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1. This report describes how the Chinese Taipei Fair Trade Commission (hereinafter referred to as the "CTFTC") collaborates with health authorities and stakeholders in handling competition law cases and advocacy initiatives under the current health insurance system, and illustrates the CTFTC's role through practical cases.

1. Introduction: Overview of the Healthcare Sector in Chinese Taipei

2. The National Health Insurance (NHI) system was implemented in Chinese Taipei in 1995. Although patients are the end-users of medical services and pharmaceuticals, the specific treatments and medications used are prescribed by physicians. Medical institutions then claim reimbursement from the National Health Insurance Administration (NHIA) of the Ministry of Health and Welfare (MOHW) based on the NHI Fee Schedule and Reference List. As a result, patients generally bear no or only partial cost of medical services and pharmaceuticals. Therefore, the end-user of the pharmaceuticals (the patient), the decision-maker of medication use (the physician), and the primary cost bearer (the NHI system) are different entities.

3. The process for introducing pharmaceuticals into medical institutions begins with an application by the clinical physician who primarily prescribes them. Upon departmental approval, the Pharmacy and Therapeutics Committee, composed of representatives of the institution such as physicians, nurses, pharmacists, and procurement staff, reviews the application based on factors such as clinical need and price and makes unanimous decisions. Once the decision is made to introduce the pharmaceutical, the institution undertakes procurement procedures such as tenders and negotiation of prices with pharmaceutical companies.

4. The initial NHI reimbursement price for a pharmaceutical is determined according to the "NHI Fee Schedule and Reference List for Medications." Subsequent price adjustments are made according to the "Regulations of Price Adjustment for NHI Reimbursed Drugs." The foregoing pricing and adjustment regulations consider factors such as whether the medication is new or proprietary, and whether the manufacturer complies with the Pharmaceutical Inspection Co-operation Scheme Good Manufacturing Practice (PIC/S GMP). Routine reimbursement price adjustments by the NHIA are made by referring to actual market transaction surveys and according to the relevant rules.

5. The price at which pharmaceutical companies provide pharmaceuticals to medical institutions is determined considering factors such as cost and profit and may be lower than the NHI reimbursement price due to the bargaining power of the medical institution. The price difference between the two is the profit of the institution, where a "black hole in drug pricing" may occur. Therefore, competition law enforcement maintains fair competition in the healthcare markets so as to avoid excessive NHI expenditures and to ensure stable medication supply and demand.

2. Relevant Cases

2.1. Cooperation with Health Authorities and Private Stakeholders

2.1.1. Joint Issuance with MOHW of the Regulations for the Notification of Drug Patent Linkage Agreements

6. According to Paragraph 1, Article 48-19 of the Pharmaceutical Affairs Act, "For any settlement agreement or other agreement involving the manufacture, sales, and marketing exclusivity period of drug related to the regulations under this Chapter executed between the applicant for a new drug license, the new drug license holder, the applicant for a generic drug license, the generic drug license holder, and the patentee or exclusive licensee of a drug patent, within 20 days after the next day to the occurrence of such matter, both parties shall notify the central competent health authority, and if reverse payment interest agreement is involved, shall also notify the CTFTC." Paragraph 3 of the same article stipulates that "If the central competent health authority considers that the agreement notified under Paragraph 1 hereof is likely to violate the Fair Trade Act, it may notify the CTFTC."

7. On March 6, 2019, the CTFTC and the MOHW jointly issued "Regulations for the Notification of Drug Patent Linkage Agreements." According to Article 3 of the Regulations, after receiving notification according to the preceding provisions, when necessary, the MOHW may require the parties addressed in the agreement to clarify the specific contents in writing or submit relevant documents and information within a designated period of time; If reverse payment interest is involved and the parties have not notified the CTFTC, the MOHW may request the parties to make notification as soon as possible.

8. Except for merger and cartel cases, which are subject to prior notification or exemption application mechanisms, the Fair Trade Act (hereinafter referred to as the "FTA") does not subject business conduct to other ex-ante review mechanisms. Contracts or agreements between undertakings, where the terms of transaction are agreed based on free will, are generally governed by contract law. Only when related conduct involves "competition restraint" or "unfair competition" and violates the FTA will the CTFTC intervene and investigate.

9. Therefore, the notification under the "Regulations for the Notification of Drug Patent Linkage Agreements" is of a nature of notice. In the absence of notification, the CTFTC may still investigate contracts or agreements between pharmaceutical companies that potentially violate the FTA based on complaints or ex officio.

2.1.2. Competition Advocacy by the CTFTC Regarding the Establishment of the Good Neighbor Pharmacies Platform by the Pharmacists Association and the Drafting of a Reference Fee Schedule for Home Delivery Services by Pharmacists

Regarding the Pharmacists Association Facilitating the Establishment of a Pharmaceutical Procurement Platform for Small Pharmacies

10. To address issues such as rising prices and shortages of pharmaceuticals caused by the Russia-Ukraine war and inflation, as well as increased pharmaceutical delivery costs due to the implementation of the Good Distribution Practice, the Pharmacists Association of Chinese Taipei resolved in December 2023 to establish the logistics platform named "Good Neighbor Pharmacies" in collaboration with the Yes Chain Pharmacy so as to assist

small pharmacies in dealing with problems such as shortages and sourcing of pharmaceuticals.

11. The platform operates as follows: small pharmacies may freely decide whether to join the alliance as members and use it as one of their sources of pharmaceuticals. The alliance guarantees that members obtain pharmaceuticals at prices no higher than market rates. Members may decide without being restricted by the alliance whether to procure pharmaceuticals from the alliance or other suppliers. The alliance does not limit the items or quantities procured by members, nor does it restrict resale prices. The goal of the alliance is to strengthen its bargaining power as membership grows, thereby achieving stable supply.

12. The CTFTC conducted competition advocacy with the Pharmacists Association regarding whether, following the establishment of the "Good Neighbor Pharmacies," there would be a price cartel among its members, restrictions on resale prices, or discriminatory treatment in membership review, in order to prevent the platform from violating the FTA.

Drafting a Fees Standard for Home Delivery by the Pharmaceutical Personnel

13. Due to the rise of digitalization and telemedicine, the MOHW has in recent years promoted the "Regulations of Medical Diagnosis and Treatment by Telecommunications" and the "Pilot Program of Home Care for Acute Symptoms under the NHI." Accordingly, the demand for home delivery of medications by pharmacists may increase. As the delivery of medications is part of the dispensing practice and must be performed by pharmaceutical personnel, where home delivery is currently a self-pay service, the Pharmacists Association considered to establish a fees standard for home delivery by pharmaceutical personnels in order to achieve reasonable remuneration for pharmacists. In September 2024, it consulted the CTFTC on whether the establishment by the Association of the fees standard for reference would violate the FTA.

14. The CTFTC opined that the establishment by a trade association of price schedules of goods or services for reference is sufficient to influence the pricing decisions of its members, to form price coordination, and provides upstream enterprises with opportunities to engage in price-fixing with regard to downstream enterprises. Therefore, trade associations shall not establish price schedules for reference. Accordingly, the fees standard for home delivery considered by the Pharmacists Association is a "benchmark" of reference for pricing the services of pharmacists, where the incentive of consumers to collect price information and compare prices would be weakened due to small price differentials. Even if the Pharmacists Association does not force its members to charge according to the standard, the prices therein would have caused an anchoring effect in the market, influencing the pricing decisions of individual members and even non-member enterprises, thus impeding market competition.

2.2. Sanctions and Suspension of Investigation

2.2.1. The Case of Cartel on Generic Colorectal Cancer Drugs by TTY Biopharm Company Limited and Lotus Pharmaceutical Co., Ltd.

15. The colorectal cancer drugs marketed by TTY Biopharm Company Limited (hereinafter "TTY"), Taiwan Otsuka Pharmaceutical Co., Ltd. (hereinafter "Otsuka"), and Lotus Pharmaceutical Co., Ltd. (hereinafter "Lotus") were "three-same" drugs—the same ingredient, dosage form, and dose—and were all reimbursable under NHI and mutually substitutable. In 2018, the CTFTC received a complaint that TTY acted as the sales agent

for both the colorectal cancer drugs of Otsuka and Lotus, effectively becoming the sole supplier in the market, raising concerns about cartel in violation of the FTA.

16. Penetrating pharmaceutical marketing channels in different countries is difficult for pharmaceutical companies as pharmaceutical marketing requires professional pharmaceutical knowledge by marketing personnel and responses to differences between countries such as those in healthcare systems, insurance regimes, and regulations. Thus, marketing cooperation via agreements is typical or normal in the pharmaceutical industry. However, an infringement occurs when benefits are exchanged in the name of cooperation, with one party to the agreement effectively receiving benefits in exchange for refraining from entering the market, thereby affecting the functioning of the pharmaceutical market.

17. Upon investigation, the CTFTC found that in addition to marketing its own colorectal cancer drugs, TTY had signed exclusive distribution agreements with both Otsuka and Lotus. The agreement between TTY and Otsuka was considered normal vertical agency and did not involve cartel in violation of the FTA. However, the distribution agreement between TTY and Lotus stipulated that TTY pay Lotus periodic royalties to acquire exclusive distribution rights to the colorectal cancer drugs of Lotus, and restricted Lotus from further marketing the drug on its own or through others. However, TTY never placed orders for products of Lotus or marketed the drugs, and despite 12 years without actual sales to TTY, Lotus continued to renew the agreement, which contradicted normal business logic.

18. Between 2013 and 2014, the average price of Lotus's drugs was less than half of TTY's, clearly indicating a stronger competitive edge for the former. If Lotus entered the market, it would probably pose a competitive threat to TTY. Thus, TTY had a strong motivation to deter Lotus from engaging in competition. Meanwhile, Lotus was compensated in the form of royalties for the exclusive distribution agreement without producing or marketing the drugs, which provides a strong incentive not to engage in competition.

19. The CTFTC further found that the agreements signed in 2009, 2013, and 2018 between TTY and Lotus all clearly authorized TTY exclusive distribution rights to colorectal cancer drugs without specifying purchase quantities, prices, or revenue-sharing arrangements between the parties. This indicated that the royalties were unrelated to how TTY marketed the drugs. Furthermore, in contrast to receiving commissions from distributing Otsuka drugs, TTY not only received no commission from distributing Lotus drugs but also paid royalties that were high and increasing. Yet, TTY never sold the colorectal cancer drugs of Lotus. Thus, in the name of exclusive distribution, the agreements effectively were meant to prevent Lotus from marketing its colorectal cancer drugs in the market, allowing TTY to obtain roughly 80% market share in the relevant drug market. In 2021, the CTFTC concluded that the exclusive distribution agreement between TTY and Lotus involved reverse payments and mutual restrictions on competition in the relevant market of colorectal cancer drug, which was sufficient to impact the supply and demand functions of the colorectal cancer drug market and constituted cartel in violation of the FTA, with administrative fines of NT$220 million (approximately USD 7.1 million) and NT$65 million (approximately USD 2.1 million) imposed on TTY and Lotus respectively.

20. In this case, enforcement by the CTFTC prevented the enterprises from depriving the NHI system, medical institutions, and patients of potential benefits of price reductions that might have been brought by market entry of the relevant drugs, reducing choice of drugs available to physicians, or adversely affecting NHI drug price adjustments.

2.2.2. Joint Increase of Registration Fees by YeeZen General Hospital and Ten-Chen Hospital

21. The CTFTC received a complaint in 2022 against YeeZen General Hospital and Ten-Chen Hospital jointly raising their outpatient registration fees from NT$200 to NT$250 (approximately USD 6.5 to USD 8.1) on September 1, 2022. The CTFTC found later that the two hospitals not only raised the outpatient registration fees simultaneously, but also increased emergency registration fees from NT$300 to NT$350 (approximately USD 9.7 to USD 11.3) previously on January 1, 2022. The timing, amount, and scale of increase in registration fees were identical, thereby appearing to be a concerted price adjustment.

22. The CTFTC realized that the registration fee is an administrative charge of medical institutions and is not considered a "medical expense" as defined in Article 21 of the Medical Care Act. Therefore, approval by local health bureaus is not required. However, to prevent significant discrepancies in fee standards among medical institutions that could impact access to healthcare, the MOHW published in 2010 a reference range for registration fees. Accordingly, medical institutions must submit a filing to the local health bureau where the registration fees are more than NT$150 (approximately USD 4.8) for outpatient or NT$300 (approximately USD 9.7) for emergency care.

23. Based on the tiered medical care system promoted by MOHW, medical institutions are categorized into four levels: medical centers, regional hospitals, district hospitals, and local clinics. Accordingly, institutions in each level provide medical services of varying content depending on operational scale related to factors such as staffing, equipment, and technology. The level of competition and substitutability between different medical institutions also varies. For the present case, YeeZen and Ten-Chen are the only two district hospitals in Yangmei District, Taoyuan City; all the other medical institutions are local clinics.

24. Due to geographical considerations in patient choice and the proximity and overlapping specialties of YeeZen and Ten-Chen, the two hospitals are highly substitutable from the patients' perspective. Furthermore, the entry barrier is high as establishing new hospitals is difficult. The market structure is conducive to the formation and maintenance of cartels and the conditions of the relevant market incentivize the two hospitals to form a cartel.

25. The CTFTC found that the two hospitals applied for outpatient and emergency registration fee increases with the local health bureau at different times. However, Ten-Chen Hospital, which applied later, was informed of the planned and unpublished outpatient and emergency registration fee increases of YeeZen. A comparison of relevant documents revealed that the two hospitals obviously circulated pricing data or files and agreed to increase both emergency and outpatient registration fees on the same date. In 2023, the CTFTC determined that the two hospitals had agreed to the joint registration fee increases, which constituted cartel in violation of the FTA, and imposed administrative fines of NT$900,000 (approximately USD 29,000) and NT$700,000 (approximately USD 22,600) respectively.

2.2.3. The Case on Resale Price Maintenance by Maxigen Biotech Inc. on Intra-Articular Injection Agents

26. In 2024, a complaint alleged that Maxigen Biotech Inc. (hereinafter "Maxigen") restricted the price at which downstream distributors sold intra-articular injection agents to medical institutions. The products of intra-articular injection agents, categorized as medical devices, primarily contain hyaluronic acid and are used for treating osteoarthritis pain.

Based on the package insert of the medical device license issued by the Food and Drug Administration, the treatment and effectiveness duration vary by the dosage forms of single-dose, three-dose, and five-dose. Physicians choose dosage forms based on patient needs and purposes of use, and NHI reimbursement points are the same for products with the same dosage form.

27. In 2021, Maxigen signed a distribution agreement with its downstream distributor to market intra-articular injection agents. It was agreed that Maxigen sold the intra-articular injection agent products to the distributor, which would then be resold to medical institutions by the distributor. In March 2023, the distributor submitted quotations to medical institutions and ordered the products from Maxigen. Upon learning of the prices quoted by the distributor, Maxigen deemed them too low and demanded that the prices be doubled. The intra-articular injection agent products were not to be provided until the distributor renegotiated prices with the institutions.

28. Maxigen stated that it demanded the distributor to raise quoted prices after referring to the prices of other distributors and claimed that the distributor could attract orders of medical institutions through non-price factors such as service, quality, or technology. However, the CTFTC found upon investigation that price differences were limited under market conditions and that price was the main competitive factor in procurement by medical institutions. In addition, Maxigen provided no supporting evidence for its claims. The CTFTC deemed the statement presented by Maxigen not the promotion of inter-brand competition or other economically reasonable justifications of competitive concerns.

29. In 2025, the CTFTC determined that the request by Maxigen that the distributor renegotiate prices with the medical institutions constituted resale price maintenance in violation of Article 19 of the FTA, and imposed an administrative fine of NT$300,000 (approximately USD 9,700).

2.2.4. Aspen Raising Prices of Cancer Drugs

30. Since 2017, the European Commission (hereinafter the "EC") has been investigating Aspen Pharmacare (hereinafter "Aspen"), a South African company, on excessive pricing through raising prices of six cancer drugs. In February 2021, the EC determined that, Aspen significantly raised prices for six drugs including the Alkeran and Myleran tablets in 2011 after expiration of patents for the drugs. In some EU Member States, Aspen achieved price increases by means such as threatening to withdraw the drugs from the markets.

31. The EC found upon investigation that from 2013 onward, Aspen's gross margins on the six relevant drugs rose significantly and remained high between 2014 and 2019, with estimated total profits of more than EUR 200 million between 2013 and 2019, and that Aspen potentially abused its dominant position by excessive pricing on drugs for which the patents had expired in violation of Article 102(a) of the Treaty on the Functioning of the European Union (TFEU) and Article 54(a) of the EEA Agreement. Aspen committed to the EC to reduce the average price of the six drugs by 73% for 10 years. The EC remains capable of resuming investigation and litigating the case, which depends on implementation of the commitments by Aspen.

32. In addition to the EC, the Italian competition authority also found upon investigation that Aspen violated Article 102(a) of TFEU in the marketing of five drugs. Aspen Healthcare Taiwan Limited (hereinafter "Aspen Healthcare"), a subsidiary of Aspen, marketed Alkeran and Myleran tablets in Chinese Taipei. These drugs contained the same active ingredients as two of the products under the aforementioned investigation of the EC, and their NHI prices in Chinese Taipei rose nearly threefold in 2017 and 2018

respectively. The CTFTC thus initiated a probe in June 2021 into the company for potentially improper price increases regarding the drugs in violation of Article 9(2) of the FTA.

33. In August 2022, Aspen Healthcare applied for suspension of investigation under Article 28 of the FTA and Point 5(2) of the "CTFTC Disposal Directions (Guidelines) on Suspension of Investigation." Aspen Healthcare committed to applying for price reductions of Alkeran tablets and injections within two weeks of receiving the investigation suspension decision by the CTFTC and not to seek price increases for five years from the effective dates for the new prices unless gross margins for relevant drugs fell below 20%.

34. In December 2022, the CTFTC accepted commitments by Aspen Healthcare and suspended investigation of the case. With assistance from MOHW during investigation and commitment by the enterprise to price reduction, the case contributed to reducing NHI spending, benefited patients with particular diseases, spared administrative and investigatory resources while avoiding future litigation, thereby exemplifying cooperation between competition and healthcare authorities for public welfare.

3. Future Directions for Enforcement

35. The CTFTC has accumulated practical experience in handling competition law cases involving mergers, cartels, and vertical restraints in the healthcare sector, contributing to the maintenance of market order. Given the involvement in the healthcare sector of various stakeholders such as pharmaceutical companies, patients, healthcare institutions, and the NHI system, the CTFTC faces enforcement challenges in detecting cartels, assessing pricing conduct, and defining relevant markets in specific cases. Future efforts should therefore focus on enhancing collaboration with health authorities and stakeholders to understand market dynamics and to identify or detect potential competition concerns so as to inform future enforcement.