

Interview: Bhupendra Singh - Chairman, National Pricing Authority (NPPA), India



"Our pricing system is 'market-based' rather than cost-based"

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Bhupendra Singh, chairman of the Indian National Pharmaceutical Pricing Authority (NPPA), provides an overview of the current mechanisms governing the pharmaceutical and life sciences industry in India, highlighting the challenges of the current pricing climate, and the ultimate goal of providing affordable and accessible medicines to the nation's roughly 1.3 billion citizens.

What is the role of the NPPA within India?

For the NPPA, pricing is just one of several areas of focus and along with ensuring affordability, NPPA also ensures the availability and accessibility of medicines. We cover the entire value chain, and to this purpose the availability of the products in the country is crucial so while capping the prices we do ensure that viability for the manufacturer is not adversely affected. In fact, we take care of the interests of the entire supply chain, ranging from the manufacturers, the distributors to retailers and finally the consumers. In most cases, the profit margins of the manufacturers remain unaffected and it is only the 'trade margins' get curtailed.

What are your main objectives as chairman of the NPPA?

At present, about 20 percent of the drugs manufactured or imported in India are under price control based on the National List of Essential Medicines prepared by the Ministry of Health and Family Welfare. Our responsibility is to ensure that these drugs are available at affordable costs as per the government's guidelines, which we have implemented accordingly. Furthermore, under

exceptional circumstances, the NPPA can cap the price of any other drug which is not part of the National Stockist of Field Medicines. As chairman, one needs to supervise all the responsibilities assigned to the NPPA.

How do you settle upon a price for any given drug?

As mentioned above, NPPA caps the prices of only about 20 percent of the drugs sold in India so the remaining 80 percent are under no price control and the prices are fixed by the manufacturers/importers. Our pricing system is 'market-based' rather than cost-based, as it was before 2013. A market based system is always industry-friendly because it does not look into the profit margins of the industry and takes into account the prices under which the drug is being sold.

To give you an example, if we were to cap the price of paracetamol, we would firstly collect the data of all the manufacturers/marketers of paracetamol, their market shares, and the complete market size of paracetamol along with at what prices the drug is being retailed by them in the market. For price capping we take into account the market share of each of them except the companies with less than one percent market share which are excluded from price calculation.

Supposing there are a total of 100 companies out of which 70 companies are left with one percent or more share, we add up the 'price to the retailer' of these companies and then we divide it by the number of companies (70 in this case) and that becomes the new ceiling price for paracetamol. All companies selling above this 'ceiling price' are required to bring down the prices up to or within the ceiling price.

Can you tell us more about the new policy on medical device pricing and the rationale behind it?

Presently we have 23 devices that have been notified as drugs, bringing them under the monitoring of NPPA for ensuring that the prices of these drugs have not increased by more than ten percent in a year and for price capping if found essential in public interest. The government has made a separate rule for devices that will be applicable as of 1st January 2018. We are monitoring the prices of these 23 devices and out of these there are five devices which have been notified as essential and brought under price control including 'coronary stents' which became quite a debated topic across the world; especially as three US multinationals were adversely affected by that.

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Before price capping on coronary stents we examined the import prices, what prices they were being sold to the distributor, and what price they put on the devices as the maximum retail price. In the case of cardiac stents, the hospitals were the end users since they were dispensing the stents to the patients. What we found, supposing the manufacturer's selling price was \$300, it became \$450 at the level of distributors and ended up being \$3000 at the level of patients. How can any society or any government allow this? The question is, where are the profit margins going? Is it not becoming 'profiteering' instead of reasonable & healthy profit margins? Moreover, in price capping we are not touching the industry margin and slashing only the exorbitant margins being paid in marketing the devices which mostly affects the private hospitals overcharging the patient.

What needs to improve in order to provide more affordable medicines and devices?

All the players in the medical devices industry and specially the manufacturers need to realise that affordability is good economics in the form of economy of scale specially in price sensitive markets. Before the price cap, we were having about five hundred thousand angioplasties in the year 2016 and after price cap on stents we expect them to reach six hundred thousand this year. If you make a product affordable, the demand increases accordingly and as a result more and more patients can afford angioplasty at a reduced price. This way, both the consumer and the manufacturers are going to benefit from it.

In the market-based price control system that we follow in India we consider all factors to ensure that it does not have negative repercussions on the margins of the companies. Drugs and the devices industry need to appreciate the virtue of increased affordability in order to create a win-win situation for the industry and for the consumers. This makes lots of sense in a country like India where the reach of health care is largely untapped leaving a very wide area for industry to grow on economy of scales.

I hear that every hospital can buy the same medical devices for a different price. Is every hospital in India now price controlled?

The device manufacturers do sell to different hospitals at different prices since there is always a huge margin gap between their selling price (to distributor or hospitals) and the maximum retail price (MRP) printed on which devices could be sold to patients by the hospitals. For example, say a device is sold by some manufacturer to a hospital at \$300, it may carry any notified maximum retail price (MRP) say \$1500 or even more (if the device is not price capped by NPPA). The hospital can sell it to patients for up to \$1500 or use these inflated profits to offer some discount as well. Manufacturers can offer more margins to hospitals in the case of bulk purchases so essentially it is

the hospitals & and the doctors which dictate the market in the case of most medical devices and also appropriate the maximum profits in the trade. In a competitive market, the manufacturers are under pressure to sell devices at very inflated prices to keep the private hospitals happy.

In India, there is no control on hospital charge like procedure cost, doctors' fees or hospitalisation charges. However, if the price of any drug or device has been capped by NPPA, all hospitals need to follow that price.

What would you say is needed to improve and enhance access to innovative high-quality treatments?

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A market-based pricing system does not hit the profit margin of manufacturers including their cost of R&D and innovation. Even when India had a cost-based pricing, it accounted for the innovation cost. The excessive margins which are being paid for by 'market promotion' are not getting ploughed back in innovation as could be seen from the example of coronary stents above. The price difference between the selling price by the manufacturer (\$300) and the price to patient (\$1500) is not going into R&D.

Accessibility is taken care of largely by the government healthcare system while private sector is focused in urban and semi urban areas. Moreover, affordability is not necessarily an antithesis to accessibility as it is often presented by the industry. Affordability is equally necessary along with profitability to increase accessibility for long-term sustainability of any private healthcare system. The device manufacturers and private hospitals need to work out an affordable pricing system based on healthy profits but not motivated by profiteering since the choices of the patients are not 'free' and since the 'life' is a much more 'sacred' 'commodity' than others even in a free market.

Do you believe the role of NPPA should evolve or change?

I do believe that the NPPA's role should evolve and change as per the changes in the healthcare system and it is changing as well. A change of the total ecosystem is needed, too. However, it is important to note that our role is not only to control the prices of the pharmaceutical drugs in India, we also deal with the entire supply chain while trying to create a balance between the interests of all the stakeholders, including industry, the trade channel and the consumer.

What do you identify as your biggest challenge in your current role?

The biggest challenge is to convince the industry that our pricing is helping them instead of harming them. At the end of the day, we create affordability in an expensive market in a country like India, which has an out of pocket expenditure of about 60 to 70 percent of spending on medicines. I am positive that if more and more people have greater access to medicines, sales will increase accordingly – the ‘economy of scale’ has to be kept in mind. At times, it becomes difficult to counter the voices being raised against the Indian price control system which I feel is one of the most industry-friendly systems across the world. Our pricing is market-based and does not hurt the industry as it is being projected by some sections knowingly more because of fear of disturbance in ‘status quo’ and not because of much loss in their profitability. The satisfying thing, however, is that in spite of apprehensions about price control we are witnessing growing investment by multinationals in India. They are acquiring businesses in India and this is testament to the fact that there is a huge untapped potential for growth in the health care sector in India. The Indian GDP expenditure on health has increased and in the future, it is going to increase further. There are many opportunities for businesses in India. Our price control policy is industry-friendly, limited in its scope to only 20 percent of drugs on the market, and fairly reasonable.

What has been your biggest achievement as chairman of the NPPA?

We have brought down the prices of number of medicines in a very short period of time. The biggest challenge was capping the prices of coronary stents. The heart is a very sensitive part of the body and if someone needs intervention in a hospital because of cardiac dysfunctions, the first thing coming to mind is fear for life. In the hospital, it is the surgeon who decides for the patient which company’s stent should be used. Patients have no time to make any choices or go for market survey and fall for higher priced stents. For this reason, capping the price of stents and ensuring their availability and accessibility was the biggest challenge in my present assignment. Since the stakes of stent manufacturers were high, the price cap was opposed by industry, doctors and hospitals. However, since the market data about exorbitant margins was put in public domain, the opposition gradually silenced. Now things have stabilised and as a result of price cap the market of cardiac stents in India has increased and some companies are thinking of long term commitment in India in case of coronary stents and other medical devices.

“There are a lot of opportunities in India in the form of the sheer number of patients.”

What role will NPPA play in partnership with all stakeholders in the process of learning, collaborating and trying to create a new healthcare system for India?

There are a lot of opportunities in India in the form of the sheer number of patients. If you take the entirety of South-East Asia, the population is less than the Indian population. There is a growing realization and emphasis on the healthcare sector. With the liberalised FDI policy and 'Make in India' put in place as one of the India's national missions to attract foreign direct investment, being directly monitored by our benevolent Prime Minister, I truly believe India is the best place to invest in the manufacturing of drugs and devices. The government and NPPA are open to consider all concerns of the industry and collaborate for development of a vibrant healthcare system in India.

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