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

LOK SABHA
UNSTARRED QUESTION NO. 3350
TO BE ANSWERED ON 07TH AUGUST, 2026

REGULATION AND PATIENT SAFETY IN DENTAL IMPLANTOLOGY

3350. SHRI PARSHOTTAMBHAI RUPALA:

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

(a) whether the Government is aware of the absence of a comprehensive national regulatory framework governing dental implants, implant biomaterials, artificial teeth and implantology practices, resulting in potential patient-safety risks, if so, the details thereof;
(b) whether the Government proposes to mandate scientific evaluation of implant devices, including fatigue, biocompatibility, sterility and corrosion testing and establish a National Dental Implant Registry with mandatory device traceability and adverse-event reporting, on the lines of international best practices, if so, the details thereof; and
(c) whether the Government proposes to prescribe mandatory practitioner certification, accreditation of implant centres, standardized informed-consent protocols and ethical advertising norms for dental implant procedures, if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE

(SMT. ANUPRIYA PATEL)

(a) & (b): All Medical Devices including dental implants, implant bio materials, artificial teeth etc., are regulated under the provisions of Drugs and Cosmetics Act 1940 and Medical Devices Rules 2017, regarding quality, safety & performance of the Medical Devices in the country.

Under the said rules, requirements of scientific evaluation of medical devices including implantable medical devices are prescribed and the manufacturer has to perform all the tests applicable as per existing standards for biocompatibility, sterility along with other tests as applicable for its compliance before grant of license. The scope of standards, essential principles for safety & performance and Quality Management System (QMS) are mandatory for ensuring the safety & quality of the medical device throughout the device life cycle. Further, the existing rules are aligned with global regulatory practices followed by stringent regulatory authorities.

As regard to adverse-event reporting mechanism, the Indian Pharmacopoeia Commission (IPC), functions as the National Coordination Centre (NCC) for the Materiovigilance Programme of India (MvPI). The programme collects and analyses suspected adverse event associated with medical devices, including devices used in dentistry to ensure medical device safety.

Further, as part of Quality Management System (QMS) implementation, the manufacturer has to adhere to the requirements of Quality Risk Management for vigilance reporting and all Adverse Events (AE) are monitored by the manufacturer as per their Quality Risk Management protocol. The manufacturer also needs to submit Post Market Surveillance (PMS) report mentioning all Adverse Events to the Licensing Authority, for ensuring Quality, safety & performance of the Medical Device throughout the product life cycle.

(c): As prescribed at present, any registered Dentist may perform dental implant procedures.

****