GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4042
ANSWERED ON:20.03.2015
REGULATION ON MEDICAL DEVICES EQUIPMENT
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the medical devices/equipment notified under the Drugs and Cosmetics Act and the number out of them under the price regulation;

(b) whether the Indian companies manufacturing devices/equipment are required to get certification from the American and European drug regulators to sell these medical devices/equipment to the hospitals in the country;

(c) if so, the details thereof and the reasons therefor indicating the tenders submitted by the Indian companies to the hospitals in this regard and purchase of medical devices/equipment made from Indian and foreign companies, separately during the last three years and the current year;

(d) the steps taken/proposed to be taken by the Government to change the existing regulation requiring American/European certification and to put in place its own mechanism/standards to regulate the manufacturing, marketing and quality of medical devices/equipment in the country; and

(e) the measures being taken by the Government to set up medical device testing laboratories and make them available at affordable cost in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIJAGAT PRAKASH NADDA)

(a): Only 14 categories of the medical devices notified under the Drugs and Cosmetics Act, 1940 and Rules made thereunder are regulated as drugs. The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals regulates the pricing of medical devices. The Authority has informed that the pricing of two devices, namely, 'condom' and, 'Intrauterine Device (IUD)' containing copper is regulated under the provisions of the Drugs Price Control Order, 2013.

(b) to (d): As per Notification GSR 690(E) dated 25.09.2015, the medical devices in India are required to conform to the Indian Standards laid down from time to time by the Bureau of Indian Standards. If there are no Bureau of Indian Standards then these need to conform to the International Standards such as International Organization for Standardization, or other International Pharmacopeia Standards and such other standards as may be specified for this purpose. In case, national or international standards are not available, the devices need to conform to the manufacturer's validated standards. There is, however, no legal requirement to get certification from United States Food and Drug Administration or any other regulator for medical devices/equipment. In order to ensure adherence to quality standards in some cases of procurement particularly of high end equipment, the technical specifications mention United States Food and Drug Administration approval/ certification. The details of all such tenders are not maintained centrally in the Department of Health and Family Welfare.

(e): The current emphasis of the Department of Health and Family Welfare is on strengthening of the existing laboratories. Medical devices are currently tested in the following laboratories:

(i). National Institute of Biologicals, Noida - For testing diagnostic devices viz. HIV, HBsAg and HCV;

(ii). Central Drugs Testing Laboratories, Mumbai - For testing of Intra Uterine Devices viz Cu-T & Tubular Kings which are included in Schedule R to the Drugs and Cosmetics Rules, 1945; and

(iii). Central Drugs Testing Laboratories, Chennai - For testing of Condoms.