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

LOK SABHA
UNSTARRED QUESTION NO. 2112
TO BE ANSWERED ON 12TH DECEMBER, 2025

REGULATION OF LOW-RISK-SELF-CARE MEDICAL DEVICES

2112. SHRI ANURAG SINGH THAKUR:
SHRI JAGDAMBIKA PAL:

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

(a) the steps taken/proposed to be taken by the Government to ensure greater affordability and accessibility of low-risk self-care medical devices for citizens;

(b) whether the Government proposes to streamline or ease the MD-42 registration requirements for low-risk self-care medical devices, particularly in view of the rapidly growing manufacturing clusters such as Baddi, Nalagarh, Sansarpur Terrace and other regions of Himachal Pradesh and if so, the details thereof;

(c) whether the Government has taken any measures to eliminate the fragmented compliance system and introduce a "One Nation, One Licence" framework for low-risk medical devices to support ease of doing business and faster citizen access and if so, the details thereof, State wise; and

(d) the steps taken/proposed to be taken by the Government to introduce a more risk proportionate and differentiated regulatory framework for Class A and Class B medical devices, distinct from the more stringent requirements for Class C and D devices, keeping in view India’s expanding domestic manufacturing capacity?

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

(a): As per the information provided by Department of Pharmaceuticals (DoP), the National Pharmaceutical Pricing Authority (NPPA) under DoP fixes the ceiling price 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 Drugs (Prices Control) Order, 2013 (DPCO, 2013). NPPA also fixes the retail prices of new drugs as defined under DPCO, 2013. In addition, for the non-scheduled drugs, DPCO, 2013 provides that no manufacture shall increase the maximum retail price (MRP) of such drugs by more than 10 per cent of their MRP in the preceding 12 months.

Four medical devices i.e Bare metal stents, drug eluting stents, condoms and intra uterine devices are included in the NLEM, 2022 and hence notified under Schedule-I and their ceiling prices have been fixed by NPPA.

Also, NPPA has fixed the ceiling price for Orthopedic Knee Implants in the year 2017 and capped the trade margin of oxygen concentrators, pulse oximeter, blood pressure monitoring machine, nebuliser, digital thermometer and glucometer during June/July 2021, in public interest.

NPPA vide SO. 1232(E) dated 31.03.2020 notified that all medical devices shall be governed under the provisions of DPCO, 2013 w.e.f 01.04.2020. Accordingly, manufacturers of non-scheduled medical devices required not to increase the MRP of such devices by more than 10% of the MRP during period of the preceding 12 months.

(b) to (d): Under the Medical Device Rules, 2017, import of all classes of Medical Devices (Class A, B, C & D) as well as manufacture of Class C & D Medical Devices are regulated by Central Drugs Standard Control Organization (CDSCO), while manufacture of Class A & B Medical devices is regulated by the concerned State Licensing Authorities (SLA) appointed by the State Governments.

Under the said rules, in order to simplify the process, separate provisions for registration certificate to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device has been introduced through Form MD-41 (application) and Form MD-42 (Registration certificate). Also the requirement for prior inspection of the premises for grant of registration certificate is exempted, requirement of educational qualification and experience is simplified and the decision regarding registration certificate is taken within the time period of 10 days by the State Licensing Authority. Besides, low-risk Class A (non-sterile, non-measuring) devices are permitted through a self-certification and online registration process without any mandatory pre- or post-licence inspection. Further, for uniformity and transparency, a common portal for States/UT viz www.cdscomdonline.com. has been made operational.

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