

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

**LOK SABHA  
UNSTARRED QUESTION NO. 996  
TO BE ANSWERED ON 18<sup>TH</sup> SEPTEMBER, 2020**

**USE OF DRUGS UNDER CLINICAL TRIAL FOR COVID-19**

**996. SHRI MARGANI BHARAT:**

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

- (a) whether the Government has permitted the use of drugs under the clinical trials for treating COVID-19, rare genetic diseases and paediatric disorders without amending New Drugs and Clinical Trial Rules;
- (b) if so, the details thereof and the drugs that the Government is likely to permit to use under the above exemption; and
- (c) whether Government is aware of the countries using drugs under clinical trial for COVID-19; and
- (d) if so, the details thereof and the drugs likely to be imported by the Government in this regard?

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

(a): Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health & Family Welfare grants permission to import/manufacture new drugs under the provisions of New Drugs and Clinical Trial Rules, 2019. No permission for manufacture/import of any new drug for treatment of COVID-19, rare genetic diseases and pediatric disorder, for which there is no provision in the existing New Drugs & Clinical Trial Rules, 2019, has been granted by CDSCO.

(b): Does not arise.

(c) & (d): As per information available in public domain, various drugs are under clinical trial for COVID-19 and are being used for treatment of COVID-19 patients by other countries.

However, CDSCO has approved manufacture/marketing of the following three drugs for Restricted Emergency Use in the country for treatment of COVID-19 infection:

- a. Remdesivir Injectable formulations,
- b. Favipiravir tablets, and
- c. Itolizumab injection.