

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

**RAJYA SABHA  
UNSTARRED QUESTION NO.917  
TO BE ANSWERED ON 9<sup>TH</sup> FEBRUARY, 2021**

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

**917 DR. BANDA PRAKASH:**

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

- (a) whether 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 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;
- (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) & (b): There are certain provisions under Drugs and Cosmetics Rules, 1945 and New Drugs and Clinical Trial Rules, 2019, which allow import/ manufacture of unapproved Drugs for personal use.

- Rule 36 of Drugs and Cosmetics Rules, 1945 allows for import of small quantities of drugs for personal use under a personal permit to be obtained from Central Drugs Standard Control Organisation (CDSCO).
- Under Rule 91 of New Drugs and Clinical Trial Rules 2019, there are provisions under which a manufacturer can manufacture unapproved new drug which is under clinical trial, for treatment of patient of life threatening disease obtaining necessary permission from CDSCO and license from the State Licensing Authority under Drugs and Cosmetics Rules, 1945.

As and when such applications are received, the same is examined and action taken as per the provisions of above rules.

(c) & (d): No such information is available in this regard.

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