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

LOK SABHA
UNSTARRED QUESTION NO. 991
TO BE ANSWERED ON 05TH DECEMBER, 2025

REGULATION OF MEDICAL DEVICES

991. SHRI G LAKSHMINARAYANA:

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

(a) whether the existing legal and regulatory framework governing medical devices, including classification, approvals, quality control and post-market surveillance, it aligns with global standards such as United States Food and Drug Administration (USFDA) or European Union Medical Device Regulation (EU MDR) and if so, the details thereof;

(b) the number of medical devices approved by Central Drugs Standard Control Organization (CDSCO) during the last five years, risk-classification-wise;

(c) the number of adverse events, safety complaints and product recalls reported;

(d) whether the Government proposes to introduce a standalone Medical Devices Act, separate from the Drugs and Cosmetics Act and its key features and timelines and if so, the details thereof;

(e) the current staffing strength and technical capacity of Central Drugs Standard Control Organization (CDSCO) to regulate medical devices;

(f) whether expansion or creation of a dedicated medical device regulator is being considered and if so, the details thereof; and

(g) the number and outcomes of inspections or audits conducted on high-risk devices such as implants, ventilators and diagnostics during the last five years?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) to (f): To have a comprehensive regulatory provisions for import, manufacture, sale and distribution of medical devices based on risk based criteria, the Ministry of Health & Family Welfare, Government of India has notified the Medical Devices Rules, 2017 vide G.S.R. 78(E) dated 31.01.2017 under the provisions of the Drugs and Cosmetics Act, 1940. Said rules are effective from 01.01.2018 to regulate the clinical investigation, manufacture, import, sale and distribution of the medical devices in the country.

Under MDR 2017, the medical devices are required to conform to standards specified by the Bureau of Indian Standards (BIS) or those notified by the Central Government. In the absence of such standards, devices must comply with standards of the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), or other recognized pharmacopoeial standard or the validated manufacturer's standards, wherever applicable.

Under the rules, import of all classes of Medical Devices (Class A, B, C & D) as well as manufacture of Class C & D Medical Devices are regulated by CDSCO, while manufacture of Class A & B Medical devices are regulated by the concerned State Licensing Authorities (SLA) appointed by the State Governments. However, sale and distribution of all classes of Medical Devices are regulated by the SLAs. The number of medical devices approved by the Central Drugs Standard Control Organization (CDSCO) during the last five years (from 2020 till date) is as under:

Class A	Class B	Class C	Class D
3613	22286	26096	6288

To strengthen post-market surveillance of medical devices, the Ministry of Health and Family Welfare established the Materiovigilance Programme of India (MvPI) with Indian Pharmacopoeia Commission (IPC) as its National Coordination Centre. Under the said Programme, in last 5 years (from 2021-22 till date), a total of 46,593 Medical Device Adverse Events (MDAEs) have been reported.

A dedicated medical device vertical has been sanctioned for CDSCO with 249 regulatory posts.

(g): CDSCO has conducted 1,253 audits/inspections between 2020 and 2024 for evaluating applications for manufacturing licences of high-risk medical devices (Class C & D), and based on inspection findings, approval of medical devices is granted or further information is sought.

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