Key points for transfer pricing in the ethical pharmaceutical industry

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In brief

The ethical pharmaceutical industry is less susceptible to economic ups and downs than most other industries because it is driven by the prevention and treatment of disease and the provision of healthcare. The Japanese ethical pharmaceutical market is, in addition, characterized by universal health care coverage supported by the national health insurance ('NHI') system, as well as the national drug pricing system. Japanese affiliates of foreign multinational enterprises (MNEs) (i.e., inbound companies) need to pay particular attention to these market characteristics in their transfer pricing.

This newsletter outlines notable characteristics of the Japanese pharmaceutical market and the points that should be focused on for transfer pricing purposes for inbound ethical pharmaceutical operations.

In detail

1. Characteristics of the Japanese pharmaceutical market

In 2020, the average life expectancy in Japan reached 81.64 years for men and 87.74 years for women[1], and the aging rate (the ratio of people 65 years or older to the total population) was 28.8%[2], both of which were the highest in the world. One of the characteristics of the Japanese social security system is the NHI system, which provides public health insurance for the entire nation. With respect to insured medical care, patients are eligible for advanced medical care in exchange for insurance premiums and up to a 30% co-payment. While public funding is used as the financial source to maintain the NHI system, health care expenditures have remained at high levels due to the above-mentioned aging population – in the 40 trillion yen range since 2013.[3] The government is aiming to reduce national treasury expenditures by curbing health care expenditures related to maintaining the NHI system.

[1] The Ministry of Health, Labour and Welfare, an international comparison of average life expectancies https://www.mhlw.go.jp/toukei/saikin/hw/life/life20/dl/life18-04.pdf (in Japanese).
[2] White Paper on the Aging Society 2021 (Chapter 1. Global Trends in Aging) https://www8.cao.go.jp/kourei/whitepaper/w-2021/zenbun/pdf/1s1s_01.pdf (in Japanese).
[3] The Ministry of Health, Labour and Welfare: National health expenditures in Japan https://www.mhlw.go.jp/toukei/saikin/hw/k-iryohi/19/index.html (in Japanese).

Another major characteristic of the Japanese medical system is the national drug pricing system[4]. Drugs covered under the NHI system are prescribed based on the official drug price list established by the government (a list of the names and reimbursement prices of drugs covered under the NHI system). These prices are, in principle, revised every year to be consistent with their actual distribution prices.

While the difference between the official drug price and patients' co-payments will be borne by the national treasury, because of the above-mentioned tightening of the government health expenditure budget, there is an increasing downward pressure on official drug prices when they are revised.

2. Key notable points for inbound companies operating in the Japanese ethical pharmaceutical market

When operating as an inbound company in the Japanese ethical pharmaceutical market, a western pharmaceutical company typically acts as a limited risk distributor ('LRD') engaged in the sales of products developed overseas. In transfer pricing for such a LRD, it is common to evaluate the arm's length nature of the pricing in transactions with the related foreign supplier through a benchmark analysis, by comparing the profit margins of comparable companies and the Japanese entity, and to allocate any remaining profits to the foreign parent entity.

However, in the above-mentioned benchmark analysis, it will be extremely difficult to select comparable Japanese companies, because there are no independent pharmaceutical trading companies in Japan that directly import drugs from overseas pharmaceutical manufacturers for resale to customers in Japan. Since the Japanese tax examiners typically require the use of local comparables only, this can present a risk of challenge, and makes an APA an option to be considered by inbound pharma companies.

In determining their transfer pricing, inbound pharmaceutical companies should pay particular attention to the official drug pricing system. Under the Japanese drug pricing system, official drug prices are, from 2021 onward, subject to revision ('NHI price revision') every year (previously every two years). The official drug prices are revised to be consistent with the prevailing market prices established through price competition among pharmaceutical wholesalers selling to pharmacies and hospitals. Therefore, official drug prices are generally reduced by NHI price revisions.

The official drug price list is updated four times a year in order to add new drugs, and another re-pricing rule ('market expansion re-pricing') has been introduced to make it possible to lower the official prices of existing drugs at the time of these updates (without waiting for the above-mentioned annual NHI price revision), where their annual sales exceed a certain threshold.

Furthermore, starting in 2022, a change was made to the calculation of the price premium for drugs subject to the cost accounting method of pricing, which applies to new drugs having no available comparator drugs. Under the cost accounting method, the drug price is calculated as the sum of the total product cost (i.e., manufacturing costs, research and development costs and sales costs), operating profit, distribution costs and consumption tax, plus an applicable price premium. Under the change, where the ratio of disclosed product costs to total product costs (the 'cost-disclosure ratio') is less than 50%, no price premium will be allowed.[5] Thus, where an imported drug that is subject to the cost accounting method of pricing is supported only by its transfer price, without the disclosure of a breakdown of the total product cost, no price premium will be allowed for that drug.

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[4] The Ministry of Health, Labour and Welfare: Major contents of FY2022 official drug pricing reform https://www.mhlw.go.jp/content/12404000/000883142.pdf (in Japanese).

[5] Ibid. (p.8)

In addition, a provision has been added to the law stating that, where the transfer price charged by an overseas entity serves as the basis for pricing under the cost accounting method, 'the upper limit shall be the minimum transfer price charged for export to other countries.' Thus, where the transfer price is used for purposes of the cost accounting method of pricing for imported drugs, it will be limited to the transfer price charged for exports from Japan to other countries.

In response to this tightening of the official drug pricing system, Japanese and western pharmaceutical industry associations have expressed their objections from the viewpoint of transparency and predictability[6].

Under the official drug pricing system, inbound ethical pharmaceutical companies, which operate in Japan mostly as LRDs, may need to disclose the details of overseas manufacturing costs to obtain a price premium where the cost accounting method of pricing is used. This may present a significant hurdle, because they may not have access to such data, due to the complexity of their supply chains. In such case, their profitability in the Japan market will be negatively impacted. In particular, western mega-pharma companies focus on investment efficiency and measure investment value, taking into account the costs of obtaining approvals and performing clinical trials that are needed to attain expected returns. Therefore, if Japan maintains its current drug pricing policy, such pharma companies may not be able to achieve sufficient returns in Japan due to decreasing drug prices, and they may reconsider and revise their investment in the Japanese market, where they may not be able to expect growth opportunities.

On the other hand, the Japanese tax authorities generally expect western pharmaceutical companies operating in Japan to earn a certain profit margin based on their LRD functions, even if the profitability of the drugs they sell is squeezed by reductions in the official drug prices. Therefore, in such cases, these companies may need to reduce the transfer prices of their products in order to maintain the expected profit margin.

The above describes notable key points for Japanese affiliates of foreign pharmaceutical MNEs. Inbound companies with multiple pharmaceutical products generally earn different margins on different products due to the competitive situation, official drug price revisions, etc. Therefore, it is challenging for them to evaluate transfer prices on a product-by-product basis and, as a result, they often evaluate their transfer prices by testing the Japanese affiliate's profit margin on a company-wide basis. Additionally, they may set transfer prices at the beginning of the fiscal year ('FY') for the full FY, and then make transfer pricing adjustments (true-ups) based on the actual results at the end of the FY so that the Japanese affiliate earns the target profit margin.

Although the Japanese ethical pharmaceutical market is matured, it is the third largest in the world and a key market for inbound companies as well. Approximately 80% of the top-selling items are imports, and since 2015, Japan has continuously recorded more than 2-trillion-yen deficit on its drug trade balance[7].

Image and reputation are important in the pharmaceutical industry because the industry offers life-related products. Therefore, for example, many enterprises use preventive measures, such as bilateral APA, in order to avoid unnecessary tax audits and additional tax.

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[6] Central Social Insurance Medical Council, Special Committee on Drug Prices (182nd session): https://www.mhlw.go.jp/content/12404000/000852314.pdf (in Japanese); Joint Statement by JPMA, PhRMA and EFPIA: https://www.jpma.or.jp/news_room/release/news2022/rfcmr00000002t2u-att/message_e.pdf

[7] The Ministry of Health, Labour and Welfare: Summary of Annual Report on Statistics of Production by Pharmaceutical Industry in 2020 (Table 24: Changes in drug export value, and Table 28: Changes in drug import value).

The takeaway

In setting and implementing their transfer pricing, inbound pharmaceutical companies should be sure to pay attention to the above-discussed implications and market characteristics of the pharmaceutical industry in Japan.

Let's talk

For more information or a deeper discussion of how this issue might affect your business, please contact:

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