

May, 2017

Capping on Coronary Stent Prices.

Government Order REGD. NO. D. L.-33004/99 dated February 13, 2017, the NPPA (National Pharmaceutical Pricing Authority) founded under the Department of Pharmaceuticals had directed all companies manufacturing coronary stents in India, to maintain production/import/supply of coronary stents and to submit weekly reports and weekly production plans of coronary stents produced and distributed to NPPA and the Drugs Controller General of India (DCGI).

According to the said notification issued by the National Pharmaceutical Pricing Authority (NPPA), prices of drug eluting stent would be fixed at ₹29,600, while that of bare metal stents would stand at just ₹7,260. In comparison, the prices of drug eluting stents now range between ₹40,000 and ₹1.98 lakh. Similarly, bare metal stents cost patients between ₹30,000 and ₹75,000 on an average.

While this pricing cap is exclusive of taxes, it has been stated that the manufacturers may add local taxes/VAT and no other charges in the calculation of MRP, if they have actually paid such taxes or if it is payable to the government on the ceiling price specified in column.

As per the data shared by NPPA, prices of stents jump exponentially by as much as 1,000 per cent from the production till the time it reaches patients, with hospitals enjoying abnormally high margins of 650 per cent, in some cases.

Pursuant to the said notification at least three pharmaceutical stent maker multinational companies (MNCs) have filed applications with India's drug pricing regulator to withdraw their "new generation" stents from the country, claiming the current stent pricing regime in India makes the sale of their stents here unviable.

Besides, there still exists some ambiguity with regard to the fact that such companies can indeed withdraw their products from the market especially in the light of recently invoked rules Department of Pharmaceuticals had recently invoked rules to prevent stent makers from taking their brands off the market before a stipulated time.

Violation of the above said notification exposes the defaulters to be liable to pay the overcharged amount along with interest thereon under provisions of the Drugs (Prices Control) Order, 2013, read with the Essential Commodities Act, 1955. It is pertinent to know that any manufacturer intending to discontinue production or import of stents has to notify the NPPA at least six months in advance and follow the ceiling prices till clearance from the government.

The exact text and copy of the Government Order can be downloaded from [here](#).

Should you need any clarification or would like to discuss any aspect related to the above or generally any aspect related to the Indian Law, please feel free to contact:

Salman Waris, Partner, TechLegis Advocates & Solicitors

Email: salman.waris@techlegis.com

Ph: +91-9891427685