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

LOK SABHA UNSTARRED QUESTION NO. 1111 TO BE ANSWERED ON 03rd DECEMBER, 2021

MANUFACTURING OF COVID-19 VACCINES

1111: DR. T. SUMATHY (a) THAMIZHACHI THANGAPANDIAN:

SHRI D.M. KATHIR ANAND:

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

- (a) whether the Government has ascertained that the two approved COVID-19 vaccine manufacturers of Covishield and Covaxin have achieved the optimum production capacity, if so, the details thereof;
- (b) whether the Government or Indian Council of Medical Research has approved any other companies other than the said two companies to manufacture and produce COVID-19 vaccines in India;
- (c) if so, the details thereof and if not, the reasons therefor;
- (d) whether the Central Drugs Standard Control Organisation (CDSCO) has granted import permission/ license for importing and manufacturing of COVID-19 Vaccines to meet the demand in the country; and
- (e) if so, the details of the permission granted and the total number and quantum of vaccines expected through this arrangement?

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

(a) ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) (COVISHIELD) is manufactured by M/s Serum Institute of India Pvt., Ltd., Pune, while the Whole Virion Inactivated Corona Virus Vaccine (COVAXIN) is manufactured by M/s Bharat Biotech International Limited, Hyderabad.

As communicated by the M/s Serum Institute of India, the current monthly vaccine production capacity of Covishield is approx. 250-275 Million doses per month.

Further, as communicated by M/s Bharat Biotech International Limited, Hyderabad, the current monthly vaccine production capacity of Covaxin is approx. 50-60 Million doses/month. Both companies have achieved close to 90% of present production capacity.

(b) to (e): As per the provisions of New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetics Act, 1940 and in light of urgent need due to COVID pandemic in the country, CDSCO has granted permissions to following COVID-19 vaccines other than COVAXIN & COVISHIELD for prevention of COVID-19 for restricted use in emergency situation:

Permission For Manufacture of COVID-19 vaccines:

- Gam-COVID-Vac Combined vector vaccine [SPUTNIK-V] manufactured by M/s Ra (biologicals), Panacea Biotec Ltd., New Delhi using imported Ready to Fill (RTF) bulk from M/s Generium JSC, Russia on 02.07.2021.
- Novel Corona Virus 2019-nCoV vaccine [ZyCoV-D] manufactured by M/s Cadila Healthcare Limited, Ahmedabad on 20.08.2021.
- 3. Ad26.COV2-S (recombinant) COVID-19 Vaccine manufactured by M/s Biological E limited, Hyderabad using imported bulk of M/s Johnson & Johnson Pvt. Ltd on 18.08.2021.
- Gam-COVID-Vac Combined vector vaccine [Sputnik–V] manufactured under technology transfer from M/s RDIF, Russia by M/s Hetero Biopharma Limited, Hyderabad on 07.10.2021.

Permission For Import of COVID-19 Vaccines:

- 1. Gam-COVID-Vac Combined vector vaccine [SPUTNIK-V] to M/s Dr. Reddy's Laboratories Ltd, Hyderabad on 12.04.2021.
- 2. mRNA-1273 COVID-19 vaccine (Moderna) to M/s Cipla Limited, Mumbai on 29.06.2021.
- 3. Ad26.COV2-S (recombinant) COVID-19 Vaccine to M/s Johnson & Johnson Pvt. Ltd., Mumbai on 07.08.2021.
