



Bharat Biotech Announcement on COVAXIN® Pricing, Procurement

Bharat Biotech hereby communicates the following message regarding pricing of COVAXIN® for Central Government, State Governments, and Private Hospitals, we believe it is pertinent to place facts on record for the Media and the public at large, so that they can understand and appreciate our efforts.

Vaccine pricing depends on numerous factors: At the outset, one must remember that the pricing of vaccines and other pharmaceutical products heavily relies on a series of factors; the cost of goods & raw materials, product failures, at risk product development outlays, product overages, the entire capital expenditure for setting up sufficient manufacturing facilities, sales and distribution expenses, procurement volumes and commitments besides other regular business expenditures.

In this context, let us look at the specifics. The whole-virion Inactivated Vero Cell vaccines (COVAXIN® derives from this technology platform) are highly complex to manufacture since the critical ingredient is based on live viruses which require highly sophisticated, multiple level containment and purification methods. Such high standards of purification automatically lead to significant process losses and low yields save the outcome of a highly purified and safe vaccine. This is evident from the excellent safety contours of COVAXIN® with an impressive supply of more than 40 million doses to date. It is emblematic that Bharat Biotech has not sought Indemnity from the Govt of India for any adverse events from COVAXIN®.

Complex manufacturing process: In fact, the sheer complexity of the COVAXIN® manufacturing process is manifested by the fact that it requires about 10,000 sq meters of area to manufacture around 200 million doses of the vaccine annually. In comparison, the same quantity of live virus vaccines can be manufactured from mere 1,500 sq meters. Due to the highly contagious nature of the live SARS-CoV-2 virus, more stringent Biosafety Level-3 (BSL-3) containment facilities are required for the manufacturing of COVAXIN®.

Every batch of manufactured product is subjected to more than 200 quality control tests, prior to its release. It is exactly this complexity that has kept away other companies from developing vaccines, especially whole virion inactivated vaccines. The SARS CoV2 virus provided by ICMR-NIV is also equally available to other manufacturers who wish to develop and manufacture such a vaccine. Companies would need access to cell lines, BSL3 manufacturing & quality control facilities, and several well trained technical teams, to manufacture COVAXIN®.

Why is COVAXIN® more expensive for the private sector: Another key point of discussion has been about pricing our vaccines for private sector players which is significantly higher than that given to governments and large procurement agencies. This is purely due to fundamental business reasons, ranging from low procurement volumes, high distribution costs and retail margins among few others as explained above.

As directed by the Govt of India, less than 10% of our total production of COVAXIN® to date has been supplied to private hospitals, while most of the remaining quantity was supplied to State and Central Governments. In such a scenario the weighted average price of COVAXIN® for all supplies realized by Bharat Biotech is less than ₹ 250 / dose. Going forward, ~75% of the capacity will be supplied to State and Central Governments with only 25% going to private hospitals.



The supply price of COVAXIN® to the government of India at ₹ 150 / dose, is a non-competitive price and clearly not sustainable in the long run. Hence a higher price in private markets is required to offset part of the costs. There are live examples of such pricing policies where Human Papilloma virus vaccine is priced for GAVI supplies at ~ \$ 4.5 / dose (~ ₹ 320), but is also available in the private market at ~ ₹ 3500 / dose. Rotavirus vaccines are supplied to the Govt of India at ~ ₹ 60/ dose, but is also available in the private market at ~ ₹ 1700 / dose. The prices for COVID-19 vaccines internationally have varied between ~ \$10 to ~ \$37 / dose, (~ ₹ 730 - ~ ₹ 2700/ dose).

Private procurement is only discretionary: Unlike most medicines and therapeutics, vaccines are provided free of cost by the Govt of India to all eligible Indian citizens. Thus, the procurement of vaccines by private hospitals is optional and not mandatory, albeit it gives a choice to citizens who are willing to pay for better convenience. In our view, the question of product pricing is only of extraneous interest to all concerned, especially when the same vaccine is made available free of cost.

Bharat Biotech has so far invested over ₹ 500 crores at risk from its own resources for product development, clinical trials and setting up of manufacturing facilities for COVAXIN®. The support from The Indian Council of Medical Research (ICMR) was with respect to provision of the SARS CoV2 virus, animal studies, virus characterization, test kits and partial funding for clinical trial sites. In return for this valuable support, Bharat Biotech will pay royalties to ICMR and the National Institute of Virology (NIV), based on product sales. Royalties are also payable to Virovax towards the licensure of IMDG agonist molecules.

Bharat Biotech is investing in new facilities and repurposing existing ones across several states in India for enhancing the production of COVAXIN®. It is pertinent to mention here that the urgent need to set up a significant number of manufacturing facilities and to divert existing ones for COVAXIN®, has resulted in reduced production of other vaccines at our facilities, leading to loss in revenues. We have been extremely diligent in selecting manufacturing facilities and partners, with the required levels of containment, capabilities and expertise. Product development activities towards the development of vaccines against newer variants is also underway at our facilities.

Low product price realization dispirits domestic R&D: Lastly, it should be noted that companies such as Bharat Biotech, which are innovators with specialized expertise in product development, and large scale manufacturing, should be allowed to maintain a differential pricing strategy for Governments and private hospitals. It is distressing to see that a large country like India has a very basic level of innovation in vaccines and pharmaceutical products.

It may well be argued that the low-price realization for home-grown innovators constraints innovation and product development in India. In the absence of a dual pricing system, Indian vaccine and pharmaceutical companies risk being reduced to mere contract manufacturers with intellectual property licensed from other nations.

To learn more about Bharat Biotech, visit www.bharatbiotech.com

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