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

RAJYA SABHA
UNSTARRED QUESTION NO. 1086
TO BE ANSWERED ON 09TH DECEMBER, 2025

QUALITY CONTROL AND REGULATION OF EYEGLASSES AND LENSES IN THE COUNTRY

1086. DR. AJEET MADHAVRAO GOPCHADE:

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

(a) whether there is any Government mechanism to regularly check and ensure the quality of eyeglasses and optical lenses in the country;

(b) whether Government is aware that substandard eyeglasses and lenses are adversely affecting the vision of citizens;

(c) whether Government is aware that several foreign countries have enacted laws to establish optical councils or regulatory bodies for quality standards;

(d) whether Government has examined such legislations to adopt suitable measures in the country; and

(e) whether Government proposes to set up a scientific system for quality testing of eyeglasses and lenses, and if so, the details thereof?

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

(a) to (e): 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 registered NABL accredited laboratories for testing of medical devices on behalf of

manufacturers and Central Medical Device Testing Laboratories 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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