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

**LOK SABHA**
**UNSTARRED QUESTION NO. 4053**
**TO BE ANSWERED ON 19TH MARCH, 2021**

## COVID VACCINES DEVELOPED BY FOREIGN COUNTRIES

**4053. SHRI DAYANIDHI MARAN**:

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

(a) whether the Government proposes to allow the usage, sale and distribution of foreign orgin COVID vaccines developed by foreign countries;

(b) the regulatory requirements being imposed on foreign manufacturers for approval of their medicines;

(c) whether the indigenous/local vaccines are also required to furnish the same requirements for regulatory approvals;

(d) if so, the details thereof; and

(e) whether the Government has conducted any consultations, discussions, review of vaccines such as Pfizer, Moderna etc., if so, the details thereof?

## ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE**
**(SHRI ASHWINI KUMAR CHOUBEY)**

(a): The Central Drugs Standard Control Organization (CDSCO) had received applications regarding grant of import permission to import (marketing authorization) the following vaccines developed by foreign countries:

i) M/s Dr. Reddy's Laboratories Ltd., Hyderabad for grant of import permission to import (marketing authorization) from Russia for emergency use of COVID-19 Vaccine in the country on 19.02.2021. The proposal was deliberated in the Subject Expert Committee (COVID) meeting of CDSCO held on 24.02.2021 and as per the recommendation of the committee, the firm has been requested to submit immunogenicity and safety data of Phase II and III trial as per approved protocol for further consideration of the Committee.

ii) M/s Pfizer Limited, Mumbai for grant of permission to import (marketing authorization) for emergency use of its COVID-19 vaccine in the country on 04.12.2020. However, the application was withdrawn by the firm on 05.02.2021.

(b) to (d): The detailed guidelines and requirements for approval to conduct of clinical trial and marketing authorization permission of New Drugs including vaccines are specified in Second Schedule of the New Drugs and Clinical Trial (ND & CT) Rules, 2019.

The approval of new drug or vaccine for manufacturing and marketing is based on the submission of adequate data including Chemistry, Manufacturing and Control (CMC), non-clinical (animal studies), clinical trial data as per Rules and outcomes of evaluation of the same in consultation with Subject Expert Committee (SEC) of CDSCO.

In the case of import from other countries, before approval of such new drug or vaccine in India, local clinical trial may be required to be carried out as per the provisions of New Drugs and Clinical Trials Rules, 2019 to generate evidence of efficacy and safety of the vaccine in Indian population.

(e): CDSCO received an application from M/s Pfizer for grant of permission to import its COVID-19 vaccine in the country on 04.12.2020. The proposal was deliberated in the SEC (COVID) meeting held on 03.02.2021. The committee noted that incidents of palsy, anaphylaxis and other SAE's were reported during post marketing and the causality of the events with the vaccine was under investigation. Also, the firm had not proposed any plan to generate safety and immunogenicity data in Indian population. After detailed deliberation, the committee did not recommend for grant of permission for emergency use in the country at that stage. However, the firm on 05.02021 withdrew its application.

CDSCO has not received any application for approval of COVID-19 Vaccine of M/s Moderna.