GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH RESEARCH

RAJYA SABHA
UNSTARRED QUESTION NO.250
TO BE ANSWERED ON 20TH JULY, 2021

MOU SIGNED BETWEEN ICMR AND BHARAT BIOTECH

250 SHRI MALLIKARJUN KHARGE:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) the exact terms of the MoU signed between ICMR and Bharat Biotech for the development of the COVID vaccine, Covaxin;

(b) the total R&D cost from the public exchequer incurred upon the development of Covaxin;

(c) the reasons for ICMR claiming 5 per cent royalty on the sale of each dose of Covaxin; and

(d) the reasons for why Covaxin manufacturing was not permitted to multiple companies apart from Bharat Biotech right from early 2021 since ICMR holds the IP Rights (for claiming 5% royalty) for Covaxin?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a): Key Terms of the Memorandum of Understanding (MoU) between Indian Council of Medical Research (ICMR) and Bharat Biotech for development of an indigenous COVID-19 vaccine are as follows:

i. Collaboration for development of COVID-19 inactivated whole cell Vaccine.
ii. ICMR to provide well characterized virus strain for vaccine development.
iii. Bharat Biotech International Limited (BBIL) to develop the final vaccine formulation.
iv. Non-Exclusive License granted to commercialize product within 2 year period.
v. Payment of initial seed money of Rs. 5 Lakhs for transfer of inactivated virus strain to be paid by Licensee as one-time payment.
vi. Royalty Obligations - 5% on Net Sales, to be remitted on half yearly basis.
vii. IP to be jointly owned by ICMR and BBIL.
viii. It has been agreed that COVID vaccine will come in the joint name of ICMR and Bharat Biotech.
ix. ICMR logo to be put on the product.
x. Bharat Biotech will supply vaccines free of cost for the clinical trial.
xi. BBIL had agreed to provide vaccine at a reasonable and negotiated price to ICMR as well as all Central and State Government bodies/ affiliates etc. as and when the vaccine is available for use.
xii. BBIL to prioritize in-country supplies over the export of the vaccine, as and when the vaccine is available.

(b): ICMR has not provided any funds to BBIL for COVAXIN development. However, funds have been spent in various activities undertaken by ICMR-National Institute of Virology (NIV), Pune for COVAXIN development. Also phase 3 clinical trials of COVAXIN have been funded by ICMR. The trials have been conducted at 25 sites in 25,800 participants. Total estimated expenditure of ICMR: Rupees 35 crores

(c): Percent royalty was decided on the following basis:

1. Benchmarking Royalty percentages in the Licensing of Vaccine Technologies followed by other Government Departments / Institutes.
   For example: Brucella vaccine Technology, developed by Indian Council of Agriculture Research (ICAR) was transferred by Biotechnology Industry Research Assistance Council (BIRAC), a Department of Biotechnology, Ministry of Science and Technology, Government of India company to M/s. Hester Biosciences Pvt. Ltd, Gujarat at 5% Royalty on Net Sales, payable for 10 years in the year 2019.
2. Benchmarking Royalty percentages/ expectations followed by International Organizations such as World Health Organization (WHO) and United Nations Development Programme (UNDP).

(d):

- ICMR-NIV, Pune had isolated live SARS-CoV-2 virus in March 2020, which paved the way for development of an indigenous vaccine. ICMR was approached by Bharat Biotech International Ltd. (BBIL) with a request to hand-over the live SARS-CoV-2 virus isolate at ICMR-NIV, Pune, in April 2020. BBIL wanted to develop an inactivated vaccine for SARS-CoV-2 using the well characterized virus strain available at ICMR-NIV, Pune.
- At that time, the Indian companies pursuing the development of COVID- 19 vaccines were Bharat Biotech International Ltd., Zydus Cadila, Serum Institute of India (SII), Panacea Biotec, Indian Immunologicals, Biological Evans and Mynvax.
- ICMR agreed to hand-over the strain to BBIL due to the following reasons:
  - During the COVID-19 pandemic, ICMR has largely supported the “Make in India” or “Atmanirbhar Bharat” initiative. The revised circular dated 4th June 2020 issued by the Department for Promotion of Industry and Internal Trade also emphasized on the need to promote local/indigenous products. As is evident from above, BBIL had a purely indigenous product developed in partnership with ICMR-NIV, therefore it was considered important to support and hand-hold this indigenous product and make a promising vaccine available to the citizens of India.
  - BBIL had a validated BSL-3 facility ready for use. This is essential, as during the preclinical studies, it is essential to challenge the small animals with SARS-CoV-2 virus. Other companies with interest in SARS-CoV-2 vaccine development like Serum Institute of India were not interested in developing indigenous vaccine. Other companies like Cadila, Biological E did not have a validated BSL-3 facility available. Besides, ICMR team had inspected and

approved the BBIL BSL-3 facility in October 2019 as at that time BBIL proposed to use the BSL-3 for development of inactivated Polio Vaccine. The facility has now been re-purposed for Covid-19 vaccine development.

- ICMR-NIV had previously worked with BBIL for development of indigenous vaccine for Japanese encephalitis (JE).
- The company has a well-established track record of developing inactivated vaccines: Japanese encephalitis, DPT, chikungunya, zika etc.
- The vero-cell platform (used for developing COVID-19 vaccine) of BBIL is WHO pre-qualified and is fully safe as the above mentioned vaccines have been manufactured using this platform.

- Except BBIL and Zydus Cadila no other company has an indigenous vaccine candidate. Besides, BSL-3 facility which is absolutely essential for developing SARS-CoV-2 inactivated vaccine was also not available with the vaccine manufactures. Zydus Cadila has a DNA vaccine candidate which has a different development process. ICMR-NIV also conducted non-human primate studies for their vaccine candidate. ICMR's intent of sharing the virus with BBIL and thereafter providing it technical support was due to its ability to develop reliable and safe inactivated vaccines and also to provide an indigenous vaccine to the Nation on a fast-track basis under the public health emergency due to COVID-19.
- Therefore, a Non-Exclusive License was given with a clear mandate to commercialize the product COVID Vaccine within a two year period starting April 2020 to expedite the product development efforts by the Company.

- BBIL had agreed to provide vaccine at a reasonable and negotiated price to ICMR as well as all Central and State Government bodies/ affiliates etc. as and when the vaccine is available for use.

Due to the reasons given above, other companies were not permitted to develop COVAXIN from early 2021.

However, now the Department of Biotechnology has been given the task of upscaling Covaxin production within multiple sites in India. Under Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission, being implemented by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking (PSU) of the Department of Biotechnology (DBT), efforts have been made, since March-April, 2021, to strengthen vaccine manufacturing. In this regard, facility augmentation of Bharat Biotech and 3 Public Sector Enterprises (PSEs) including Haffkine Biopharmaceutical Corporation Ltd, Mumbai; Indian Immunologicals Limited (IIL); Hyderabad and Bharat Immunologicals Biologicals Limited (BIBCOL), Bulandshahr; for augmented production of Covaxin are being supported. Further, Technology transfer of Covaxin production to Gujarat COVID Vaccine Consortium (GCVC), including Hester Biosciences and OmniBRx Biotechnologies Pvt Ltd, led by Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat, is being facilitated by the Department of Biotechnology. These efforts are expected to enhance the production of Covaxin from the present 1 Cr. per month to 10 Cr. per month in the coming months.