

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

**LOK SABHA  
UNSTARRED QUESTION NO.2779  
TO BE ANSWERED ON 12<sup>TH</sup> March, 2021**

**APPROVAL OF VACCINE**

**2779. SHRI SUSHIL KUMAR SINGH:**

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

- (a) whether the Government is contemplating to approve the vaccines of the companies whose vaccines have already undergone phase 3 trials outside India;
- (b) if so, the details thereof;
- (c) if not, the reasons therefor;
- (d) whether the Government is contemplating to allow companies to spend its CSR funds on vaccinating its employees and their families or the general community;
- (e) if so, the details thereof?

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

(a) to (c): Approval of New Drugs including Vaccine is regulated as per the provisions of New Drugs and Clinical Trials Rules, 2019 under Drugs & Cosmetics Act, 1940.

The vaccine which has under gone Phase III clinical trial outside 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 before approval of such vaccine in India.

(d) & (e): The broad framework of Corporate Social Responsibility (CSR) is provided through Section 135 of the Companies Act, 2013 ('Act') Schedule VII of the Act and Companies (CSR Policy) Rules, 2014. Schedule VII of the Act mentions areas and activities that can be undertaken by companies as eligible CSR activities.

Ministry of Corporate affairs vide General Circular No.21/2014 dated 18.06.2014 had clarified that entries mentioned in Schedule VII are broad based and has to be interpreted liberally. Further, vide General Circular No.10/2020 dated 23.03.2020, it had been clarified that CSR funds may be spent for various activities related to COVID-19 under item No.(i) and (xii) of the Schedule VII relating to promoting healthcare including preventive healthcare and sanitation, and disaster management.

Vaccination for COVID-19 is an eligible CSR activity under item (i) and item (xii) of the Schedule VII. However, the implementation of these activities has to be in conformity with Companies (CSR Policy) Rules, 2014. Under the rule 2(1)(d) of the said rules, any vaccination activities which target only employees and their family members shall not be an eligible CSR activity.