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

LOK SABHA
UNSTARRED QUESTION NO. 2216
TO BE ANSWERED ON 01ST AUGUST, 2025

MEDICAL DEVICES REGULATORY AUTHORITY

2216. THIRU DAYANIDHI MARAN:

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

(a) whether the Government plans to establish an independent medical devices regulatory authority, separate from the drug-centric Central Drugs Standard Control Organization (CDSCO) to ensure sector-specific expertise and faster approvals and if so, the details thereof;

(b) whether any steps have been taken/proposed to be taken by the Government to strengthen post-market surveillance including the creation of a publicly accessible adverse events database akin to the US FDA's MAUDE or the EU's EUDAMED and if so, the details thereof;

(c) whether the Government considered implementing a comprehensive regulatory framework for Software as a Medical Device (SaMD) especially AI-based diagnostics and if so, the details thereof;

(d) whether the Government is likely to adopt value-based procurement and expand Health Technology Assessments to prioritise high-impact, cost-effective devices and if so, the details thereof; and

(e) whether there is an intent to rationalise GST slabs on medical devices to improve affordability, especially for critical diagnostics and implants and if so, the details thereof?

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

(a): A separate medical device vertical has been created under Central Drugs Standard Control Organization (CDSCO) to specifically regulate medical devices in the country.

(b): In order to strengthen the post-market surveillance system and reporting of adverse events/side effects for medical devices in the country, Ministry of Health & Family Welfare has set up Materiovigilance Programme of India (MvPI) to monitor the safety of medical devices in the country in the year 2015. The Indian Pharmacopoeia Commission (IPC) is National Coordination Centre (NCC) for the MvPI. This is a strategic initiative launched by

the Ministry of Health & Family Welfare, Government of India. Under the said program there are at present 596 functional Medical Device Adverse Event Monitoring Centres (MDMCs) all over the country which is entrusted with the responsibility to report adverse events due to the use of medical devices in the country.

MvPI has issued a comprehensive guidance document to assist hospitals, healthcare professionals, and other stakeholders in identifying and reporting adverse events associated with medical devices. IPC has launched indigenously developed Adverse Drug Monitoring System (ADRMS) Online Portal, an electronic tool to report the adverse events with the use of medical device.

Further, there is provision, under the Medical Devices Rules, 2017, stipulating that subsequent to approval of a medical device, the applicant is required to submit Periodic Safety Update Reports (PSURs) to Central Drugs Standard Control Organisation (CDSCO). Post Marketing Surveillance including any suspected unexpected serious adverse event, recall, Periodic Safety Update Report (PSUR) are monitored by the CDSCO as per provisions mentioned in Chapter IV, V, VII, VIII, XI of Medical Devices Rules 2017.

(c): Softwares which fall under medical device definition as per Ministry of Health and Family Welfare notification S.O. 648(E) dated 11.02.2020 are regulated under the provisions of Medical Devices Rules, 2017.

(d): Health Technology Assessment India (HTAIn) was approved as an attached office in Department of Health Research in May 2023. The objective is to provide a health technology assessment system that evaluates cost effectiveness and appropriateness of use of the existing and new health technologies in healthcare services by prioritizing high impact and cost effective Devices. It gives recommendation in use of HTA evidence in procurement, introduction of new technologies, State health programs and Health Benefit packages. 98 studies have been approved.

(e): As informed by Department of Revenue, most medical devices attract a GST rate of 12%. GST rates are prescribed on the recommendations of GST Council, which is a constitutional body comprising members from States/UTs and Centre. In its 45th meeting of the GST Council held on 17th September 2021, the Council constituted a Group of Ministers (GoM) on GST Rate Rationalization. One of the terms of reference for the GoM was review of the current rate slab structure of GST, including special rates, and recommend rationalization measures.

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