



Announcement on Procurement Process

During the past few weeks, there have been reports in the media at large misrepresenting the procurement process of COVAXIN®, in Brazil and other countries. We wish to provide the following clarification -

- The procurement process for COVID-19 vaccines and several vaccines for routine immunization follow a common process which is widely accepted, and established in Industry
- Based on a country's requirement, the company receives a letter of intent (or MOU) for procurement
- The company then proceeds to apply for emergency use authorization (EUA) in the respective country
- Once EUA is received, the Ministry of Health (MOH) would proceed to place a firm order by releasing a purchase order, with the required initial quantities. In several countries, MOHs have placed orders for procurement prior to the approval of vaccines such as USA, EU, India, etc. However, procurement happens only post EUA.
- In order to secure a firm Purchase Order from the country, the company proceeds to raise a Pro Forma Invoice to the MOH, towards the supply of vaccine
- Based on the invoice, the MOH pays the amount in advance
- Once the payment is received, the company proceeds to supply the agreed quantities and within the agreed timelines
- In the specific case of procurement of COVAXIN® by MOH Brazil, since the first meetings with MOH Brazil during Nov 2020, until 29th of June 2021, a step-by-step approach has been followed towards contracts, and regulatory approvals, during this ~ 8 long month-long process. On 4th June 2021, ANVISA authorized the exceptional import of the Covaxin vaccine by the Ministry of Health for distribution and Use Under Controlled Conditions". As of 29th June 2021, Bharat Biotech has not received any advance payments nor supplied any vaccines to MOH Brazil. Bharat Biotech has followed a similar approach towards contracts, regulatory approvals and supplies in several countries worldwide, where COVAXIN® is being supplied successfully
- The pricing of COVAXIN® has been clearly established between \$15-20 per dose for supplies to Governments outside India. The pricing for Brazil has also been indicated at \$ 15 per dose. Bharat Biotech has received advance payments from several other countries at the above price points, with supplies in process, pending approvals
- Precisa Medicamentos is Bharat Biotech's partner in Brazil, providing assistance, guidance and support with regulatory submissions, licensure, distribution, insurance, conduct of phase III clinical



trials, etc. Bharat Biotech follows a similar partnership model in all countries, where its vaccines are supplied, as it does not have its own offices in these countries

- Bharat Biotech and Precisa Medicamentos are conducting a 5000 subject phase III clinical trial in Brazil, which was recently approved by ANVISA. The trial will be conducted by the Albert Einstein Institute
- Bharat Biotech has a large portfolio of 20 products which are exported to more than 123 countries and has thus far delivered more than 4 billion doses of vaccines across the world
- Dr. Krishna Ella is a scientist, technocrat and first-generation entrepreneur educated in India and the United States. He completed his Undergraduate and Master's degrees in Agriculture from India, and was conferred with PhD from the University of Wisconsin—Madison USA. He has also worked in the United States for several years before returning to India in 1996
- Dr. Ella and his wife Mrs. Ella founded Bharat Biotech in 1996 with a mission to drive innovation and large-scale manufacturing in the field of human vaccines. Since then, Dr. Ella has also founded or acquired 13 other organizations. This includes Madison Biotech, which he founded in 2020 for the purpose of external R&D and sales and marketing of vaccines. More than 3,000 personnel are employed in 6 cities across all these organizations. We wish to dispel any notion or implication of any wrongdoing whatsoever, as all these are affiliate companies founded / acquired and operated by Dr. Krishna Ella

COVAXIN® Product Development – Towards a global Covid-19 vaccine

- Bharat Biotech's vaccine research, development, and manufacturing practices are driven by science and validated by empirical evidence. Its commitment to vaccine discovery data transparency has an impeccable record and has been proven with 10 scientific publications even with its newest COVID-19 Vaccine - COVAXIN®, covering all aspects of product development, within 12 months
- COVAXIN® has been formulated to enable shipping and long-term storage at 2-8°C, it does not need diluents or frozen storage conditions, thereby reducing infrastructure, distribution and logistics costs. It is also formulated to adhere to a multi-dose vial policy, thereby reducing open vial wastage, saving money for procurement agencies and governments alike
- Bharat Biotech's commitment to continuous improvement of COVAXIN® is currently under way with additional clinical trials to establish safety and efficacy in children between 2-18 years of age in India. Further, a clinical trial to determine the safety and immunogenicity of a booster dose is also in process. Several research activities are being carried out to study Variants of Concern and assess their suitability for follow-up booster doses
- COVAXIN® has now received Emergency Use Authorizations in 16 countries including, Brazil, India, Philippines, Iran, Mexico, etc. with EUA's in process in 50 countries worldwide. Bharat Biotech is in



discussions with WHO to obtain Emergency Use Listing for COVAXIN®. The product has been exported to several countries, with additional requests for supplies being received

- Bharat Biotech has established COVAXIN® manufacturing at four facilities within India, and further expansion is in process to reach an annualized capacity of 1 billion doses by the end of 2021. Technology transfer activities are in progress to companies in the United States and other countries

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