
The authors analyse the impact of specific Mexican requirements on the transfer pricing structure and intercompany transactions in the pharmaceutical industry in light of Action 8 of the Action Plan on Base Erosion and Profit Shifting.

1. Introduction

One feature of the pharmaceutical industry is that primary brands are mainly in the hands of multinational companies. This is due, among other reasons, to (i) the fact that multinational companies hold the preponderance of patents on the main pharmaceutical products and (ii) the restraints imposed by governments to ensure quality control of pharmaceutical products. In Mexico, as in other countries, there are specific requirements imposed on pharmaceutical companies before a pharmaceutical product may be placed on the market. Therefore, health and importation permits for pharmaceutical products must be properly considered, as they undeniably add to the costs and burdens of companies in the industry.

This article will analyse the impact in Mexico of those specific requirements on the transfer pricing structure and intercompany transactions in light of Action 8 of the Action Plan on Base Erosion and Profit Shifting (BEPS Action Plan) recently published by the OECD. The article also evaluates transfer pricing challenges faced by pharmaceutical companies in respect of government intervention and presents possible ways to address those challenges.

2. The Mexican Pharmaceutical Market

In the Latin America pharmaceutical industry, Mexico is the second largest market with USD 14.4 billion of revenues, surpassed only by Brazil (which leads the region). The Mexican pharmaceutical industry is dominated by several multinational corporations, while smaller firms are also players in generics and biosimilars (also known as follow-on biologics) and are focused on a small number of new products. Although the pharmaceutical industry in Mexico has traditionally manufactured and sold its products locally, producing stable and healthy profit margins, it is currently undergoing rapid transformation, including significant manufacturing activity coming in from or going out to centralized locations, patent expirations and other circumstances.

Competition from generic products in Mexico has been particularly strong in the last few years, although patented drugs still account for 74% of pharmaceutical sales in Mexico. Nevertheless, generic products will continue to drastically change the way pharmaceutical companies operate in the industry. Consequently, many companies are implementing a so-called multi-brand strategy in order to penetrate the generic market, in addition to their current lines of business. Most of these generic products are made by small local companies rather than multinationals.

Given the elimination of the mandatory Mexican manufacturing plant requirement in 2008, new players have entered the market, while existing players have been consolidating operations and moving certain manufacturing operations out of Mexico. There are currently approximately 200 registered pharmaceutical companies in Mexico, but only approximately 40 facilities are producing pharmaceutical products. Furthermore, the manufacturing process in Mexico is mainly secondary manufacturing, and biosimilars (also known as follow-on biologics) are marketed after expiration of their patents.

Profitability, which has been a feature of the industry, has given rise to tax and transfer pricing planning, but has also drawn the attention of the tax authorities to the industry’s transfer pricing. The pharmaceutical industry is currently one of the targets of the Mexican tax authorities as a result of the implementation of the Base Erosion and Profit Shifting (BEPS) project in Mexico.

Generics pharmaceutical products were once patent protected, and are now copied and sold by companies other than the original owner of the patent. Biosimilars are new versions of innovative biopharmaceutical products that are marketed after expiration of their patents.

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This is also due to the latent threat of Brazilian, Indian and Chinese exports.

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which involves processing active pharmaceutical ingredients (APIs) so that they can be used as a drug.  

In relation to the distribution process, pharmaceutical products have traditionally been sold through a few large independent distributors, which account for almost 50% of the sector. However, supermarkets and drugstore chains have recently been gaining market share and are becoming important players in the industry through vertical integration strategies of pharmaceutical companies.

Furthermore, the Federal Commission for Protection Against Health Risks (Comisión Federal de Protección contra Riesgos Sanitarios, COFEPRIS) has been working on aligning its regulations with the guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. Given the Mexican requirement to renew health permits every five years, new applications for registration have been delayed, and the resulting ease of market entry has been seriously affected by legal and regulatory frameworks.

3. Regulatory Restrictions in the Mexican Pharmaceutical Market

The extent and nature of government intervention in the pharmaceutical industry is, in fact, its distinguishing feature. Regulation and legal frameworks can affect the ease of market entry in several ways. A company wishing to market its products must first demonstrate that its drugs are safe and effective, to the satisfaction of the national regulator. In Mexico, this role is performed by the Office for the Control of Health Products (Dirección General de Control de Insumos para la Salud, DGCIS), as well as by the COFEPRIS. Operating licences (known as “health permits” in Mexico) and “certifications of qualified personnel appointed as responsible” require registration at that Office. Once the health registration has been processed, an importation permit may be requested by the company. Both permits must be held by the same entity, which prevents other companies from registering for the distribution of goods that are not necessarily part of their core business.

In order to obtain a health permit for a pharmaceutical product in Mexico, pre-clinical, pharmacological and toxicological studies must also be undertaken, among other processes. Studies carried out abroad are usually acceptable, although additional toxicological tests may be required, depending on the therapeutic features of the drug. New trials must also be undertaken for additional therapeutic indications of drugs previously approved. The law provides that requests for new health permits must be resolved within six months. Nevertheless, in practice, most actions to obtain a health permit take much longer. Such permits are currently valid for only five years, after which time the company must request an extension.

Once a health permit has been issued, the holder of that health permit (which is responsible for registration, quality control and compliance with regulatory requirements) may apply for an importation permit from either the COFEPRIS or the customs authorities. An importation permit is usually approved within three months. An importation permit is generally not transferable to another company until approval is obtained; therefore any change in the holder may bring with it a risk of loss of the income from the operation and added costs to the operation. Due to red tape, the process of changing an importation permit can take up to nine months.

4. Impact of Regulatory Restrictions on Operating Strategies

There are understandable reasons why governments regulate the entry of a drug into the market and the manner of its manufacture and sale, but such regulation undeniably adds to the costs and burdens of companies in the industry. In this regard, the OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations (2010) (OECD Guidelines) recognize that government policies may affect the profits that can be realized by companies. For instance an importation permit may require separate compensation, which may add costs to the global operation if the importation permit is owned by an entity other than the company responsible for manufacturing and distributing the pharmaceutical products.

On the other hand, health permit restrictions on ownership of pharmaceutical products with the same API for companies with so-called second-brand strategies may add complexity to the operational structure, which must therefore be properly evaluated. In this regard, the OECD Guidelines indicate that economic circumstances that may be relevant for determining market comparability include the nature and extent of government regulation of the market. On this basis, regulatory restrictions should be analysed as a factor determining comparability.

Furthermore, as a health permit provides protection of intellectual property, it should also be properly analysed taking into consideration the new chapter VI of the OECD Guidelines. Paragraph 6.91 of the OECD Guidelines clearly specifies that the pharmaceutical industry involves different types of intangibles, which, in combination, may be extremely valuable. Interactions between these intan-

8. The secondary manufacturing process follows primary manufacturing, which is the production of the active pharmaceutical ingredients (APIs) that give a medication its efficacy and potency, from simpler raw materials. The primary manufacturing process uses one or more of the following methods: fermentation, extraction, chemical modification, and bulk sterile or non-sterile finishing.

9. PwC, Mexico, supra n. 6.


14. Paras. 1.73-1.77 OECD Guidelines.
15. The pharmaceutical industry works with different types of intangibles, including patents, approval to market, the product in a given geographic market and trademarks. In combination, these intangibles can be extremely valuable. In isolation, one or more of them may have much less value. For example a trademark without patent and regulatory marketing approval may have limited value, as the product cannot be sold without marketing approval and generic competitors could not be excluded from.

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gibles, as well as the relative contribution to value creation where different companies hold rights to the intangibles used, are very significant in performing a transfer pricing analysis with regard to the intangibles.

Considering the above issues, the discussion below analyses the impact of the health permit and importation permit in Mexico on the transfer pricing structure and intercompany operation challenges faced by pharmaceutical companies in respect of government intervention, and discusses possible ways of addressing those challenges.

4.1. Second-brand strategies with health permit restrictions

Increasing sales of generic pharmaceutical products in Mexico have led many pharmaceutical companies to purchase other generic businesses or develop their own generic lines. From a marketing standpoint, this is known as a second-brand or multi-brand strategy, and is implemented when a company with existing brands finds another segment of the market with a different brand proposition. The strategy is based on the principle that if the primary brand has become successful, the company can develop a second brand with limited expense and leveraging off the position of the first product. Another advantage of this strategy involves securing an additional shelf share, leaving little room for the products of competitors.

Due to a restriction imposed by the Health Law (Ley General de Sanidad), the second-brand strategy for pharmaceutical companies in Mexico does not allow the same entity to hold a health permit for two different products (under different brand names) with the same API. As a result, the health permit must be held by a different entity.

Figure 1 shows an example of an operating scheme for a group with second-brand strategy for patented pharmaceutical products manufactured with the API imported from foreign suppliers, while the generic products are manufactured with the API purchased from local suppliers (such that there is no need for an importation permit). As shown in Figure 1, as the health permit holder may allow other companies to make use of the permit and the manufacturer of the API for the generic product is located in Mexico, it is possible for the manufacturer to purchase the API or finished goods directly from suppliers. The challenge under this model is to determine the arm’s length compensation of the holder of the health permit for the generic products. Therefore, it is crucial to consider the contributions of all parties in supplying the capabilities necessary to obtain the permit. 17

The highest value associated with the large inbound pharmaceutical industry in Mexico is clearly centred on the research and development and resulting patents developed by these entities. These activities are almost exclusively conducted outside of Mexico with personnel on payrolls abroad. For most – if not all – such groups, it is clear that Mexico does not participate in these activities and the resulting value. The holder of the health permit acts as a “guarantor” as regards registration, quality control and regulatory requirements in the pharmaceutical industry.

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16. In general, two types of patent protection are available for products, namely (i) a product patent, which covers the actual substance itself and (ii) a process patent, which covers only the method of manufacture.
17. Para. 1.91 OECD Guidelines.
In this context, health permits for patent-protected products are available only to the owner of the patent or to the licensee, which enters into a licence agreement with the owner of the patent.

This health permit may not be obtained without the licence of the patent owner, and if the licence agreement is terminated, the health permit is no longer of value to its holder. On the other hand, health permits for generic products are readily available to any qualified applicant and do not have the effect of restricting the number of competitors in the market. Therefore, in theory, holding this type of health permit does not present a material barrier to entry and may not have a discernible impact on the manner in which the benefits of operating in the local market are shared between independent enterprises. Nevertheless, a time element should also be taken into consideration, as the process of obtaining a health permit in Mexico takes time and may provide the company with a temporary competitive advantage.

However, the tax authorities can become confused in considering routine in-country clinical testing and permits with the value creation, while these activities, in and of themselves, do not result in the creation of significant value and would not even be possible if they did not have the legal authority of the foreign owners of those intangibles to perform such tasks and to carry out such registrations. The Mexican tax authorities could attempt to argue that this profitability should be attributed to the consumers in Mexico, but that would be inconsistent with the authors’ interpretation of the OECD Guidelines (which focus on where the value was created).

When analysing the compensation payable to the holder of the health permit, it is crucial to consider whether the funding of that process was provided by the holder of the health permit or by another local manufacturer or foreign related entity. If the funding is provided by a party other than the health permit holder, the funding process can be carried out (i) directly by the legal owner of the patent through a reimbursement/cost-plus mechanism or (ii) indirectly through guaranteed compensation under a limited-risk model. Even then, the company needs to gather the required documentation for the health permit and submit it to the authorities. In the case of an existing drug (such as a patented product), multinational companies very often already have supporting documentation and studies, and the Mexican company may rely on them when requesting a health permit. For registration of generic products, even though some local companies may not have the support of the multinational group, they may rely on the safety and efficacy data provided by the product innovator, so as to avoid the need for costly clinical trials. Notwithstanding the funding process, it is also critical to determine which entity is assuming the product risk related to the health permit. The product risk relates to sales on the Mexican market as concerns the product liability risk that arises when a company’s products fail to perform at accepted or advertised standards. Even though, from the legal perspective, the holder of the health permit is entitled to obtain resources from the product, and it may seem that this right implies also assuming the related risks and obligations, in practice, the product risk is not typically assumed by the holder of the health permit.

Regarding the product risk, in order to absorb the risk, the company must have the capacity to bear the consequences of the risk, should it materialize. In practice, the COFEPRIS requires no capital as a guarantee for any potential product risk. Therefore, the company holding the health permit in Mexico may not have the capacity to bear the consequences of the product risk if it materializes and would be unable to fund any losses that might be expected to arise as a result of the risk assumptions.

A key determination in a functional analysis concerns which entity exercises control over protection functions, as these are of critical importance in the pharmaceutical industry. In this regard, the agreement should clearly specify the entity handling the decisions regarding the protection of intangibles and ongoing quality control over functions performed by the holder of the health permit.

Based on the above, if the local company holding the health permit performs routine functions for purposes of meeting registration, quality control and regulatory requirements under the control of the manufacturer or designated entity and receives funding to perform such activities, the holder of the health permit should attract only a return for services rendered, rather than a return for the intangible. Consequently, the holder of the health permit for generic products should expect routine compensation, which may be based on registration process costs plus an arm’s length margin, and the manufacturing company becomes the economic owner of the health permit. In order to provide support for the above, intercompany agreements and policies should clearly establish a functional profile for the local company, as well as the decision-making process. Otherwise, the health permit holder may be entitled to expect a higher return and a profit split analysis may be required to determine the contribution made by each entity.

4.2. Second-brand strategies with health permit and importation permit restrictions

The importing company holding the importation permit is entitled to import certain pharmaceutical products for further manufacture and distribution. As mentioned, in

19. In this regard, the OECD Guidelines clearly state that bearing a funding risk without the assumption of any further risk generally would entitle the

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In order to obtain an importation permit, the company must hold the health permit, which guarantees compliance with registration, quality control and regulatory requirements in the pharmaceutical industry.

Due to a restriction imposed by the Health Law on second-brand strategies for pharmaceutical companies in Mexico (discussed in the previous section), the second-brand strategy for generic products requires additional analysis of ownership of the API inventory by the holder of the permits.

Figure 2 shows an example of an operating arrangement for the group with second-brand strategy for the patented and generic pharmaceutical products manufactured with the API imported from the foreign suppliers, both requiring an importation permit.

The additional complexity of the above structure includes the importation permit, which the health permit holder must have in place in order to import the API into the Mexican market. Consequently, the importer of the API for generic products takes title to the inventory and then resells it for further manufacturing; the respective compensation should take into consideration ownership of two permits and title to the inventory.

Due to changes in the Health Law in 2008, an importation permit may be requested by any pharmaceutical company, as a manufacturing plant is no longer required to import API or pharmaceutical products. The process of obtaining an importation permit takes three months. The importing entity generally subcontracts importation services from third parties and does not own significant tangible assets.

As in the case of a health permit, if the importing company holding the importation permit and health permit (i) performs routine functions for purposes of meeting importation, registration, quality control and regulatory requirements under the control of the manufacturer or designated entity and (ii) receives compensation for performing those activities, then ownership of the importation permit and health permit should attract only a return for service rendered rather than a return for the intangible. Consequently, the holder of an importation permit and health permit for generic products should expect routine compensation (which may be based on the cost-plus method) and the manufacturing company becomes the economic owner of the importation permit and the health permit. Alternatively, a lost earnings approach could be considered if the holder did not allow the transfer of the health permit to another entity. If the holder of the permit does not allow the transfer of the permit, the new importer is required to go through the entire process of obtaining the new permit.

When analysing contributions to services related to the importation of inventory and processing the permits, it may be a challenge to identify public comparable companies. Therefore, alternative analyses may be needed to determine an arm’s length compensation for the importer of the products. In practice, comparable companies generally only render importation services, without taking title to the inventory. Therefore, a set of comparable companies rendering importation services may be used, adjusting the results to eliminate the effect of differences in the ownership of the inventory. Alternatively, it may be possible also to rely on a set of comparable distribution companies, adjusting their results for advertising and marketing or distribution functions. Comparability adjustments under this model may be more challenging, as specific information on costs and expenses of comparable companies is needed in order to adjust for expenses not incurred by the tested party.

25. Before 2009, importation permits were granted only to pharmaceutical companies in Mexico owning a pharmaceutical plant. This requirement is no longer valid, due to changes in health regulations in Mexico.
Both of the above-mentioned analyses consider (for calculation purposes) the value of the inventory (API). However, in certain cases, additional compensation for importation of the products (taking title to the inventory) may not be required if the importing company does not require additional funds to finance a purchase of inventory (payment for purchase of inventory is made after the collection of accounts receivable) and any inventory risk is transferred to the counterparty (not assumed by the importing company). In order for this markup-on-value-added model to be applicable, a supply agreement must clearly establish payment terms and specify the entity responsible for inventory risk.

In addition, if the purchase of inventory is made by the importing company from a related party for further resale to another related party, an analysis of the profitability of the related party manufacturing and distributing the product to third-party customers is also required in order to test the arm’s length nature of the global transaction, showing that the value of inventory is at market value. In this regard, it is crucial to take into consideration that the overall result of the Mexican operation – if the importation permit is owned by a company other than the local manufacturer and distributor – may be higher than if that permit were owned by the same entity that manufactures and/or distributes.

5. Conclusion

The profitability that has been a feature of the Mexican pharmaceutical industry has drawn the attention of the tax authorities to the industry’s transfer prices. Understanding the ways in which the industry works, the needs which drive the companies within it and the factors which affect its transfer pricing practices will all help to facilitate a better understanding of the problems in transfer pricing contexts and make it possible to face industry challenges related to regulatory restrictions. Consequently, companies need to be able to seek a commensurate level of profit for activities related to the use of health and import permits, as well as to maintain proper, detailed documentation describing the facts and circumstances surrounding regulatory requirements in Mexico.