

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

**LOK SABHA
UNSTARRED QUESTION NO.1669
TO BE ANSWERED ON 16th DECEMBER, 2022**

CENTRAL DRUGS STANDARD CONTROL ORGANISATION

**1669: SHRI VIJAYAKUMAR (ALIAS) VIJAY VASANTH:
SHRI MARGANI BHARAT:**

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

- (a) whether it is a fact that the Central Drug Standard Control Organisation (CDSCO) is effectively regulating the medical devices industry in view of the concerns being expressed regarding standard and quality of the medical devices, if so, the details thereof;
- (b) whether the Government is aware of the fact that they have only 20 CDSCO-approved medical device testing labs compared to the size of the country, if so, the details thereof;
- (c) whether it is a fact that the government is considering to set up a new regulator for medical devices, if so, the details thereof;
- (d) whether the Government is aware of the fact that there is a new licensing method has been launched from October this year; and
- (e) whether the Government is aware that the CDSCO in its existing structure and expertise is mainly Pharma centric, if so, the details thereof?

ANSWER

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

(a): Central Drugs Standard Control Organisation (CDSCO) regulates the medical devices under Medical Device Rules (MDR) 2017. To ensure the quality of medical devices in the country, compliance of the provisions of the MDR, 2017 is required. This includes comprehensive provisions to regulate Clinical Investigation, Manufacture, Import, Sale and Distribution of the notified medical devices as per risk based classification.

For class A&B the manufacturing license is granted by the concerned State Licensing Authority after conformity assessment by registered notified body. The manufacturing license for class C&D medical devices, is granted by Central Licensing Authority after inspection carried out by the Medical Device Officers notified by the Government.

A manufacturer has to comply with the Bureau of Indian Standards (BIS). If these are not available then manufacturer has to comply International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) standards. If ISO/IEC standards are not available then manufacturer has to comply with pharmacopoeial/ manufacturer validated standards.

(b) to (e) : CDSCO has registered 28 NABL accredited laboratories for the testing of medical devices on behalf of the manufacturer. Six Central Medical Device Testing Laboratories are notified by Government of India for testing the legal samples.

Ministry of Health & Family Welfare has published a gazette notification S.O. 648 (E) dated 11.02.2020 and G.S.R. 102(E) dated 11.02.2020, in order to regulate all medical devices in phase wise manner, whereby Class A and B medical devices are under licensing regime from 01.10.2022 and class C and D medical devices will come under licensing regime from 01.10.2023.

CDSCO has a separate division for medical devices. There are 236 notified Medical Device Officers working in the zonal/ sub-zonal/ port offices and head office of CDSCO. 23 Drugs Inspector (Medical Devices) and 03 Assistant Drugs Controllers (Medical Devices) are working for medical devices regulation.
