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

LOK SABHA
UNSTARRED QUESTION NO.3975
TO BE ANSWERED ON 19TH March, 2021

CENTRAL DRUGS STANDARD CONTROL ORGANISATION

3975. SHRI SHANTANU THAKUR:

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

(a) the main objectives and salient features of the functioning of Central Drugs Standard Control Organisation (CDSO);

(b) whether CDSO is responsible for approval of new drugs in the country; and

(c) if so, the details thereof along with the drugs approved during the last three years?

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

(a): The regulatory control over the import, manufacture, distribution and sale of drugs, cosmetics and notified medical devices in the country are regulated under the provisions of the Drugs and Cosmetics Act, 1940 & Drugs and Cosmetics Rules, 1945, Medical Devices Rules, 2017 and New Drugs and Clinical Trials Rules, 2019 made thereunder.

The main functions of the Central Licensing Authority in Central Drugs Standard Control Organisation (CDSCO), Ministry of Health & Family Welfare are as under: -

1. Approval of New Drugs including vaccine, biotech products under New Drugs and Clinical Trials (ND&CT) Rules, 2019 to ensure their quality, safety and efficacy;

2. Grant of Permission to conduct clinical trials to ensure that clinical trial is conducted as per the ND&CT Rules, 2019 and Good Clinical Practices guidelines;

3. Registration and control on the quality of imported drugs under Drugs and Cosmetics Rules, 1945; Cosmetics under Cosmetic Rules, 2020 and notified medical devices under Medical Devices Rules, 2017;

4. Grant of License to Manufacture Class C and Class D Medical Devices under Medical Devices Rules,2017;

5. Participating in the meeting of Drugs Consultative Committee (DCC) & Drugs Technical Advisory Board (DTAB) under Drugs & Cosmetic Act.

6. Approval of License for manufacture of large volume parenteral, vaccines and biotechnology products and operation of blood banks and also of such drugs as may be notified by Government from time to time under the provisions of Drugs and Cosmetics Rules in the country as Approving Authority.

(b) & (c): Central Licensing Authority in CDSCO approves import/manufacture and marketing of new drugs under New Drugs and Clinical Trials (ND&CT) Rules, 2019.

For manufacture/ import of new drug in the country, the manufacturer/ importer is required to obtain new drug permission from CDSCO before obtaining the manufacturing license/ import license. Details of such permissions granted during the last three years are as below:

Year	**Number of Permissions**
2018	239
2019	208
2020	415
Total	862