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

LOK SABHA
UNSTARRED QUESTION NO. †1034
TO BE ANSWERED ON 24TH JULY, 2026

AI-BASED MEDICAL DEVICES AND SOFTWARE

†1034. DR. SAMBIT PATRA:

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

(a) whether the use of AI-based medical devices and software is increasing in the country, if so, the details thereof;

(b) whether the use of AI-based software for cancer screening and diagnosis is increasing in the country, if so, the details thereof along with the steps taken/proposed to be taken by the Government to regulate such software;

(c) the steps taken/proposed to be taken by the Government to ensure patient safety in view of the increasing use of AI-based medical software, if so, the details thereof; and

(d) the safeguards implemented by the Government to ensure the security of patient data in view of the increasing use of AI-based medical software?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) to (d): All medical devices, including the software intended to be used for medical purposes (Medical Device Software) are regulated under the provisions of Medical Devices Rules, 2017.

In respect of AI-enabled medical devices and software, the applicant is required to submit comprehensive technical documentation in accordance with the said rules. The key technical documentation requirements include:

(i). Essential Principle Checklist to demonstrate conformity with applicable safety and performance requirements;
(ii). Verification and validation documentation including software;
(iii). Risk analysis and control documents;
(iv). Clinical evidence in support of safety, performance and effectiveness;
(v). Quality Management System documents;
(vi). Software version release certificates if any;
(vii). Post Marketing Surveillance documentation 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.

CDSCO has developed and published various guidance documents, classification lists, and Frequently Asked Questions (FAQs) to provide clarity on the requirements under the Medical Devices Rules, 2017.

The Ministry of Health and Family Welfare has launched the 'Strategy for AI in Healthcare in India' (SAHI) and the 'Benchmarking Open Data Platform for Health AI' (BODH) on 17th February 2026 during the India AI impact summit. SAHI is a national guidance framework to enable the safe, ethical, evidence-based, responsible and inclusive adoption of artificial intelligence across India's healthcare system. 'Benchmarking Open Data Platform for Health AI' (BODH) provides a structured mechanism for testing and benchmarking AI solutions before deployment at scale. SAHI has been developed after intensive consultation with all the major stakeholders of the healthcare ecosystem, including acedemia.

Ayushman Bharat Digital Mission (ABDM) provides a sandbox environment and integration toolkits that allow health technology developers to integrate their applications/ software, including AI screening tools.

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