

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

**LOK SABHA
STARRED QUESTION NO. 166
TO BE ANSWERED ON THE 2ND AUGUST, 2024**

PATENT ON COVAXIN

***166 PROF. SOUGATA RAY:**

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

- (a) whether the Indian Council of Medical Research (ICMR) has filed any application for the Intellectual Property Rights as inventor of Covaxin;
- (b) if so, the details thereof and if not, the reasons for not submitting such an application;
- (c) whether ICMR or any other Government agencies like National Institute of Virology has spent funds for the development of Covaxin, if so, the details thereof;
- (d) whether any other agency/private players have applied for the Intellectual Property Rights as inventor of Covaxin and if so, the details thereof; and
- (e) whether the Government has taken any action to protect its authority on Covaxin and if so, the details thereof?

**ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)**

(a) to (e) A Statement is laid on the Table of the House.

**STATEMENT REFERRED TO IN REPLY TO LOK SABHA
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(a) and (b): As informed by Indian Council of Medical Research (ICMR), recently, a joint Indian patent application has been filed by Bharat Biotech International Limited (BBIL) with ICMR-National Institute of Virology (NIV) as a co-applicant. The details of the patent application have been shared by BBIL with ICMR.

(c) ICMR has spent an estimated amount of Rs. 35 crores towards development of Covaxin. A detailed breakup of funds expended is enclosed as an Annexure. A much larger component of the total development cost of Covaxin was spent by Bharat Biotech International Limited (BBIL) company.

(d) Bharat Biotech International Limited (BBIL) along with ICMR-NIV are the co-applicants of the patent of Covaxin. In the initial application filed by BBIL, ICMR-NIV had not been included as a co-applicant. However, it was informed by BBIL that the inclusion of ICMR-NIV was inadvertently missed and it has now filed a correction in Patents Office.

(e) Usefulness of Covaxin to the nation and the world has been well acknowledged beyond doubt. Upon its development by BBIL with technical assistance of ICMR, Government was the recipient of the most doses of the Vaccine and it used the same in the national interest. This was India's first WHO-approved indigenous Covid-19 vaccine, and was distributed and protected the lives of people during the pandemic. Government also ensured the quick access, availability and use for the masses at the most affordable cost. This Public-Private partnership collaboration underlined the commitment of India towards promotion of our indigenous industry and has been recognized as an important contribution towards Atmanirbhar Bharat.

Approximate expenditure incurred by ICMR
on Development of Covaxin

S. No.	Activity	ICMR Expenses (in lakhs of Rupees)
1	Cost of virus isolation, animal challenge studies, testing vaccine neutralization against variant strains of SARS-CoV-2, BSL-4 operational and miscellaneous costs	720
2	Laboratory testing of samples from phase 1, 2 and 3 clinical trials	780
3.	Phase 3 clinical trial – funding of 25 sites for screening & recruiting 25,800 participants	2000
	TOTAL EXPENDITURE	3500
