

List of medical devices under public monitoring

Ministry of Health and Family Welfare

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The Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health and Family Welfare, regulates the safety, efficacy and quality of 23 devices under the provisions of Drugs and Cosmetics Act, 1940 and Rules there under, out of which 15 medical devices are notified under Section 3(b)(iv) of the Drugs and Cosmetic Act.

Medical Devices Rules, 2017 have been implemented with effect from 01.01.2018 which have detailed provisions for regulation of manufacture, import, sale and distribution of medical devices covered under the said Act to ensure their quality. Further, the DTAB has agreed to include all implantable medical devices, CT scan equipment, MRI equipment, Defibrillators, Dialysis Machine, PET equipment and X-Ray Machine under the purview of section 3 (b) (iv) of the Drugs and Cosmetics Act, 1940 with the objective of ensuring their quality.

Out of the 23 medical devices, listed as drugs, 4 devices namely (i) Cardiac Stents, (ii) Drug Eluting Stents (iii) Condoms and (iv) Intra Uterine Devices have been included in the National List of Essential Medicines and are under price control by virtue of being included in Schedule-I to the Drugs (Price Control) Order, 2013 and their ceiling prices have been fixed.

Further, the Government has also notified the ceiling prices of Orthopedic Knee Implants for knee replacement system under paragraph 19 of the Drugs (Price Control) Order, 2013. The MRPs of remaining medical devices, being under non-scheduled category, are monitored to ensure that no manufacturer increases the maximum retail price by more than ten percent of the price during the preceding 12 month period.

The Minister of State (Health and Family Welfare), Sh Ashwini Kumar Choubey stated this in a written reply in the Rajya Sabha here today.

MV/LK

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