

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

**LOK SABHA  
UNSTARRED QUESTION No. 523  
TO BE ANSWERED ON THE 4<sup>TH</sup> FEBRUARY 2022**

**VACCINES SIDE EFFECTS**

**523. SHRI MANISH TEWARI:**

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

- (a) whether the Government is aware that the vaccines currently being administered to pregnant and lactating women carry a risk of infection and other side effects;
- (b) if so, the details thereof;
- (c) whether the phase-3 trial data of vaccines approved for vaccinating children aged 15-18 years, namely the Covaxin and Zydus Cadila, have not been published or peer reviewed;
- (d) if so, the details thereof; and
- (e) the reasons for approval of such vaccines by the Government which could potentially cause more harm than benefits?

**ANSWER**

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

(a) to (e) On the basis of review of available scientific evidence, recommendations of domain knowledge experts and stake holder consultation, Ministry of Health & Family Welfare approved Covid-19 vaccination of lactating women on 19th May 2021 and of pregnant women on 2nd July 2021.

Central Drugs Standard Control Organization (CDSCO) the National Regulator based on the recommendations of Subject Expert Committee (SEC) has granted permission to COVAXIN of M/s Bharat Biotech & ZyCoV-D of M/s Cadila for restricted use in emergency situation in the age group 12 years and above as per provisions of the New Drugs and Clinical Trials (NDCT) Rules, 2019.

The publication in national/international journals of clinical trial results of specific vaccines are usually done by the company/scientists who have developed and manufactured these vaccines. It is not a mandatory requirement under New Drugs and Clinical Trials (NDCT) Rules, 2019.

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