

# A Procompetitive Approach – Benign for the COVID-19 Vaccine Market in India

*By G.R. Bhatia & Aaditya Ranbir Sahgal | L & L Partners Law Offices*



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In order to quell the second wave of the coronavirus pandemic, and also to keep its third wave at bay, the government and its public health bodies have prescribed various protocols relating to usage of face masks, social distancing, and ensuring proper ventilation in light of scientific consensus that transmission of the virus may take place by airborne means. The time-tested maxim “prevention is better than cure” holds in the present scenario, especially when Indian society, in a most unfortunate manner, witnessed an insufficient and ill-equipped healthcare system while also experiencing acute shortage of protective COVID-19 vaccines.<sup>3</sup>

There is widespread consensus in the scientific community that vaccines work effectively in controlling pandemics. For instance, the earlier smallpox and polio pandemics,<sup>4</sup> and the ongoing corona-virus pandemic have been found to be substantially tamed in countries where more than 50 percent of the population has been vaccinated. Vaccine efficacy is the degree to which a vaccine provides protection, controls transmission and reduces the incidence of disease in controlled conditions. The smallpox vaccine, with 95 percent efficacy, eradicated the disease and oral polio vaccine, with an efficacy of 98 percent, has almost eliminated polio from the world. The COVID-19 vaccines that have been approved in India so

far offer greater than 70 percent efficacy and are considered to be an effective tool to fight the pandemic. The data from the corona-virus pandemic is compelling in favour of vaccination as an effective tool to fight the once-in-a-century public health crisis, specifically in relation to individuals with comorbid diseases who are at high risk. At this stage, the view has been expressed that vaccines are the only hope.<sup>5</sup>

The World Health Organisation claims that safe and effective vaccines are game changing tools, and equitable access to safe and effective vaccines is critical to ending the ongoing pandemic.<sup>6</sup> Therefore, it is encouraging to see an increasing number of vaccine candidates being proven effective in regulatory trails and going into development. AstraZeneca/Oxford, Johnson & Johnson, Moderna, Pfizer/BionTech, Sinopharm and Sinovax have already been approved by the World Health Organization as they have met the prescribed safety and efficacy tests. Further, there are several other vaccine candidates whose clinical trials are at advanced stage. In addition, some national regulators have also assessed and evaluated their home grown COVID-19 vaccines for use in their countries.<sup>7</sup> The World Health Organization has advised to “take whatever

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<sup>1</sup> G R Bhatia is Partner & Head of Competition Law Practice, L & L Partners Law Offices (formerly Luthra & Luthra Law Offices), New Delhi. He is former Additional Director General, Competition Commission of India/MRTP Commission. He was member of Committee constituted by Government of India to suggest draft of National Competition Policy. He has been ranked as a lead antitrust counsel by Chambers & Partners from 2012-2021. Views expressed in the present article are personal.

<sup>2</sup> Aaditya Ranbir Sahgal, Associate, L&L Partners Law Offices (formerly Luthra & Luthra Law Offices).

<sup>3</sup> Economic Times, *The devastating second wave of Covid-19 in India has exposed potholes in the healthcare sector* (April 30, 2021). Available at <https://health.economictimes.indiatimes.com/health-files/the-devastating-second-wave-of-covid-19-in-india-has-exposed-potholes-in-the-healthcare-sector/4906>.

<sup>4</sup> The Conversation, *From smallpox to polio, vaccine rollouts have always had doubters. But they work in the end* (June 8, 2021). Available at <https://theconversation.com/from-smallpox-to-polio-vaccine-rollouts-have-always-had-doubters-but-they-work-in-the-end-161803>.

<sup>5</sup> Prajapati and Narasimha. *J Infect Dis Epidemiol* 2020, 6:147

<sup>6</sup> Money Control, *Indigenous nasal vaccines could be game changer, says WHO chief scientist Dr Soumya Swaminathan* (May 23, 2021). Available at [COVID-19 | Indigenous Nasal Vaccines Could Be Game Changer, Says WHO Chief Scientist Dr Soumya Swaminathan \(moneycontrol.com\)](https://www.moneycontrol.com/news/indigenous-nasal-vaccines-could-be-game-changer-says-who-chief-scientist-dr-soumya-swaminathan-1081231.html).

<sup>7</sup> “Covaxin” manufactured by Bharat Biotech falls in this category.

vaccine is made available to you first.”<sup>8</sup> Thus, all vaccines are interchangeable and thereby enhanced inter-brand and intra brand competition in covid vaccine market

Such a recommendation is indicative of the investments made by pharmaceutical companies in research & development, obtaining regulatory approvals after required compliances in a bid to enter into market, in addition to the cost of manufacturing. Needless to say, the vaccine market is a source of great economic potential for vaccine manufacturers. Therefore, many more vaccine candidates are awaiting approval in addition to those already approved. “More the merrier” is an accepted principle especially from the point of view of the “market.” All these raise hopes that the invisible hand of the market forces will eventually trigger competition in the COVID-19 vaccine market. With respect to the longevity of this market, it would have to be seen how the scientific developments around the pandemic unfold. For instance, the polio vaccine is still administered to children in line with best inoculation practices even though polio has been eradicated.<sup>9</sup> Alternatively, in the case of influenza, scientific research and efforts therefrom have not been able to quash the illness altogether, however, humans have adapted to living along with it including with the use of vaccines. By the same analogy, the market for COVID-19 is likely to exist and subsist for long time and thus there is an obvious need for fostering competition between manufacturers.

On the domestic front, the Government of India aims to vaccinate all adult Indians by the end of 2021. For this purpose, 1.75 billion doses are

required to be produced and/ or imported, with a minimum of 7.12 million vaccination doses administered on a daily basis between now and December 2021 to cover the entire adult population.<sup>10</sup> This is of utmost importance to mitigate the possibility of a third wave.<sup>11</sup> While this is a daunting task, the Government of India’s actions indicate that it is making a concerted effort to defeat the pandemic, as are most countries around the globe. Indian authorities had long ago approved “Covishield” manufactured by the Serum Institute of India and “Covaxin”<sup>12</sup> manufactured by Bharat Biotech, of which upwards of 330 million doses have already been administered, combined, along with a small number of Sputnik V doses imported from Russia.<sup>13</sup> Further, thirteen vaccine candidates are in clinical trial in India which include Novavax and Covovax to be manufactured by the Serum Institute of India, ZyCoV-D of Zydus Cadila, Sputnik Light, and Becov2 of Biological E. Entry of more players is expected to put pressure of competition and discipline the existing incumbents.

To help ramp up manufacturing capacity in respect of Covishield and Covaxin, the Government of India had extended credit facilities, and placed orders with advance payments towards the vaccine manufacturers. It is also in negotiation with US based vaccine makers namely Pfizer, Moderna and Johnson & Johnson. Further, it has also made clear that any vaccine that is approved by United States FDA or the World Health Organization can be

<sup>8</sup> World Health Organization, *COVID-19 advice for the public: Getting vaccinated*. Available at <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines/advice>.

<sup>9</sup> Ministry of Health and Family Welfare, *Pulse Polio Programme in India*. Available at <https://main.mohfw.gov.in/sites/default/files/186048546481489664481.pdf>.

<sup>10</sup> Money Control, *Minimum 71.2 lakh average daily vaccination doses needed till December to mitigate coronavirus third wave: CII* (June 17, 2021). Available at <https://www.moneycontrol.com/news/trends/minimum-71-2-lakh-average-daily-vaccination-doses-needed-till-december-to-mitigate-coronavirus-third-wave-cii-7048581.html/amp>.

<sup>11</sup> The Economic Times, *Uday Kotak calls for doing “whatever it takes” to ensure production, supply and distribution of vaccines* (April 13, 2021). Available at <https://bfsi.economicstimes.indiatimes.com/news/industry/uday-kotak-calls-for-doing-whatever-it-takes-to-ensure-production-supply-and-distribution-of-vaccines/82044692>.

<sup>12</sup> The Times of India, *Covid-19: WHO accepts expression of interest for Covaxin emergency use listing* (June 18, 2021). Available at <https://timesofindia.indiatimes.com/india/covid-19-who-accepts-expression-of-interest-for-covaxin-emergency-use-listing/articleshow/83618620.cms>.

<sup>13</sup> The Indian Ministry of Health and Family Welfare maintains a daily tracker of vaccines administered on its home-page at <https://www.mohfw.gov.in/>.

imported for use in India.<sup>14</sup> On the global front, it has co-piloted the proposal for the waiver of patent rights (limited to 3 years only) at the World Trade Organization. Thus, such steps seem to indicate that the Government of India seeks to foster competition between vaccine makers to ensure the availability of vaccines on fair terms, and at the same time does not wish to completely negate the rights of patent holders. A patent waiver for the time being is a soft touch approach and can be perceived to be “reasonable” and not anti-competitive.

The Government of India has set up a Task Force under the chairmanship of Niti Aayog<sup>15</sup> to oversee all aspects of the COVID-19 inoculation plan from identification of vaccines to buying, financing, and distribution, including the prioritisation of certain groups of citizens. The Task force is expected to function by and large independently in procurement, transportation, allocation to States/Union Territories in non-discriminatory manner and on the basis of publicly known laid down criteria. The setting up of such a Task Force is consonant with the recommendation that even in sectors where regulation is required, it should be competition based/driven.<sup>16</sup> A lack of indemnity has been cited as a reason why foreign firms are hesitant to bring their vaccine into India,<sup>17</sup> and after having realised that most developed nations have already offered such indemnity, the Government of India is contemplating providing such indemnity to domestic as well as foreign makers and thus seek to ensure “competition neutrality” between two sets of suppliers.<sup>18</sup>

As under the latest vaccine policy, the Central Government will procure 75 percent of total

vaccines manufactured which would be supplied to the States and Union Territories for inoculation drives to be undertaken by them. The remainder 25 percent of total manufactured doses will be allowed to be purchased by private hospitals/establishments at a price negotiated between vaccine maker and the private hospitals.<sup>19</sup> The effect of this on market delineation in an antitrust perspective would be interesting to see, as States will not be competing with each other as “buyers” any longer, with the Government of India undertaking the role of buyer for such States, and the dual price mechanism for producer/suppliers of vaccines may give them better operational freedom and incentives to ramp up capacity. To ensure that those who opt for vaccination at private hospitals are not fleeced by the verticals in the downstream market, the Government of India has capped vaccine service charges leviable by hospitals.<sup>20</sup>

The rising issue of vaccine hesitancy, especially in rural areas, is a matter of great concern and if it is not stopped at the earliest, very soon there will be more vaccines than people willing to take them.<sup>21</sup> A social responsibility thereby devolves on all citizens – both natural persons and corporate entities – to create awareness about the usefulness of vaccination in order to quell vaccine hesitancy. This is all the more imperative when there is widespread recognition of the fact that “no one is safe unless everyone is safe.” It would also be of interest to note how/if vaccine hesitancy affects an antitrust analysis of the market for COVID-19 vaccines in terms of demand suppression. It would be fallacious to assume that the vaccine manufacturers operate independent of social factors such as vaccine

<sup>14</sup> Business Standard, *Any Covid vaccine that is approved by FDA, WHO can come to India, says Paul* (May 13, 2021). Available at [https://www.business-standard.com/article/current-affairs/any-covid-vaccine-that-is-approved-by-fda-who-can-come-to-india-says-paul-121051300908\\_1.html](https://www.business-standard.com/article/current-affairs/any-covid-vaccine-that-is-approved-by-fda-who-can-come-to-india-says-paul-121051300908_1.html).

<sup>15</sup> Niti Aayog, A National Institution for Transforming India, Government of India.

<sup>16</sup> Para 10.2.1 of Draft National Competition Policy 2011.

<sup>17</sup> Business Today, *Pfizer, Moderna, Serum & the indemnity issue; what is it and what it means for India?* (June 3, 2021). Available at <https://www.businesstoday.in/sectors/pharma/pfizer-moderna-serum-institute-and-the-indemnity-issue-what-is-it-and-what-it-means-for-india/story/440730.html>.

<sup>18</sup> Competition neutrality is a cornerstone of “sound competition regime.”

<sup>19</sup> Ministry of Health & Family Welfare, *Revised Guidelines for implementation of National COVID Vaccination Program* (released on 08 May 2021). Available at <https://www.mohfw.gov.in/pdf/RevisedVaccinationGuidelines.pdf>.

<sup>20</sup> *Ibid.*

<sup>21</sup> *Supra* Note 10

hesitancy, which may have the potential to affect sales (and resultantly affecting revenues and scalability efforts thereby impacting pricing structures). In such a context, it would be relevant to note that vaccine hesitancy is not an isolated phenomenon and can be witnessed in a wide range of countries in Europe<sup>22</sup> and the Middle East<sup>23</sup> too, for instance, amongst others spanning developed and developing countries. However, active steps are being taken around the world including in India to incentivise people to partake in inoculation drives.<sup>24</sup>

In order to inculcate a spirit of competition in inoculation programs between States/Union Territories, it has been suggested that an index to rank States based on COVID-19 preparedness should be prepared. It is relevant to note that, the National Smart Cities Mission Program used a competition-based method for selecting cities for funding therein. Surat and Indore have bagged smart city award 2020 and UP wins in the State category<sup>25</sup>. Likewise, in Australia, the National Competition Council has been given a specific role to assess progress in

implementing the competition reforms and recommend grants to States linked with satisfactory progress. It is believed that States will mount similar initiatives at District levels. Hopefully, the Government will consider these welcome suggestions.<sup>26</sup> Such incentives would also mean that incentives in the inoculation drives operate at two levels: at the level of the State Government and also the District/municipalities level.

The two doses of vaccine are “prime-doses” and any dose given thereafter is a booster dose. Pfizer and Moderna have recently announced that people who have received both doses of vaccine will probably need a booster shot this year and might need annual shots thereafter. If that is the case, the “market for COVID-19 vaccine” is going to stay for a long time, and making it gradually competitive (in both upstream and downstream markets) would ensure the availability of vaccines in abundance, in acceptable quality, and at affordable prices.

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<sup>22</sup> The Atlantic, *The Vaccine Hesitant Man of Europe* (19 March 2021). Available at <https://www.theatlantic.com/international/archive/2021/03/france-vaccine-hesitancy-astra-zeneca/618316/>; Forbes, *Covid-19 Vaccine Hesitancy Is Worse In E.U. Than U.S.* (08 March 2021). Available at <https://www.forbes.com/sites/joshuacohen/2021/03/08/covid-19-vaccine-hesitancy-is-worse-in-eu-than-us/?sh=64e2c4cd611f>.

<sup>23</sup> DW, *Coronavirus: Arab countries struggle with high vaccine hesitancy* (16 April 2021). Available at <https://www.dw.com/en/middle-east-covid-vaccine-rollout-hesitancy/a-57227395>.

<sup>24</sup> Volpp KG, Cannuscio CC, *Incentives for Immunity - Strategies for Increasing Covid-19 Vaccine Uptake*, N Engl J Med. 2021 May 26. doi: 10.1056/NEJMp2107719; The New York Times, *100\$ as Incentive to Get a Shot? Experiment Suggests it Can Pay off* (04 May 2021). Available at <https://www.nytimes.com/2021/05/04/upshot/vaccine-incentive-experiment.html>.

<sup>25</sup> Time of India, June 28, 2021

<sup>26</sup> Annexure IV, “Salient features of National Competition Policy of Select Countries” - Draft National Competition Policy 2011.