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

RAJYA SABHA UNSTARRED QUESTION NO. 1067 TO BE ANSWERED ON 07TH DECEMBER, 2021

EFFICACY OF COVISHIELD AND COVAXIN

1067: SHRI K. SOMAPRASAD:

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

- (a) whether Government has ascertained the efficacy of Covishield and Covaxin, if so, the details thereof;
- (b) the details of vaccines allowed in India so far against COVID-19; and
- (c) the details of recognition of Covaxin by other countries so far?

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

(a) COVISHIELD vaccine of M/s Serum Institute of India is technology transfer of Oxford/AstraZeneca vaccine developed by Oxford University & AstraZeneca. The efficacy studies for Oxford/AstraZeneca vaccine were conducted overseas by Oxford University & AstraZeneca and M/s Serum Institute of India has conducted Phase II/III immune-bridging clinical trial in the country. The overall interim efficacy of the Oxford/AstraZeneca vaccine at the time of approval of COVISHILED has been reported to be 63.09%.

M/s Bharat Biotech International Ltd has conducted Phase III efficacy trial of COVAXIN in the country wherein the efficacy of the vaccine has been reported as 77.8%.

(b): 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.
- 2. 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.
- (c) COVAXIN was granted Emergency Use Listing (EUL) by the World Health Organisation (WHO) on 3 November 2021. WHO EUL is sufficient for travel in a large number of countries, however, some countries issue specific notifications for inclusion of vaccines for travel purposes. The details of such countries is attached as **Annexure**.

Annexure

1	Andorra	37	Panama
2	Antigua & Barbuda	38	PHILIPPINES
3	AUSTRALIA	39	POLAND
4	Azerbaijan	40	Qatar
5	BAHRAIN	41	St. Kitts and Nevis
6	BELARUS	42	SAN MARINO
7	BOTSWANA	43	SERBIA
8	Canada	44	Sierra Leone
9	Cambodia	45	Singapore
10	Columbia	46	Slovak Republic
11	Commonwealth of Dominica	47	Slovenia
12	Costa Rica	48	Sri Lanka
13	ESTONIA	49	State of Palestine
14	Finland	50	Switzerland
15	GUYANA	51	Thailand
16	Hong Kong	52	Trininad & Tobago
17	HUNGARY	53	Turkey
18	Iceland	54	United Kingdom
19	IRAN	55	United States of America
20	Israel	56	VENEZUELA
21	Kazakhstan	57	Vietnam
22	Kyrgyz Republic	58	ZIMBABWE
23	LEBANON		
24	Malaysia		
25	Maldives		
26	MALI		
27	MAURITIUS		
28	MEXICO		
29	MYANMAR		
30	Namibia		
31	NEPAL		
32	New Zealand		
33	Netherlands		
34	NICARAGUA		
35	OMAN		

36 PARAGUAY