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

RAJYA SABHA
UNSTARRED QUESTION NO. 2035
TO BE ANSWERED ON 10TH MARCH, 2026

STATUS OF SECURE AI FOR HEALTH INITIATIVE

2035. SHRI KARTIKEYA SHARMA:

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

(a) whether the Central Drugs Standard Control Organisation (CDSCO) has a dedicated regulatory pathway for rapid approval of AI-enabled Class C medical devices for early detection of breast cancer and tuberculosis;

(b) the status of the Secure AI for Health Initiative (SAHI) in benchmarking indigenous mammography and chest X-ray algorithms using Indian clinical data; and

(c) whether a roadmap exists to integrate such AI screening tools with the Ayushman Bharat Digital Mission for point-of-care screening and diagnostics at rural Health and Wellness Centres?

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

(a):   The Central Drugs Standard Control Organisation (CDSCO) has regulatory pathway for regulation of all medical devices which covers Artificial Intelligence (AI)-enabled medical devices. The technical documentation requirements for high-risk medical devices are prescribed under the provisions of the Medical Devices Rules, 2017.

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

(i)   Essential Principles 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.

The Chapters IV and V of the Medical Devices Rules, 2017 contain provisions relating to the grant of manufacturing licences and import licences, respectively, for the commercialization of medical devices in the country. The timeline for each activity is clearly prescribed under the Medical Devices Rules, 2017.

(b):   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 17.02.2026 during the India AI Impact Summit. SAHI is a national guidance framework for safe, ethical, evidence-based, and inclusive adoption of Artificial Intelligence across India's healthcare system. Benchmarking Open Data Platform for Health AI (BODH) has been developed in partnership with IIT Kanpur and provides a structured mechanism for testing and validating AI solutions before deployment at scale.

(c):   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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