Price-control as a regulatory philosophy fundamentally dents the image of a country

*India’s $5 billion medical device market may be going through an existential threat.*

ETHealthWorld  |  June 18, 2018, 15:41 IST

By Avirup Bose, Associate Professor and Assistant Director, Centre for International Trade and Economics Laws, Jindal Global Law School

India’s $5 billion medical device market may be going through an existential threat. The Indian healthcare industry has been
registering a double-digit growth rate, with a CAGR of 17% in
the last five years. However, India’s drug pricing authority –
the National Pharmaceutical Pricing Authority (NPPA),
notified the Medical Devices Rules, 2017, which has come
into effect from January 2018, allowing the NPPA to notify 15
medical devices as drugs, effectively bringing them
automatically under price control regulation.

In their book, Forty Centuries of Wage and Price Controls by
Robert Schuettinger and Eamon Butler, first published in
1979, vividly documents a four-thousand-year historical
record of economic catastrophe caused by price control
policies. In its very essence, price control – a populist
regulatory device, seldom works for a nation’s economy, its
consumers or its regulatory philosophy. In the case of NPPA,
it fails to achieve the very purpose for which it is being
imposed – better access to drugs and medical devices.

Pharmaceuticals are often characterized as making windfall
gains at the expense of hapless patients, which is often used
as a justification for imposing price-controls. However,
academic research shows that more than four-fifths of the
value created by new drugs flows to patients in the form of
health benefits, and less than one-fifth flows to
manufacturers. New drugs and medical devices do generate
financial rewards for their innovators, but also decades of
healthy life to patients, improving the overall life-expectancy
of a nation.

Unfortunately, Indian regulators – like the NPPA, for example
do not perform a cost-benefit analysis of how imposition of
price-control measures would discourage investment,
innovation and job-creation in the Indian pharmaceutical
industry – something that the Indian government is vocally
committed to promote.

On balance, by cutting short the price of drugs and medical
devices, the regulator could ensure that innovation falls by
even more. Crude price-controls would severely stifle
introduction of new drugs and devices in Indian markets. A
report by IMS Health – a leading Indian healthcare market
research agency, reveals that price-control measures by
NPPA has ensured a 75% decline in new drug launches since 2011. The statistic would be similar for medical devices, if the NPPA continues to subject the medical device market to the same failed regulatory strategy.

With drastically reduced margins of profits, drug and device manufacturers would have less incentive to reach rural markets. This is precisely the reason why price-control as a strategy fails to protect the very people for whom its introduction is justified by the regulatory agency. Rural poor and low-income households (even in tier II and III cities) are deprived of the availability of price-controlled drugs and devices. In an IMS Health report – “Accessing the Impact of Price Control Measures on Access to Medicines in India”, finds that – there is no significant penetration of price-controlled drug molecules in rural markets. Furthermore, the study finds that consumption of price-controlled medicines in rural areas have dropped by 7% in the past 2 years.

Imposition of price-control mechanisms on the medical device market will lead to the same results, disproportionately affecting the most vulnerable sections of the Indian medical consumer.

Moreover, what is most draconian of the NPPA’s price-control strategy, is it adopts a “one price fits all” strategy. The NPPA does not distinguish between advanced technologies, within the same medical device, product class and subjects newer technology medical devices to the same price-control measures as older technology products, resulting in technologically advanced stents to be sold at a greater loss, than the older technology products.

Given that NPPA has extended such price-controls over additional medical devices, firstly cardiac stents and then on orthopedic implants (and have now announced it may add price-caps on three more products) - it has affected the way foreign firms visualize the Indian medical device market. The lack of predictability in India’s regulatory strategy has ensured that foreign suppliers take an overall bearish view towards the entire Indian medical device market. Further, the NPPA, can deny manufacturers to withdraw their supplies from the market to avert a public health crisis using section 21 of
Price-control as a regulatory philosophy fundamentally dents the image of a country, which is desirable of making it an international manufacturing and investment destination. For example, the US Trade Representative (USTR) is considering to revoke India’s special tariff status – under the US’s ‘Generalized System of Preference’ (GSP) – which provides preferential treatment to its exporters from developing countries, including duty free entry of certain goods, chemicals, gems and textiles. In 2017 India was the biggest beneficiary of GSP with subsidies worth $5.6 billion – a status it may lose given NPPA’s price-control strategy.

Price-control and health care should not be confused. Slashing prices of drugs and medical devices is a lazy quick-fix which has no commensurate reduction in medical expenses for Indian patients. Since February 2017, when the price of stents were slashed by about 85%, hospitals have started leveraging margins on consumables and services to offset stent price margin losses, with negligible benefits reaching the final consumer. Strangely, the regulator’s answer to that problem seems to be considering price control on more medical devices and consumables! In-spite of Indian drug prices being one of the lowest in the world, out-of-pocket expenditure of Indian patients on healthcare is as high as 61%.

India, where two-thirds of the population is denied quality healthcare needs a comprehensive healthcare plan. No doubt that medical expenditure is increasing, but not because of super-normal profit made by pharmaceutical companies but because of profiteering by some private hospitals, and a host of other reasons. Recently, the Competition Commission of India has found that a prominent hospital chain had marked up price of syringes by over 525% for their inpatients. Doctors’ consultation fees, cost of operation procedures, diagnostic tests, hospital bed rentals – all add up to the rising cost of medical expenditure for Indian patients. For which the Indian government needs to spend more on healthcare. Currently, India spends around 1.2% of its GDP on healthcare, compared to 3% in China and 4.3% in Brazil.
Furthermore, as per the 2018 Global Healthcare Access and Quality (HAQ) index, India is 145 among 190 nations and ranks lower than neighboring Bangladesh, and even sub-Saharan Sudan and Equatorial Guinea.

Can the Fortis-IHH deal overcome "surprise" Daiichi roadblock?