Transfer pricing challenges in pharmaceutical industry

Akshay Kenkre of TransPrice discusses one of the most contentious issues in pharmaceutical industry relating to approach of the tax authorities to compare branded Active Pharmaceutical Ingredients with generic API and with plausible solutions to defend this approach.

Introduction to Pharmaceuticals Industry

Pharmaceuticals industry has been a big contributor to the evolution of mankind. The study of medicines is one of the oldest disciplines of science and has been a boon to the human species. The prehistoric medicines were mainly the plants and herbs which evolved over the years to the modern version of medicines, thanks to enormous research and development (hereinafter: R&D). Countries like Switzerland, Germany, Italy, UK, USA, and Belgium are the pioneers in this industry with strong R&D initiatives and drug discoveries.

Due to the sensitivity fact to the human life and increase in financial links between the drug manufacturer and the physicians, this industry is one of the most regulated industries in terms of pricing, quality and also intellectual property. One of the leading drug administrators in the pharmaceutical industry is the Food and Drug Administration (hereinafter: FDA). Most of the global drugs have to be approved by FDA for its effectiveness and safety.

The products of the pharmaceutical industry can be divided into bulk drugs (i.e. Active Pharmaceutical Ingredients) and finished formulations. Active Pharmaceutical Ingredients (hereinafter: API) are the raw materials which cannot be directly consumed by humans. They are converted in to consumable form through a manufacturing process commonly known as secondary manufacturing. Secondary manufacturing is a low-value added activity, involving more standard and fewer specialists, skills and processes, and basic know-how. Further, products can be classified as branded drugs and generic drugs. A branded drug is an outcome of original R&D and is marketed under a specific trade name by a pharmaceutical manufacturer. In most cases, the branded drugs are under patent protection and command higher price in market. On the other hand a generic drug is essentially an imitation of an original branded drug and is sold under its chemical or ‘generic’ name. When the patent protection on the original drug expires, copies or reproductions of the drug can be made.
Transfer Pricing in Pharmaceutical Industry

For various reasons, such as high level of regulation and control, to maintain quality of drugs, etc, most of manufacturing and research activities in the pharmaceutical industry is done by the group companies Thus, in a multinational pharmaceutical group the typical related party transactions that are undertaken includes:

(a) Import of API for secondary manufacturing;
(b) Import of finished formulations for distribution in local market;
(c) Contact manufacturing of API/ finished formulations;
(d) Contract R&D services or R&D support services; and
(e) Clinical trial services.

Apart from above transactions, branding and marketing activity (i.e. development and management of marketing intangible) is also one of the significant function managed by the group companies.

In this article we shall focus on the transfer pricing challenges faced by the pharmaceutical companies in respect of transaction relating to import of API and discuss the possible ways to address this challenge.

Import of API for secondary manufacturing

API is the most vital content of finished formulation (i.e. medicine). API constitutes nearly all of the value-added contained in the finished physical product. Most of the value adding activity occurs at the level of manufacturing APIs. Majority of MNE pharmaceutical companies require members of their group to procure branded API manufactured within the group (rather than using generic version of the API). There are several technical, business and commercial reasons (to be discussed below) for procuring APIs from group company. Due to the vast research and development process gone in to manufacturing of branded API, generally the import prices of branded API are higher than the generic API.

During the transfer pricing audit it has been experienced that the approach of the tax authorities is to compare the import price of branded APIs with generic APIs available from alternative sources like customs database, etc. The prices mentioned in such databases may be lower than the prices at which the taxpayer imports the API from its AE. The tax authority consider such data as comparable uncontrolled transactions and use Comparable Uncontrolled Price (hereinafter: CUP) method to determine the arms length price (hereinafter: ALP) of controlled transaction. This often results in downward adjustment to the import price of the taxpayer. A recent ruling of Supreme Court of Canada in case of GlaxoSmithKline Canada Inc is one such ruling were Canadian tax authorities compared
generic API with branded API imported by the taxpayer from its AE and carried out the transfer pricing adjustment.

However, comparison of branded/originally researched API with generic API may not be the right approach because every API is unique and will differ in properties in many ways. Drugs with similar chemical compositions may have very different uses or effects, and drugs that achieve a similar effect may be substantially different in composition, in the method of use, in dosage, in side effects, etc. Because of this unique nature it is very difficult to compare one API with another although the effect of API may be similar. Some of the key differences in branded API and the data of generic APIs considered by the tax authorities as CUP are as follows:

<table>
<thead>
<tr>
<th>Particulars</th>
<th>Branded API</th>
<th>Generic API</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical composition</td>
<td>Known as the API is developed by the group company</td>
<td>Unknown. Usually details of chemical composition are not publicly available</td>
</tr>
<tr>
<td>Therapeutic effectiveness</td>
<td>Known</td>
<td>Unknown and may be different as well</td>
</tr>
<tr>
<td>Stability, Efficacy, Potency, dosage, side effects</td>
<td>Known</td>
<td>Unknown and may be different as well</td>
</tr>
<tr>
<td>Level of testing during development stage</td>
<td>Significantly high</td>
<td>Level of testing is unknown</td>
</tr>
<tr>
<td>Research expenditure incurred for development</td>
<td>Very high</td>
<td>Significantly lower</td>
</tr>
<tr>
<td>Product liability if any faced by manufacturer</td>
<td>Product liability recourse to a supplying entity is available.</td>
<td>Generally not available.</td>
</tr>
</tbody>
</table>

It is for these above reasons comparison of generic API with branded API is not a right approach, unless the above differences are known and a reliable adjustments can be made for such differences, which is seldom possible. While preparing transfer pricing study report it is essential that the taxpayer should document these differences. Also during the transfer pricing audit these differences should be highlighted before tax authorities.

Apart from the above differences the commercial reasons for importing of specific APIs from the AEs has to be well documented and brought out clearly to the revenue authorities. Few of the possible advantages that the taxpayer may receive by importing API from the group company than from any other source are as follows:
1. **Use of Brand Name**

   Usually import of original research drug (i.e. Branded API) from the AEs entitles the importer to use global brand name for the corresponding formulation developed from the said API. This helps importer to market its product and enjoys premium over the other players in the market. This is therefore a matter of significant competitive advantage for the importer. While providing such a defence, it has to be ensured that no compensation is paid by the importer company for usage of brand name separately (Royalty for brand name). Such an advantage to the importer company has to be complimentary in nature and not by payment of any consideration.

2. **Quality**

   With import of API from AEs the minimum quality is ensured and the formulation can meet the standard lead by company and market. In such a case, a well drafted agreement with proper responsibilities assigned for quality control and warranties should be brought out. It has to be ensured that the agreement is in sync with the quality requirements as laid down by the group.

3. **Group insurance or hedging**

   By importing API from the group company the importer company is generally insured of any defects in terms of manufacturing of API and quality of the final output. Further, any damages or claims that may occur over the importer company can be back to back insured and recovered from the foreign AE. Again a well drafted agreement with insurance clause has to be brought out and documented.

4. **Cost and time involved in switching to different source of API**

   The process of secondary manufacturing of finished formulations is to great extend dependent on the manner in which the API is produced, as well as the quality and efficacy of the API. In order to evaluate whether generic drugs available from third parties can potentially replace the original researched drugs imported from AEs, the importer would have to undertake prolonged and highly expensive tests to prove that the third party API meet all the requirements of the Group in terms of stability, quality, efficacy, etc. The company would also have to incur costs for modifying its production processes to suit the new raw material, which will entail significant financial investments. All of this would be a time consuming process and importer of API may lose its market share if it is unable to serve the market in time.

   All the above technical and commercial reasons for non-comparability of branded API with generic API should be properly documented in the transfer pricing study report.

   In view of the aforementioned fundamental differences between branded API and generic API as well as non availability of comprehensive and reliable comparable data, the CUP
method cannot be selected as the most appropriate method, to determine arms length price of such transaction. Instead, Transactional Net Margin Method (hereinafter: TNMM) should be explored, as product differences have least impact on the profit margin.

Conclusion

In this article we have discussed one type of cross border related party transaction in pharmaceutical company. The issue of branded v/s generic API is one of the most controversial issues faced by majority of MNE pharmaceutical companies across the globe. A key message for all the pharmaceutical companies facing this issue is to document technical differences as well as business and commercial rationale supported by appropriate agreement and policy manual. Also during the transfer pricing audit and litigation, these points of differences should be put across very firmly before tax authorities.

\footnote{Canada v. GlaxoSmithKline Inc. (2012 SCC 52): Supreme Court of Canada did not conclude on the final outcome of the matter and remitted the case back to Tax Court of Canada with certain guiding factors to be taken into consideration for determining correct transfer price.}