Department of Biotechnology

Ministry of Science & Technology

Government of India

January 5, 2021

Interaction with the Hon'ble Minister of Science & Technology, Earth Sciences and Health & Family Welfare on 'DBT's response to COVID-19'

Background Note

I. E-Book on DBT's response to COVID-19

II. CEPI centralized network lab of India at THSTI

III. Successful manufacturing of 100 lakh diagnostics kits by AMTZ, Vishakhapatnam

I. E-Book on DBT's response to COVID-19

- The Department of Biotechnology, Autonomous Institutions (AIs) of DBT and the Public Sector Undertaking Biotechnology Industry Research Assistance Council (BIRAC) have been working

relentlessly over the past ten months to develop effective interventions for combating the pandemic. More than 100 projects in the thematic areas of vaccines, diagnostics and therapeutics being supported.The R & D efforts have also yielded indigenous COVID diagnostic kits which have been commercialised.

- Development of 15 vaccine candidates by industry and academia being supported, of which 3 are in clinical stages of development and 4 are in advanced pre-clinical stage of development. Mission COVID Suraksha at a total cost of Rs. 900 Cr. for 12 months by BIRAC, a PSU of DBT, is under implementation.
- 9 DBT AIs, approved as Hubs for their respective City/Regional clusters, for COVID-19 testing and nation's first infectious disease mobile laboratory in Haryana has been deployed. Rapid scale-up of manufacturing of indigenous COVID-19 diagnostic kits with a production capacity of about 15 Lakh

kits/day and deployment of 5 COVID19 Biorepositories with more than 40,000 samples available to researchers and industry. The Regulatory system has also been streamlined to ease the process timelines and to cut the red tape.

- Nearly 50 BIRAC supported start-ups have developed innovative products for COVID19.
- The E-Book on S & T solutions for COVID -19 showcases the initiatives undertaken by the Department of Biotechnology for the mitigation of this Pandemic.

II. CEPI centralized network lab of India at THSTI

With hundreds of COVID-19 vaccines in development around the world, it is essential to have a system that can reliably evaluate and compare the immune response of candidates currently undergoing testing.

On 2nd October 2020, Oslo, Norway –The Coalition for Epidemic Preparedness Innovations (CEPI) had announced partnerships with five clinical sample

testing laboratories to create a centralised global network to reliably assess and compare the immunological responses generated by COVID-19 vaccine candidates. Located across multiple regions globally, the laboratories initially selected for this vaccine-assessment network were: Nexelis (Canada) and Public Health England (PHE, UK), VisMederi Srl (Italy), Viroclinics-DDL (The Netherlands), icddr,b (formerly International Centre for Diarrhoeal Disease Research, Bangladesh), and Translational Health Sciences and Technological Institute (THSTI, India). Then 2 more labs, National Institute for Biological Standards and Control (NIBSC, UK) and Q2 Solutions (USA) were added later on.

The network will use the same testing reagents—originating in the labs of Nexelis and PHE—and follow common protocols to measure the immunogenicity of multiple COVID-19 vaccine candidates (both CEPI-funded and non-CEPI funded developers). This approach will ensure uniformity in assessment and

informed identification of the most promising vaccine candidates. CEPI is actively negotiating with additional laboratories to participate in this network.

Advantages of centralising immunological response assessment

Typically, the immunogenicity of potential candidate vaccines is assessed through individual laboratory analyses, aiming to determine whether biomarkers of immune response—such as antibodies and T-cell responses—are produced after clinical trial volunteers receive a dose(s) of a vaccine candidate. However, with over 320 vaccine candidates against COVID-19 currently in development, there are likely to be numerous differences in data collection and evaluation methods. This includes potential variation in the range of correlates of immunity being measured by laboratories. Technical differences in how and where samples are collected, transported and stored can also occur, impacting the quality and usefulness of the data

produced and making comparisons between measurements in individual laboratories difficult. In addition, with the wide range of COVID-19 vaccine approaches and technologies currently being deployed (e.g., recombinant viral vectors, live attenuated vaccines, recombinant proteins and nucleic acids), standard evaluation of the true potential of these vaccine formulations becomes very complex.

Through centralising the analysis of samples obtained from trials of COVID-19 vaccine candidates, the new clinical-sample-testing network will minimise variation in results obtained, which could otherwise arise due to such technical differences when carrying out independent analysis. The samples from participating vaccine developers will instead be tested in the same group of laboratories using the same methods, therefore, removing much of the inter-laboratory variability and allowing for head-to-head comparisons of immune responses induced by multiple vaccine candidates.

Supporting global COVID-19 vaccine development

Through this new network, up to the limit of programme funding, eligible COVID-19 vaccine developers (both CEPI-funded and non-CEPI funded developers) can use the laboratories, without per sample charges, to analyse the immune response elicited by their COVID-19 vaccine candidates in preclinical and clinical phases of studies. Data obtained on the immunogenicity of CEPI-funded vaccine candidates will be used to inform and advance CEPI's COVID-19 vaccine portfolio by providing quick and accurate evaluation of its candidate vaccines.

By opening the sample testing network to other COVID-19 vaccine programmes, CEPI also aims to ensure that all eligible developers—regardless of their size—can benefit from this analysis. Certain commitments may be required for eligibility, such as making timely publication of sample testing results and sharing data that will be produced on the

immunogenicity of COVID-19 vaccine candidates to facilitate future regulatory decisions. The number of samples available for testing per developer may be limited depending on response.

The Department of Biotechnology, under Ministry of Science & Technology is implementing the Ind-CEPI mission titled 'India Centric Epidemic Preparedness through Rapid Vaccine Development: Supporting Indian Vaccine Development Aligned with the Global Initiative of the Coalition for Epidemic Preparedness Innovations (CEPI)'. Ind-CEPI Mission aims to strengthen the development of vaccines for the diseases of epidemic potential in India as well as to build coordinated preparedness in the Indian public health system and vaccine industry to address existing and emergent infectious threats in India.

THSTI has already done a great service by evaluating clinical samples of vaccine trials for their. bioefficacy by viral neutrilization assays, T cell proliferation assays and animal model studies of Covid-19 for various

partners like Serum institute, Reddy's laboratory, Bharat Biotech, Cadila Healt research etc.

The bioassay laboratory at THSTI is established to fulfil the mandate of Ind-CEPI mission. The laboratory is a GLP facility with recent accreditation from the National Accreditation Board for Testing and Calibration Laboratories (NABL) and complies with ISO 17025:2017 standard. In addition to serving the objectives of CEPI, the facility at THSTI has the ability to train personnel and state-of-the-art facilities to cater to the high standards of data required by regulatory authorities for vaccine licensure.

III. Successful manufacturing of 100 lakh diagnostics kits by AMTZ, Vishakhapatnam

DBT-AMTZ National COMManD Consortium [COVID MedTech Manufacturing Development] is a national manufacturing facility established to address the

shortage of critical medical equipment in India and move progressively towards a stage of self-sufficiency. This an excellent example of how supportive governance and progressive science could be brought together to address immediate and futuristic priorities. It is established at Andhra Pradesh MedTech Zone (AMTZ) at Visakhapatnam, Asia's first medical equipment manufacturing ecosystem, uniquely dedicated for MedTech and is supported by the Department of Biotechnology under the National Biopharma Mission.

Many medical device manufacturers have the potential to make critical equipment like ventilators and diagnostic kits, thermal scanners or medical textiles, that was much needed in COVID context as well post-COVID period. To rapidly scale up the manufacturing of such critical medical equipment, a large investment was made in plant and machinery and upgradation of existing infrastructure at AMTZ. In the past few months, production of ventilators, RT-PCR based

diagnostic tests, IR thermometers and other diagnostics equipment and reagents was successfully scaled up to address their growing demand across the country.

Infrastructure such as cartridge production units, ventilator assembly lines, lyophilization units, cold rooms, liquid filling and labelling machines and the necessary support facility for production of medical devices was put in place at AMTZ. Due to this support, AMTZ has been able to achieve production of 100 lakh tests of RT-PCR as on end of December 2020, along with 3500 ventilators and other critical medical devices. All these diagnostic kits and equipment have been used as successful intervention measures against COVID-19 pandemic in the country.