharmaceutical firms, particularly in pharmaceutical markets where the NHI reimbursement scheme is not applicable, is still governed by the FTA. Below are two cases investigated by the FTC – one relates to exclusionary conduct and the other relates to excessive pricing.

4. Cases in the pharmaceutical sector

4.1. Exclusionary conduct in the antidepressant drug market

13. Company A was the exclusive agent of 10mg Epram Tablets (a generic drug) whereas Company B was the exclusive distributor of 10mg Lexapro film-coated tablets (a brand name drug). These two antidepressant drugs contained the same active ingredient, Escitalopram, both used in the treatment of depression. The FTC was informed that in September 2008, Company A and other potential bidder(s) were invited by the Medical Center C to submit tenders. In the end Company B won the bid at a unit price of NTD 1, which was unreasonably significantly lower than the tender price of Company A, NTD 9. Following this, the FTC initiated an ex-officio investigation.

14. During the investigation, the FTC found that 10mg Lexapro film-coated tablets and 10mg Epram tablets were paid by the NHI at the price of NTD 34.4 per tablet (for the brand name drug) and NTD 27.5 per tablet (for the generic drug) respectively. In terms of the procurement process of drugs, medical care institutions are generally required to comply with the Government Procurement Act to obtain quotations and compare tender prices. After actual purchase prices were paid to winning bidders, they would make claims to the NHIA for reimbursement as prescribed in the approved pricing schedule.

15. The FTC's further investigation revealed that winning a tender to supply drugs to a medical center could be seen as a stepping stone for a pharmaceutical firm to improve its engagement in the relevant drug market competition. In other words, Company B, as an incumbent with noticeable market share, would have faced enormous competitive pressure if Company A had won the tender at issue in September 2008. Furthermore, the NHI approved price of a 10mg Lexapro film-coated tablet was NTD 6.9 higher than that of a 10mg Epram tablet. As long as medical care institutions intended to obtain more profit with a higher pharmaceutical price gap (i.e. the difference between the NHI reimbursement price and the actual purchase price), Company A was unlikely to win the tender even in a scenario where it offered 10mg Epram Tablets for free. Therefore, no rational economic reasons were found to explain why Company B offered the tender at only NTD 1.

16. The data provided by the health competent authority also showed that in the domestic market of Escitalopram-based drugs, 10mg Epram Tablets only had market shares of 1.61%, 4.89% and 5.36% from 2008 to 2010. It demonstrated that Company B's tender with the unjustified low price excluded Company A from the relevant market to the extent

where Company A could not compete effectively. The FTC concluded that Company B's exclusionary conduct, which caused the trade counterpart to enter into the deal by improper means, resulting in potential restricted competition and distortion of fair competition, constituted a violation of the FTA.

17. The FTC ordered Company B to cease its unlawful act, and imposed NTD 3 million on Company B after taking the following factors into consideration:

1. motivation, purpose, and expected improper benefit of the acts;
2. benefits derived from the unlawful act;
3. the violator's scale, operational conditions, and its market position;
4. whether or not the type of illegal acts involved in the violation had been the subject of correction or warning by the central competent authority;
5. types of, number of, and intervening time between past violations, and the punishment for such violations; and
6. remorse shown for the act and extent of cooperation in the investigation.

4.2. Different prices charged by the Regaine for its hair tonic

18. A legislator enquired with the FTC as to whether it was a violation the FTA where the Regaine charged domestic consumers an unreasonably high price, three to four times the price on the website hosted overseas. Following the enquiry, the FTC initiated an ex-officio investigation into the allegedly excessive pricing of the Regaine's supplier.

19. Regine's hair tonic is not covered by the NHI. It is a medicine designated by physicians, pharmacists and/or assistant pharmacists under the Pharmaceutical Affairs Act. Its main element, Minoxidil, was used first to treat high blood pressure with the function of relaxing the muscles in the walls of blood vessels. Then Minoxidil was applied to increase blood flow to scalps to treat Androgenetic alopecia (also known as male pattern baldness). During the FTC's investigation, it found that the Ministry of Health and Welfare (MHW) had issued more than 60 permits for hair tonic products containing Minoxidil. Considering that many suppliers provided substitute hair tonic products in Chinese Taipei, the FTC defined the product market as the "hair tonic products market".

20. The FTC's investigation indicated that the domestic price of Regine's hair tonic was indeed higher than the price listed on the website hosted overseas. However, prices domestic consumers paid were usually lower than the list price set by the Regine's supplier due to frequent member discounts or other promotional discounts for non-members, which were offered by domestic "brick-and-mortar" distributors and/or retailers. In addition to Regine's hair tonic, "brick-and-mortar" businesses also provided consumers substitute hair tonic products containing the same major element from. Domestic consumers were able to compare prices through the internet and purchase Regine's hair tonic or other substitute products online.

21. Furthermore, Regine's hair tonic transported by air generally accompanied higher operational costs, including expenses with regard to inspection, registration and management as well as sales required by the Food and Drug Administration, the MHW. As specified in the declarations for imported Regine's hair tonic provided by the supplier, the unit cost was much higher than the list price of Regine's hair on the website hosted

overseas. Following its investigation, the FTC concluded that the Regine's supplier did not violate the FTA.

5. Conclusion

22. As mentioned above, the FTC's role does not extend to price issues unless these concerns result from anticompetitive conduct. Regarding daily necessities, the FTC will conduct inspections to aim to prevent prices from being manipulated by individual businesses before major traditional holidays (i.e. the Lunar New Year, Dragon Boat Festival and Mid-Autumn Festival) and the typhoon season.

23. For the pharmaceutical industry in Chinese Taipei, drug prices under the NHI system are not decided by pharmaceutical firms themselves or the relevant product markets. When a pharmaceutical firm's drug is listed in the NHI system, its price will be regulated by the NHIA. Therefore, the pharmaceutical firm needs to consider the approved price when negotiating with every medical care institutions, which may lead to drug price gap in the NHI system. The price gap represents that approved prices the government is willing to pay to medical care institutions are often higher than the prices charged by pharmaceutical firms agreed through procurement processes. This may lead to a restriction of profitability of pharmaceutical firms, disadvantageous conditions for biopharmaceutical development and negative impacts on incentives for research and development. As a result of the NHI system, there are very few cases in relation to excessive pricing in Chinese Taipei.