UNIVERSAL PRICING OF VACCINES - A NEED OF THE HOUR

Wasim Beg*

Swarnendu Chatterjee*

Pritthish Roy*

INTRODUCTION

With the advent of the 18th century, the world for the first time witnessed how injecting foreign bodies into an ailing person's body can fight-off the disease and promote overall immunity from a further attack of the same disease.[1] On the face of it, the planet has faced innumerable breakouts of deadly diseases, which have been contained by means of mass inoculations. Fast forward 2021, when the planet is once again facing the brunt of a deadly disease, which has touched the lives of almost every person on the planet, medical science has been able to develop numerous vaccines for COVID-19, at a speed never witnessed before. What is now sincerely awaited, is the day when the entire global population gets rid of the virus and as per the World Health Organization, vaccination is the only way out, by adopting it as a welfare action, rather than letting the people struggle.[2]

India, which has been accredited with titles such as the vaccine manufacturing hub of the World[3]is struggling towards vaccinating its people at the desired rate and speed. With whatever is available as our "stock" of vaccine, the Central Government is procuring vaccines at a certain rate and allowing the same to be sold to the states at much higher prices.[4] This discriminatory pricing policy, which is being allowed by the Central

*PARTNER, L&L PARTNERS, NEW DELHI.
*MANAGING ASSOCIATE, L&L PARTNERS, NEW DELHI.
*BA LLB, THIRD YEAR, VIPS, GGSIPU, NEW DELHI.

[1]World Health Organization's article titled *"Smallpox Vaccines"* available at https://www.who.int/newsroom/feature-stories/detail/smallpox-vaccines

[2]The Harvard Gazette's Health and Medicine bulletin titled *"Vaccines can get us to heard immunity, despite variants",* available at https://news.harvard.edu/gazette/story/2021/02/vaccines-should-end-the-pandemic despite-the-variants-say-experts/

[3]Thomson Reuters report authored by Abhirup Roy, Euan Rocha and Krishna N. Das, available at https://www.reuters.com/article/health-coronavirus-india-vaccine-idUSKBN28K10E

[4]Economic Times article titled *"Why different vaccine prices for Centre and States?" SC asks Govt."*, available at https://economictimes.indiatimes.com/news/india/why-different-vaccine-prices-for-centre-and-states-sc-asks-govt/videoshow/82327290.cms?from=mdr

Government, whereby Bharat Biotech, along with Serum Institute of India is selling vaccines to different states without any uniform price fixation and thereby causing tremendous anomaly and hardship to the common people, as different hospitals in different States are charging different prices from the common mass. This has opened the floodgates of litigation questioning such discriminatory pricing.

ISSUE IN DISCUSSION

The controversy is primarily centred on the issue of discriminatory pricing strategy undertaken by various vaccine manufacturers like Serum Institute of India and Bharat Biotech, both of which are offering the vaccine at a much lower price to the Central Government as compared to the State Governments, which in turn are getting the vaccines at a lower price than the private market.[5]This differential pricing strategy has raised the hackles of the state governments — and allegations of 'profiteering' are being made against the two vaccine manufacturers. As per official communiqués, Bharat Biotech will supply its vaccine at Rs 150 to the Centre, Rs 600 to states and Rs 1,200 to private hospitals.[6] However, there has been no explanation offered by these vaccine companies as to how they are determining these discriminatory pricing policies whereby their respective products are being sold differently to different buyers. Ethically speaking, such a discrimination is uncalled for and should be considered a malefaction, especially since a COVID-19 vaccine is now an eseential commodity of the highest order. Moreover, Covishield cannot be put under the head of commercial commodity since a lot of public exchequer's money has been invested into its research and development process. Public money from India is also going into the production of vaccines because the government is funding the capacity expansion of the two Indian manufacturers.[7] SII had once stated that at Rs 150 a dose, the company was making normal profit.[8] Its profit would be considerable because the demand for the vaccine is enormous at this point in time.

[5]Business Today article titled, *"Centre defends Serum, Bharat Biotech COVID-19 vaccine pricing"*, available at https://www.businesstoday.in/current/economy-politics/centre-defends-serum-bharat-biotech-covid-19-vaccine-pricing/story/438808.html

[6]Supra 5

[7]Thomson Reuters report authored by Aftab Ahmed, available at https://www.reuters.com/world/india/india-fund-capacity-boost-serum-institute-vaccines-run-short-source-2021-04-19/

[8]Money Control editorial titled *"Covishield vaccine's revised prices still only 50% of global rates, says SII CEO Adar Poonawalla",* available at https://www.moneycontrol.com/news/business/covishields-revised-prices-still-only-50-of-global-rates-says-sii-ceo-adar-poonawalla-6798091.html

PRAYER FOR JUDICIAL ACTIVISM

As a last resort, many of the citizens and the State Governments approached the Courts of law whereby making multiple prayers such as making vaccines available to the States free of cost, manufacturing vaccines on a war-footing and other such requests which are of utmost importance. Amidst all the PILs filed in various High Courts, the Supreme Court of India in the Suo-motu case *re: distribution of essential supplies and services during the pandemic*[9] observed that it is for the Central Government to make sure that the tenets of Article 14 and 21 are not violated and mass vaccination takes place at the earliest whereby including and covering all the socially and economically marginalized communities in the Country. One interesting aspect of this case is that when the Central Government was asked to submit an affidavit, it was firm on affirming that it is clearly upon the executive to determine the pricing of the vaccines and how it is to be procured and distributed amongst the States. It further went on to remark that any intervention by the Court will seriously impair the vaccination program and the Courts should not interfere amidst the executive actions and repose faith on the application of mind of the executive.

WAYS TO CURB THE PRICES OF THE VACCINES

1. The Drug Price Control Order, 2013 (DPCO)[10] which was issued under the Essential Commodities Act, 1955.[11]

- As per the DPCO, it is very clear from a mere reading of the Order that the control of the drug prices is exclusively revolving around the discretion of the Central Government— including vaccines, which are further regulated under various Sections such as 4,[12]5,[13]8[14] and 10[15] of the Order. However, an exception has been carved

[9]Supreme Court of India- Suo Motu Writ Petition (Civil) No. 3 of 2021 available at https://main.sci.gov.in/supremecourt/2021/11001/11001_2021_35_301_27825_Judgement_30-Apr-2021.pdf
[10]Drugs (Price Control) Order, 2013 – Notified by SO 1221 (E) dated 15.03.2013, available at https://www.nppaindia.nic.in/wp-content/uploads/2018/12/DPCO2013_03082016.pdf
[11]The Essential Commodities Act, 1955 – Act No. 10 of 1955, available at https://legislative.gov.in/sites/default/files/A1955-10.pdf
[12] *Supra 10; "**4. Calculation of ceiling price of a scheduled formulation**.– (1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under: Step1. First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below: Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual*

within the DPCO, 2013 for patented drugs developed while indigenously conducting research and development, under Section 32 of the Order.[16] Therefore, the drugs

turnover for that medicine.) Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below: P(c) = P(s). (1+M/100), where P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above. M = % Margin to retailer and its value =16 (2) the ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also."

[13] *Supra 10;* ***5. "Calculation of retail price of a new drug for existing manufacturers of scheduled formulations****. – (1) the retail price of the new drug available in domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4. (2) (i) the price to retailer of a new drug, not available in domestic market, shall be fixed by the Government on the principles of "Pharmacoeconomics" of the new drug, on the recommendation of a Standing Committee of Experts formed under paragraph 15. (ii) the retail price of such new drug shall be fixed by adding sixteen percent margin to retailer on the price to retailer as fixed in item (i)*

[14] *Supra 10;* ***8. Maximum retail price.****– (1) The maximum retail price of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling price notified by the Government plus local taxes wherever applicable, as under: Maximum Retail Price = Ceiling price + Local Taxes as applicable (2) The maximum retail price of a new drug shall be fixed by the manufacturers on the basis of retail price determined by the Government plus local taxes wherever applicable, as under: Maximum Retail Price = Retail Price + Local Taxes as applicable"*

[15] *Supra 10; "****10. Pricing of the formulations covered under Drugs (Prices Control) Order, 1995.****– (1) The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of the said order, up to 31st May, 2012, shall remain effective for further one year i.e. up to 30th May' 2013 and the manufacturers may revise the prices of such scheduled formulations as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and thereafter the formula as in sub- paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such formulations. (2) The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of Drugs (Prices Control) Order,1995 after 31st May,2012, shall remain effective for one year from the date of notification of such prices under Drugs (Prices Control) Order,1995 and immediately thereafter the manufacturers may revise the prices as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and on the 1st April of succeeding financial year, the formula as in sub-paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such schedule formulations. (3) The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, up to 31st May, 2012, shall remain effective for further one year i.e. up to the 30th May'2013 and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order. (4) The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, after 31st May, 2012, shall remain effective for one year from the date of notification of such prices and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order."*

[16] *Supra 10; "****32. Non–application of the provisions of this order in certain cases.*** *- The provisions of this order shall not apply to, - (i) a manufacturer producing a new drug patented under the Indian Patent Act, 1970 (39 of 1970) (product patent) and not produced elsewhere, if developed through indigenous Research and Development, for a period of five years from the date of commencement of its commercial production in the country. (ii) a manufacturer producing a new drug in the country by a new process developed through indigenous Research and Development and patented under the Indian Patent Act, 1970 (39 of 1970) (process patent) for a period of five years from the date of the commencement of its commercial production in the country. (iii) a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India: Provided that the provision of this paragraph shall apply only when a document showing approval of such new drugs from Drugs Controller General (India) is produced before the Government. Explanation.- Notwithstanding anything contained in this Order, for the purpose of this paragraph "new drug" shall have the same meaning as is assigned to under rule 122E of the Drugs and Cosmetics Rules, 1945;"*

developed under Section 32 will not be governed under the DPCO for a total time period of 5 years from the date of its official confirmation of development. This therefore indicates to the fact that Bharat Biotech's vaccine – Covaxin – gets immunity from attracting the provisions of the DPCO, as it is a product of indigenous research and development, which was conducted under the aegis of Indian organizations like the ICMR and the National Institute for Virology (NIV). Albeit, there is no legal restraint on the Central Government which stops them from modifying/amending the DPCO, which grants such an immunity to Covaxin. However, if the government decides to include SII's Covishield in the list of drugs under price control, it cannot claim an exemption similar to Covaxin, since the former was developed in the UK and not India.[17] What we need to understand is that if the Government can regulate the prices of commodities such as sanitizers and masks[18] which can have alternatives if they are not available in their immediate form, then there is no embargo on the Central Government from doing the same with the only available (potential) cure of this deadly virus.

- The practical problem in using the current DPCO to fix the prices of vaccines is that it is targeted primarily at fixing retail prices — not wholesale prices — that is, the price at which the end consumer is buying the vaccine rather than the price at which vaccine manufacturers sell it to the state governments. In the case of the COVID vaccines, most state governments have already announced that they will ensure free provision of the vaccines, so retail prices are of concern, only for the sale of vaccine in the private market.
- It is not clear if the DPCO, 2013 — in its current form — will serve the purpose of fixing the wholesale prices at which the vaccine manufacturers are going to sell to the state government. Even presuming that the DPCO, 2013 does not apply to wholesale prices, the central government — or more specifically, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers — can always announce a specific DPCO under the Essential Commodities Act, 1955 to tackle the specific issue of pricing COVID vaccines.

[17]Oxford University's Vaccine Knowledge Project published an article titled *"COVID-19 Vaccines"* after successfully developing and undergoing trial phases of Oxford AstraZeneca vaccine. The publication is available at https://vk.ovg.ox.ac.uk/vk/covid-19-vaccines

[18]https://consumeraffairs.nic.in/sites/default/files/file-uploads/latestnews/Notification21mar2020.pdf

2. Issuing Compulsory Licenses

- The second option put forth by some, including Courts, is for the government to influence prices by **issuing compulsory licenses** for the patents covering the COVID vaccines. Theoretically, this would increase the number of manufacturers and also the supply of vaccines at a reduced price, since the Controller of Patents can fix the sale price of vaccines produced under a compulsory license.

3. Vaccine Pricing

- The third option, which has received lesser attention, involves using contractual clauses in the government's funding agreement with Bharat Biotech, to force the company to lower its rates. We do not know if such a clause exists in the funding agreement because the government has not made the agreement public.

- Rather than spending time over legal options to control prices of vaccines, the simpler solution for the central government would be to handle negotiations by itself on behalf of all states. A market where there is only one buyer, gives the buyer enormous leverage in price negotiations. It is a form of de-facto price control. Rather than pitting the states in a perverse kind of 'hunger games' for vaccines, the central government should have taken it upon itself to negotiate with all vaccine manufacturers, to ensure equitable pricing for all Indian citizens. There are enough instances where the Central Government took the lead in the inoculation program at the national level. Tuberculosis was perceived as a major cause of morbidity and mortality in the mid-1940s. In May 1948, the Government of India issued a press note stating that tuberculosis was "assuming epidemic proportions" in the country, and that it had "after careful consideration" decided to introduce BCG vaccination on a limited scale and under strict supervision as a measure to control the disease.[19] By 1955-1956, the BCG vaccination mass campaign covered all the States of the Indian Union.[20] All of it was possible by the active intervention of the Central Health Ministry led by Rajkumari Amri Kaur, India's first Health Minister. Thereafter, programs such as

[19]Madras: Tamil Nadu State Archive, Health Department, no. 809; 1950. Undated press note (but the note is accompanied by a covering letter dated 28 May 1948)
[20]Bhushan K. Assessment of BCG vaccination in India: third report. *Indian J Med Res.* 1960; 48:407–17.

National Smallpox Eradication Programme (NSEP) in 1962 and the 2010, the National Immunization Programme on measles vaccine in India – all of it was spearheaded by the Central Government and all of them were given the importance of a "National Mission". If the Central Government wants, the same can be done even today with the COVID vaccines.

CONCLUSION

There are no contrasting opinions over the fact that India is the worst-hit country in this present surge of COVID cases. Amidst all the resources, the country was eagerly looking forward to a vaccination drive which is perhaps the only potential weapon against this deadly virus. As mentioned in the beginning, these large-scale vaccination drives are a part of the welfare schemes and profiteering should take a back seat. It will be worth observing what unfolds in the near future with regards to the vaccination policy of the country and how the Central governments keeps the sanctity of the constitutional principles and fundamental right to life of over 100 billion people amidst these pressing times. We need to act and act fast - the clock is ticking at a menacing speed.