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

LOK SABHA
UNSTARRED QUESTION NO. 2429
TO BE ANSWERED ON 13TH FEBRUARY, 2026

QUALITY OF EYEGLASSES AND OPTICAL LENSES

2429. SHRI PARSHOTTAMBHAI RUPALA:

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

(a) whether the Government has instituted/proposes to institute a regulatory mechanism to periodically test, certify and monitor the quality of eyeglasses and optical lenses in the country, if so, the details thereof;

(b) whether the Government is aware that substandard eyeglasses and lenses are adversely affecting the vision of the people in the country and if so, the details thereof;

(c) whether the Government has examined international practices and foreign legislation that have established optical councils or regulatory bodies for enforcing quality standards; and

(d) if so, the details thereof along with the key elements identified from such legislations for possible adoption in the country?

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

(a) to (d): To have a comprehensive regulatory provisions for import, manufacture, sale and distribution of all medical devices including prescription spectacles, contact lenses and intraocular lenses, 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 the rules, the import of all classes of medical devices (Class A, B, C, and D) and the manufacture of Class C and D medical devices are regulated by CDSCO, whereas the manufacture of Class A and B medical devices is regulated by the concerned State Licensing Authorities (SLAs) after conformity assessment by a registered notified body. The sale and distribution of all classes of medical devices are regulated by the SLAs. CDSCO has notified NABL accredited laboratories for testing of medical devices on behalf of manufacturers and Central Medical Device Testing Laboratories are notified by Government of India for testing

of medical devices. In the event of non-compliance, appropriate actions including suspension or cancellation of licenses and prosecution initiated as per the provisions of the said Act and Rules.

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.

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