

## **COVID-19 Vaccination Drive in India**

The commencement of COVID vaccinations has focused attention on the modern medical miracle of immunisation. It has eradicated some diseases and is close to eradicating others. Universal immunisation is amongst the most effective and economical health interventions ever devised.

India has one of the largest immunization systems in the world. 27 million infants are immunised against 12 diseases annually. India's nation-wide pulse polio immunisation drive, which made India polio-free, has set global standards for programmes of this nature.

India is one of the world's largest vaccine producers. 60% of global vaccine production comes from India. Indian producers supply 1.5 billion doses annually to more than 150 countries. India is the largest supplier of the DPT, BCG and Measles vaccines globally. WHO sources 70% of its essential immunisation vaccines from India.

India is a leader in vaccine R&D with a well developed ecosystem linking the public and private sectors as well as academia and industry in networks that spur innovation. An indigenously developed low-cost Rotavirus vaccine which protects against childhood diarrhea, and another against the dreaded Japanese encephalitis, are now included under the Indian Universal Immunisation Programme.

## **CORONAVIRUS AND VACCINES**

The COVID-19 pandemic has highlighted India's position as a reliable stakeholder in global healthcare supply chains with major strengths manufacturing, R&D and innovation.

About 30 groups across academia and industry are actively involved in development, collaboration, co-development and trials for COVID-19 vaccines in India. 6 vaccine candidates, inclusive of 3 indigenously developed ones are in clinical stages of development and 3 vaccine candidates are in advanced pre-clinical stage of development. Many others are in pre- early stages of development. Two vaccines received Emergency Use Authorization on 2nd January 2021 and one of them (AstraZeneca-Oxford-Serum Institute) is being currently dispensed in the largest COVID vaccination programme in the world.

6 candidates are in clinical trials which include 3 indigenously developed vaccine candidates. These are:

Phase III trial of Inactivated whole virion vaccine by Bharat Biotech International Ltd (BBIL) and ICMR.

Phase II clinical trial of DNA vaccine candidate (ZyCovV-D) by Zydus Cadila

Phase I clinical trial of recombinant protein subunit vaccine candidate by Biological E.

Phase II/III clinical trials of ChAdOx1-S, in-licensed from University of Oxford/AstraZeneca, by Serum Institute of India Pvt. Ltd. (SIPL)

Adaptive phase II/III clinical trial for the Russian Sputnik V vaccine by Dr. Reddy's Laboratories Ltd.

Repurposed Vaccine : Phase III Clinical trial of rBCG vaccine by Serum Institute of India Pvt. Ltd. (SIPL)

2 vaccine candidates, a mRNA vaccine (Genova Biopharmaceuticals) and another using an inactivated rabies vector platform (BBIL) are in advanced stages of pre-clinical development. Many are in early stages of development.

Government institutions and regulatory authorities have worked closely during the pandemic with the private sector to strengthen the eco-system to support candidate vaccine development and create enabling regulatory framework.

The immunoassay laboratory of Translational Health Science and Technology Institute (Department of Biotechnology), one of the six labs in the world designated by Coalition for Epidemic Preparedness Innovations, for centralized assessment of COVID-19 vaccines and the National Immunogenicity & Biologics Evaluation Center at the Interactive Research School for Health Affairs, Bharati Vidyapeeth, Pune supported by the National Biopharma Mission played key roles in evaluating vaccines inter alia by supporting development of animal challenge models, proteins for performing assays and pseudoviruses for developing neutralization assays. 11 pan India trial sites that are compliant with the class-leading Good Clinical Laboratory Practice (GCP) standards were prepared for quick initiation of population based clinical trials for the vaccines. A Rapid Response Regulatory Framework to provide expedited regulator approvals for vaccine candidates was instituted by the Department of Biotechnology and the Drug Controller General of India. A Mission COVID Suraksha was launched that deployed Rs 900 crore to support vaccine development and conduct of human trials through the Biotechnology Industry Research Assistance Council (BIRAC), an industry-academic interface, created by Department of Biotechnology

These Indian responses have a significant element of support to neighbouring countries. Department of Biotechnology and Ministry of External Affairs are working together on Partnerships for Advancing Clinical Trials (PACT) to strengthen capacities for facilitating phase III clinical trials of Indian COVID vaccines in neighbouring/ friendly nations. 2 training modules with nearly 6 sessions have been

successfully completed for around 100 participants from Afghanistan, Bhutan, Bangladesh, Maldives, Mauritius, Nepal, Sri Lanka.

## **VACCINE ECOSYSTEM**

India's vaccine capacities did not appear overnight.

A few public sector companies initially entered the vaccine manufacturing space in the 1960s. Vigorous and innovative private sector companies have transformed this sector, turning it into a billion dollar industry. India biopharma companies established themselves as leading manufacturers of standard vaccines and went to produce new and more complex vaccines (e.g. meningitis, H1N1, Haemophilus influenzae type b, and pneumococcal conjugate vaccines). The indigenous development and production of the Rotavirus vaccine and the Japanese encephalitis vaccine demonstrated that India was emerging as a leader in R&D and affordable product development. This transformation has been attributed to “innovative public private partnerships, substantial investments, active engagement with global experts and innovative governmental support.” (*International Journal of Infectious Diseases, July 1, 2019*)

The Department of Biotechnology is the nodal agency for coordinating and supporting vaccine research. It has focused on building human resources, infrastructure and an enabling environment. It supports academic research and has introduced innovations such as biotech clusters, incubation centres, innovation parks, industry-academia partnerships, and funding and support to biopharma startups and SMEs. It has also built national and international research collaborations and partnerships.

The Biotechnology Industry Research Assistance Council (BIRAC) has already been mentioned. Its mission is to spur innovation across academia and industry and align it with public health concerns. It runs funding schemes such as Biotechnology Ignition Grant (BIG) Scheme, Small Business Innovation Research Initiative (SBIRI), Contract Research Scheme (CRS), Biotechnology Industry Partnership Program (BIPP) and Social Innovations Program for Products Affordable and Relevant to Societal Health (SPARSH). It also manages the National Biopharma Mission (NBM), an industry-academia collaborative Mission for accelerating early development. Cabinet approved this mission, and an expenditure of US \$250 million, in 2017. It is 50% co-funded by the World Bank.

Strengthening vaccine R&D through active engagement with global leaders has been a focus area. The Indo-US Vaccine Action Programme, a bilateral programme jointly run by Department of Biotechnology, ICMR, and the US National Institutes of Health has been recognized internationally as a model bilateral programme. Various bilateral programmes with countries like Norway, France, Australia and Finland are in existence.

India was among the first countries in the developing world to establish a National Technical Advisory Group for Immunization (2001) that involves all stakeholders in advising the government, based on information and evidence, about expansion and revision of immunisation schedules.

Vaccines against malaria and dengue have been a priority. Department of Biotechnology has supported the development of an Indian dengue vaccine candidate at the International Center for Genetic Engineering and Biotechnology and supports the clinical development through public private partnerships under NBM.

Government continues to evolve mechanisms for supporting end-to-end development and testing pipelines for vaccines. India has the political will and is augmenting capacities necessary to make it a vaccine leader.

## **VACCINE DELIVERY**

India has been a leader in the logistics of effective vaccine delivery, overcoming difficulties posed by climate and terrain. The entire vaccine supply line has been digitised through an Electronic Vaccine Intelligence Network (eVIN). The COVID vaccine rollout is being monitored through a digital Covid-19 Vaccine Intelligence Network (Co-WIN) that will be used for planning, implementation, monitoring and evaluation.

Vaccines require to be transported through cold chains. A network of 27,000 functional cold chain points (97% located below district level) is in existence. This includes cold chain equipment, health workers, and cold chain staff. Innovative cold chain equipment is used that can operate on electricity, gas or kerosene. A system of grassroots health workers going door-to-door to administer vaccines using insulated delivery kits is also in place.

## **THE PRIVATE SECTOR IN VACCINES**

Major Indian vaccine manufacturers include Serum Institute, Bharat Biotech, Panacea Biotech, Sanofis Shanta Biotech, Biological E, Hester Biosciences and ZydusCadila. They have an installed capacity to make 8.2 billion doses of different vaccines in a year. The Pune-based Serum Institute is the world's largest vaccine maker by number of doses produced and sold globally.

These biopharma majors have substantial R&D strengths and deep connections with private sector and academic institutions in India and across the world. Their R&D capacities have manifested as an impressive array of de novo vaccines, modified vaccines and patents. Bharat Biotech, for example, has so far commercialised 16 vaccines, including one against the H1N1 flu the causative organism of a 2009 pandemic. Serum Institute has produced the world's first thermostable Rotavirus vaccine that does not require constant refrigeration. It has also developed a vaccine against meningitis for use in

Africa that is both low-cost and can be transported and stored for as long as four days without refrigeration or even an icepack Other vaccines developed by Indian biopharma include typhoid, babies and Hepatitis B vaccines

The speed with which the private sector pivoted to development and production of COVID vaccines demonstrates their abilities to take quick research decisions, build partnerships, expand capacity and generate funding.

The Indian vaccine industry, through scale and economies, has impacted not just availability of vaccines in global vaccine market but has brought down prices. For example, India was able to manufacture and sell the Rotavac vaccine at almost one-fifteenth of the then-market cost in 2013.

## **INTERNATIONAL COOPERATION**

India's vaccine capacity and its ability to deliver safe and low-cost vaccines rapidly has been leveraged by global health bodies and non-state actors. Gavi, the vaccine initiative, WHO and the Gates Foundation all source vaccines in bulk from India. It has the largest number of manufacturers who have been prequalified by WHO for international procurement for low and middle income countries.

Most of these vaccines are for the global South.

India also works with another major global vaccine initiative, the Coalition for Epidemic Preparedness Innovations. BIRAC has initiated an Ind-CEPI project to strengthen development of vaccines for diseases of epidemic potential in India.

At the Global Vaccine Summit, in June 2020, Prime Minister Modi said that that India recognizes and values the work of GAVI. Announcing a contribution of US\$ 15 million to GAVI, he said that India has become a donor to GAVI while still being eligible for GAVI support.

India is, because of its strengths in the biopharmaceutical and vaccines domains, one of the major centres in the transnational efforts to counter the pandemic. India will make its vaccine strengths available to the international community for combating the COVID pandemic. Prime Minister Modi has said while launching India's domestic vaccination drive on January 18 that "We are committed that India's vaccines, our production capacity, serve the interest of the whole humanity."

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