GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION NO. **342**
TO BE ANSWERED ON **3rd FEBRUARY, 2026**

Steps to regulate the pricing and quality of medical devices

342 Shri Parimal Nathwani:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether the Ministry is taking steps to regulate the pricing and quality of medical devices;
(b) the number of devices brought under price regulation by National Pharmaceutical Pricing Authority (NPPA); and
(c) the steps taken to promote domestic manufacturing of medical devices?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) & (b): The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (DoP) fixes ceiling prices of medicines included in the National List of Essential Medicines (NLEM) issued by the Ministry of Health and Family Welfare and incorporated in Schedule-I to the Drugs (Prices Control) Order, 2013 (DPCO, 2013). All manufacturers, marketers and importers of scheduled medicines are required to sell their products within such ceiling price (plus applicable Goods and Service Tax).

Four medical devices, namely, Bare Metal Stents, Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BVS)/Biodegradable stents, Intra Uterine Devices (IUDs) and condoms are included in Schedule-I to DPCO, 2013 and ceiling prices have been notified for these four devices. In addition to these four (04) scheduled medical devices, NPPA, in public interest, fixed and notified the ceiling prices for Orthopedic Knee Implants for knee replacement system in August 2017 and capped the trade margin of covid essential medical devices i.e. oxygen concentrators, pulse oximeter, blood pressure monitoring machine, nebuliser, digital thermometer and glucometer in June/July, 2021.

Further, MoHFW through S.O.No.648(E) dated 11.02.2020 notified all the medical devices intended for use in human beings or animals as 'Drugs' under the Drugs and Cosmetics Act 1940 w.e.f. 01.04.2020. Accordingly, NPPA vide SO. No.1232(E) dated 31.03.2020 has notified that all medical devices shall be governed under the provisions of DPCO, 2013 w.e.f. 01.04.2020. The non-scheduled Medical Devices are also monitored under Para 20 of the

DPCO, 2013 and manufacturers of such medical devices are required to not increase the maximum retail price of that medical device by more than 10% of the maximum retail prices during the preceding 12 months.

Quality, safety and performance of all Medical Devices are regulated under the provisions of Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2017 administered by MoHFW. As informed by MoHFW, the Central Drugs Standard Control Organization (CDSCO) has taken various regulatory measures to streamline the regulation of Medical Devices. Such key measures are as under:

(i). In order to simplify and align medical devices regulation framework with globally accepted regulation, Government has come up with Medical Devices Rules, 2017 aligning its regulatory mechanism at par with globally harmonized regulatory system. Further, all the medical devices have been brought under the purview of said rules.

(ii). A single unified online portal has been created to facilitate the granting of various licenses and permissions under the said rules, ensuring greater transparency and accountability in the licensing process.

(iii). The rules also outline a prescribed timeline for licensing, ensuring the timely processing of applications received by the Licensing Authority.

(iv). Class A Non-sterile and Non-measuring medical devices has been exempted from the requirement of Manufacturing/Import licenses. Such devices require simple registration on the online portal.

(v). In order to have ecosystem for testing of medical devices for ensuring quality, safety, and performance of such devices, provision to notify/establish Government Medical devices Testing Laboratories by Centre/State has been incorporated and various Government Medical Testing laboratories have been notified and Medical Device Testing Laboratories for testing of medical devices on behalf of manufacturers have been registered under the said Rules.

(vi). Notified Bodies have been registered with CDSCO to carry out audits of Class A and Class B medical device manufacturing units with respect to conformance to the Quality Management System (QMS).

(vii). The MedTech Mitra portal has been created in coordination with ICMR and NITI Aayog to provide handholding support to the startup / innovator / manufacturer in respect of regulatory guidance, financial assistance, conducting clinical study, etc. for development of their devices and its commercialization.

(c): The Government has taken measures to encourage domestic manufacturing of medical devices which, *inter alia*, include Production Linked Incentive scheme for promoting domestic manufacturing of Medical Devices; Scheme for Promotion of Medical Devices Parks; and Scheme for Strengthening Medical Device Industry that provides support in critical areas of the medical device industry, covering manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure and industry promotion.

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