IMPORTING APIS FROM RELATED PARTIES AT PRICES OF LOCAL MARKET!

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Recently, the Mumbai Income Tax Appellate Tribunal in Serdia Pharmaceuticals (India) Private Limited v. Assistant Commissioner of Income Tax held that the arm's length price for importing Active Pharmaceutical Ingredients ("API") from related enterprises should be determined on the basis of price at which locally manufactured generic API are sold in the domestic market. In this case, the tax payer had adopted Transactional Net Margin Method ("TNMM") for determining the correct arm's length price of the API which was imported into India. The IT Department contended that the APIs purchased were at prices that were higher than that paid for similar APIs by other companies in India and that the Comparable Uncontrolled Price ("CUP") was the most appropriate method. The Tribunal held that the onus of selection of the "most appropriate method" for determining the arm's length price of a transaction was on the tax payer. Since in the present case, the tax payer had failed to dispose this burden, the IT Department was justified in applying CUP Method without specifying the reasons for rejection of TNMM method. Finally, it held that whenever the CUP Method could be reasonably applied in determining the arm's length price, this method should be followed.

PSA view –This decision brings out the superiority of the CUP method and also brings out other discussions on the table related to the importance of customs valuation while applying CUP, the level of weightage to be given to the business model, i.e., circumstances of business vis-à-vis price of product. This ruling has failed to appreciate the various costs which are involved in the importation of APIs like customs, freight, storage costs, etc. Also, it has shifted the onus of proving the appropriateness of the method completely on the tax payer. Therefore, ensuring the appropriateness of the correct transfer pricing method becomes imperative pertaining to any international transaction entered into by related parties. In another recent development, the office of the Drug Controller General of India has decided that it will soon start inspection of the manufacturing facilities located in foreign countries from where Indian companies are importing APIs, intermediates and finished products. This move will enable the Indian drug authorities put a quality check on the products coming into India.

Health Ministry still silent on NLEM

The endeavors of the DCGI to include of certain drugs in the category of essential medicines in accordance with the list released by the World Health Organization are still not being acted upon by the Health Ministry. The list of drugs to be included in the category of essential medicines will expand the present list of 71 bulk drugs as defined under the Drug Price Control Order to approximately 354 drugs. In addition to the inclusion of the essential medicines under price regulation, the Department of Pharmaceuticals has suggested that the

inclusion of the essential medicines should be expedited in order to seek the possibility of providing a tax benefit to the manufacturers.

PSA view –The concept of essential or life saving medicines was first provided for under the national pharma policy, and the steps to be taken by the Health Ministry are quite delayed. The inclusion of the essential drugs under the Drug Price Control Order ("DPCO") will facilitate price modulation but only to a certain extent since the National Pharmaceutical Pricing Authority may not be adequately prepared to manage the pricing requirements of such a large number of essential drugs. It will be beneficial to include the definition of life saving drugs under the DPCO to facilitate the price regulation by the NPPA, in light of the excessive delay by the Health ministry in granting approval to the list of essential drugs.

Drugs for export to carry barcodes

In order to put an end to the allegations from overseas that Indian pharmaceutical firms ship out counterfeit medicines, the government has decided that all drugs to be exported from July 1, 2011 will carry a barcode. A barcode is a machine-readable data, which contains information regarding the product, including the details of the manufacturer. This move shall allow the authorities to track the medicines exported from India. The Director General of foreign Trade confirmed on January 10, 2011 that these norms shall come into force on July 1, 2011.

PSA view –Indian drug makers export drugs worth US$ 10 billion each year to over 100 countries all over the world. This measure will firstly assure importing nations that the drugs manufactured in and exported from India are not fake and are genuine and secondly, will allow a measure of check on fake drugs with the "Made in India" tag to allow tracing of the same to the country of origin and identify the source. This will not only improve India's image as an exporter of genuine medicines and India's export of medicines, but will also assist in limiting the number of counterfeit drugs spread out in the market.

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